



FEDERAL REGISTER

Vol. 86

Wednesday,

No. 40

March 3, 2021

Pages 12257–12514

OFFICE OF THE FEDERAL REGISTER



The **FEDERAL REGISTER** (ISSN 0097-6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see www.federalregister.gov.

The seal of the National Archives and Records Administration authenticates the **Federal Register** as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at www.govinfo.gov, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, gpocusthelp.com.

The annual subscription price for the **Federal Register** paper edition is \$860 plus postage, or \$929, for a combined **Federal Register**, **Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is \$330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register**, including postage, is based on the number of pages: \$11 for an issue containing less than 200 pages; \$22 for an issue containing 200 to 400 pages; and \$33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for \$3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see bookstore.gpo.gov.

There are no restrictions on the republication of material appearing in the **Federal Register**.

How To Cite This Publication: Use the volume number and the page number. Example: 86 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	202-512-1800
Assistance with public subscriptions	202-512-1806

General online information 202-512-1530; 1-888-293-6498

Single copies/back copies:

Paper or fiche	202-512-1800
Assistance with public single copies	1-866-512-1800 (Toll-Free)

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	FRSubscriptions@nara.gov
Phone	202-741-6000

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: <https://www.gpo.gov/frsubs>.



Contents

Federal Register

Vol. 86, No. 40

Wednesday, March 3, 2021

Agriculture Department

See Animal and Plant Health Inspection Service

Animal and Plant Health Inspection Service

PROPOSED RULES

Elimination of the Voluntary Trichinae Certification Program, 12293–12294

Commerce Department

See Economic Development Administration

See National Oceanic and Atmospheric Administration

Drug Enforcement Administration

RULES

Schedules of Controlled Substances:

Placement of Lemborexant in Schedule IV, 12257–12260

PROPOSED RULES

Schedules of Controlled Substances:

Placement of 10 Specific Fentanyl-Related Substances in Schedule I, 12296–12305

Economic Development Administration

NOTICES

Trade Adjustment Assistance; Determinations, 12410

Education Department

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Campus Safety and Security Survey, 12432–12433

Evaluating the District of Columbia Opportunity Scholarship Program After the 2017 Reauthorization, 12433

Applications for New Awards:

Child Care Access Means Parents in School Program, 12427–12432

Energy Department

See Federal Energy Regulatory Commission

NOTICES

Energy Conservation Program:

Petition for Waiver of KeepRite Refrigeration from Walk-In Coolers and Walk-In Freezers Test Procedure; Grant of Interim Waiver, 12433–12440

Environmental Protection Agency

RULES

Air Quality State Implementation Plans; Approvals and Promulgations:

California; Plumas County; Moderate Area Plan for the 2012 PM_{2.5} NAAQS, 12263–12265

Ohio; Base Year Emission Inventories and Emissions Statement Rule Certification for the 2015 Ozone Standard, 12270–12272

West Virginia; 1997 8-Hour Ozone National Ambient Air Quality Standard Second Maintenance Plan for the West Virginia Portion of the Huntington-Ashland, WV-KY Area Comprising Cabell and Wayne Counties, 12265–12270

Approval and Promulgation of Air Quality Implementation Plan:

Mashantucket Pequot Tribal Nation, 12260–12263

Contaminants on the Fourth Drinking Water Contaminant Candidate List, 12272–12291

PROPOSED RULES

Air Quality State Implementation Plans; Approvals and Promulgations:

Alabama: NO_x SIP Call and Removal of CAIR, 12305–12309

Arizona; Miami Copper Smelter Sulfur Dioxide Control Measures, 12310–12312

NOTICES

Meetings:

Clean Air Act Advisory Committee, 12443

Equal Employment Opportunity Commission

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Generic Clearance for the Collection of Qualitative

Feedback on Agency Service Delivery, 12443–12445

Farm Credit Administration

NOTICES

Meetings; Sunshine Act, 12445

Federal Aviation Administration

PROPOSED RULES

Airworthiness Directives:

Airbus Helicopters Deutschland GmbH (AHD)

Helicopters, 12294–12296

NOTICES

Meetings:

Aviation Rulemaking Advisory Committee, 12511–12512

Federal Communications Commission

PROPOSED RULES

New and Emerging Technologies 911 Improvement Act: 911 Fee Diversion, 12399–12409

Standard Questions for Applicants Whose Applications

Will Be Referred to the Executive Branch for Review

Due to Foreign Ownership; Comment Request, 12312–12399

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 12446–12448

Privacy Act; Matching Programs, 12445–12446

Federal Energy Regulatory Commission

RULES

Natural Gas Pipelines:

Project Cost and Annual Limits, 12257

NOTICES

Combined Filings, 12440–12443

Environmental Assessments; Availability, etc.:

Lock 13 Partners, LLC, 12440

Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:

All Choice Energy MidAmerica, LLC, 12442

Pay Less Energy, LLC, 12441–12442

Meetings:

Data Collection for Analytics and Surveillance and Market-Based Rate Purposes; Technical Workshop, 12441

Federal Highway Administration**NOTICES**

Environmental Impact Statements; Availability, etc.:
Peoria, Tazewell and Woodford Counties, IL, 12512

Federal Housing Finance Agency**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 12448–12464

Federal Maritime Commission**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 12464
Agreements Filed, 12464–12465

Federal Reserve System**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 12465–12466

Food and Drug Administration**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Current Good Manufacturing Practice for Manufacturing,
Processing, Packing, and Holding of Finished
Pharmaceuticals, Including Medical Gases, and
Active Pharmaceutical Ingredients, 12466–12468
Generic Clearance for Data To Support Cross-Center
Collaboration for Social Behavioral Sciences
Associated With Disease Prevention, Treatment, and
the Safety, Efficacy, and Usage of Food and Drug
Administration Regulated Products, 12484–12486
Study of How Consumers Use Flavors To Make
Inferences About Electronic Nicotine Delivery
System Product Qualities and Intentions To Use
(Phase 2), 12468–12470
Final Debarment Order:
Lawrence B. Ryan, 12482–12483
Michael Gurry, 12473–12474
Food and Drug Administration Modernization Act:
Modifications to the List of Recognized Standards,
Recognition List Number: 054, 12476–12482
Meetings:
Circulatory System Devices Panel of the Medical Devices
Advisory Committee, 12483–12484
New Drug Application; Proposal To Refuse:
Sotagliflozin Oral Tablets, 200 Milligrams and 400
Milligrams; Hearing, 12471–12473
Withdrawal of Approval of Three New Drug Applications:
PolyMedica Industries Inc., et al., 12474–12476

Foreign Assets Control Office**NOTICES**

Blocking or Unblocking of Persons and Properties, 12512–
12513

Health and Human Services Department

See Food and Drug Administration
See National Institutes of Health

Homeland Security Department

See Transportation Security Administration
See U.S. Customs and Border Protection

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
COVID–19 Contact Tracing, COVID–19 Contact Tracing
Scripts, COVID–19 Contact Tracing Form, 12489–
12492
Rights Evaluation Tool, 12492–12493

Interior Department

See Ocean Energy Management Bureau

International Trade Commission**NOTICES**

Investigations; Determinations, Modifications, and Rulings,
etc.:
Certain Rolled-Edge Rigid Plastic Food Trays, 12495–
12496

Justice Department

See Drug Enforcement Administration

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Appeal to the Board of Immigration Appeals From a
Decision of a Department of Homeland Security
Officer, 12497
Crime Data Explorer Feedback Survey, 12497–12498
District/Aviation Security Officers Personal Qualifications
Statement, 12496

National Archives and Records Administration**NOTICES**

Records Schedules, 12498–12499

National Institutes of Health**NOTICES**

Meetings:
National Institute of Arthritis and Musculoskeletal and
Skin Diseases, 12486
National Institute of Diabetes and Digestive and Kidney
Diseases, 12487
National Institute on Deafness and Other Communication
Disorders, 12487

National Oceanic and Atmospheric Administration**RULES**

Atlantic Highly Migratory Species:
Atlantic Bluefin Tuna Fisheries, 12291–12292

NOTICES

Recommendations for More Resilient Fisheries and
Protected Resources Due to Climate Change, 12410–
12411
Takes of Marine Mammals Incidental to Specified
Activities:
Incidental to the Berth III New Mooring Dolphins Project
in Ketchikan, AK, 12411–12426

Ocean Energy Management Bureau**NOTICES**

Environmental Impact Statements; Availability, etc.:
Construction and Operations Plan for Vineyard Wind,
LLC, 12494–12495

Securities and Exchange Commission**NOTICES**

Meetings:
Asset Management Advisory Committee, 12501
Meetings; Sunshine Act, 12500–12501

Self-Regulatory Organizations; Proposed Rule Changes:
Cboe Exchange, Inc., 12499–12500
NYSE Arca, Inc., 12501–12503
The Nasdaq Stock Market, LLC, 12503–12509

Small Business Administration**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 12510–12511
Major Disaster Declaration:
Louisiana, 12510
Oklahoma, 12509–12510
Texas, 12510

State Department**NOTICES**

Delegation of Authority To Concur With Requests From
DoD To Enter Into Public-Private Partnerships With
Foreign Governments, 12511

Surface Transportation Board**NOTICES**

Release of Waybill Data, 12511

Transportation Department

See Federal Aviation Administration
See Federal Highway Administration

Transportation Security Administration**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Imposition and Collection of Passenger Civil Aviation
Security Service Fees, 12493–12494

Treasury Department

See Foreign Assets Control Office

U.S. Customs and Border Protection**NOTICES**

Final Determination Concerning a Transceiver, 12487–
12489

Reader Aids

Consult the Reader Aids section at the end of this issue for
phone numbers, online resources, finding aids, and notice
of recently enacted public laws.

To subscribe to the Federal Register Table of Contents
electronic mailing list, go to [https://public.govdelivery.com/
accounts/USGPOOFR/subscriber/new](https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new), enter your e-mail
address, then follow the instructions to join, leave, or
manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

9 CFR**Proposed Rules:**

149 12293

14 CFR**Proposed Rules:**

39 12294

18 CFR

157 12257

21 CFR

1308 12257

Proposed Rules:

1308 12296

40 CFR

49 12260

52 (3 documents) 12263,
12265, 12270

141 12272

Proposed Rules:

52 (2 documents) 12305,
12310

47 CFR**Proposed Rules:**

1 12312

9 12399

63 12312

50 CFR

635 12291

Rules and Regulations

Federal Register

Vol. 86, No. 40

Wednesday, March 3, 2021

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 157

[Docket No. RM81–19–000]

Natural Gas Pipelines; Project Cost and Annual Limits

AGENCY: Federal Energy Regulatory Commission, Energy.

ACTION: Final rule.

SUMMARY: Pursuant to the authority delegated by the Commission's regulations, the Director of the Office of Energy Projects (OEP) computes and publishes the project cost and annual limits for natural gas pipelines blanket construction certificates for each calendar year.

DATES: This final rule is effective March 3, 2021 and establishes cost limits applicable from January 1, 2021 through December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Richard W. Foley, Chief, Certificates Branch 1, Division of Pipeline Certificates, (202) 502–8955.

SUPPLEMENTARY INFORMATION: Section 157.208(d) of the Commission's Regulations provides for project cost limits applicable to construction, acquisition, operation and miscellaneous rearrangement of facilities (Table I) authorized under the blanket certificate procedure (Order No. 234, 19 FERC ¶ 61,216). Section 157.215(a) specifies the calendar year dollar limit which may be expended on underground storage testing and development (Table II) authorized under the blanket certificate. Section 157.208(d) requires that the "limits specified in Tables I and II shall be adjusted each calendar year to reflect the 'GDP implicit price deflator' published by the Department of Commerce for the previous calendar year."

Pursuant to § 375.308(x)(1) of the Commission's Regulations, the authority for the publication of such cost limits, as adjusted for inflation, is delegated to the Director of the Office of Energy Projects. The cost limits for calendar year 2021, as published in Table I of § 157.208(d) and Table II of § 157.215(a), are hereby issued.

Effective Date

This final rule is effective March 3, 2021. The provisions of 5 U.S.C. 804 regarding Congressional review of final rules does not apply to the final rule because the rule concerns agency procedure and practice and will not substantially affect the rights or obligations of non-agency parties. The final rule merely updates amounts published in the Code of Federal Regulations to reflect the Department of Commerce's latest annual determination of the Gross Domestic Product (GDP) implicit price deflator, a mathematical updating required by the Commission's existing regulations.

List of Subjects in 18 CFR Part 157

Administrative practice and procedure, Natural gas, Reporting and recordkeeping requirements.

Issued: February 19, 2021.

Terry L. Turpin,

Director, Office of Energy Projects.

Accordingly, 18 CFR part 157 is amended as follows:

PART 157—APPLICATIONS FOR CERTIFICATES OF PUBLIC CONVENIENCE AND NECESSITY AND FOR ORDERS PERMITTING AND APPROVING ABANDONMENT UNDER SECTION 7 OF THE NATURAL GAS ACT

■ 1. The authority citation for part 157 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 42 U.S.C. 7101–7352.

■ 2. In § 157.208(d), Table I is amended by adding an entry for "2021" at the end of the table to read as follows:

§ 157.208 Construction, acquisition, operation, replacement, and miscellaneous rearrangement of facilities.

* * * * *

(d) * * *

TABLE I TO PART 157

Year	Limit	
	Auto. proj. cost limit (Col.1)	Prior notice proj. cost limit (Col.2)
2021	\$12,600,000	\$35,600,000

■ 3. In § 157.215(a)(5), Table II is amended by adding an entry for "2021" at the end of the table to read as follows:

§ 157.215 Underground storage testing and development.

(a) * * *

(5) * * *

TABLE II TO PART 157

Year	Limit
2021	\$6,800,000

[FR Doc. 2021–04096 Filed 3–2–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–600]

Schedules of Controlled Substances: Placement of Lemborexant in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Final rule.

SUMMARY: This final rule adopts, without change, an interim final rule with request for comments published in the **Federal Register** on April 7, 2020, placing lemborexant ((1*R*,2*S*)-2-[(2,4-dimethylpyrimidin-5-yl)oxymethyl]-2-(3-fluorophenyl)-*N*-(5-fluoropyridin-2-yl)cyclopropane-1-carboxamide), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV of the Controlled Substances Act (CSA). With the issuance of this final rule, the Drug

Enforcement Administration maintains lemborexant, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV of the CSA.

DATES: The effective date of this final rulemaking is March 3, 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: 571-362-3249.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114-89), when the Drug Enforcement Administration (DEA) receives notification from the Department of Health and Human Services (HHS) that the Secretary has approved a certain new drug and HHS recommends control in the CSA schedule II-V, DEA is required to issue an interim final rule, with opportunity for public comment and to request a hearing, controlling the drug within a specified 90-day timeframe and to subsequently issue a final rule. 21 U.S.C. 811(j). When controlling a drug pursuant to subsection (j), DEA must apply the scheduling criteria of 21 U.S.C. 811 (b) through (d) and 812(b). 21 U.S.C. 811(j)(3).

On April 7, 2020, DEA published an interim final rule to make lemborexant (including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible) a schedule IV controlled substance. 85 FR 19387. The interim final rule provided an opportunity for interested persons to submit comments as well as file a request for hearing or waiver of hearing, on or before May 7, 2020. DEA did not receive any requests for hearing or waiver of hearing.

Comments Received

DEA received five comments in response to the interim final rule for the placement of lemborexant into schedule IV of the CSA. The submissions were from individual or anonymous commenters. Two commenters provided support for the interim final rule, one commenter opposed the rule, one commenter solely included a link to potential malware, and one commenter expressed views on a subject not related to the rule. As these final two comments were outside the scope of this

rulemaking, DEA did not summarize or respond to them below.

Support of the Interim Final Rule

A commenter supported controlling lemborexant as a schedule IV controlled substance, if such control helped to prevent abuse of, or the addiction to, this substance. Another commenter noted HHS, in its analysis, found that lemborexant had similar abuse potential to other schedule IV sedatives such as suvorexant and zolpidem, and therefore, agreed with HHS's recommendation of schedule IV control for lemborexant. In addition, this commenter referenced a study, conducted by Eisai, Inc. (the Sponsor of the new drug application for Dayvigo (lemborexant)), and recommended that DEA add this particular study analysis regarding abuse and dependency potential to DEA's final rule, under the "Determination to Schedule Lemborexant" section, to further support DEA's placing lemborexant in schedule IV.

DEA Response: DEA appreciates the support for this rulemaking. DEA determined in the interim final rule, and re-affirms in this final rule, that there is substantial evidence of a potential for abuse of lemborexant, and lemborexant warrants control in schedule IV. Regarding the commenter's request that DEA include the study analysis in this final rule, DEA assumes that the commenter is referring to the human abuse potential (HAP) study conducted by Eisai, Inc. In the event the commenter is referencing this study, DEA asserts that the HAP study conducted by the Sponsor was included in both the DEA and HHS lemborexant eight-factor reviews and in the interim final rule located in the "Determination to Schedule Lemborexant" section in Factor 2 and in the "Determination of Appropriate Schedule" in section 3 of the interim final rule.

Opposition to the Interim Final Rule

A commenter claimed that DEA did not rely on the pharmacological data for lemborexant or follow any of the other factors required to be considered under 21 U.S.C. 811(c) to determine the placement of lemborexant in schedule IV. Instead, the commenter stated that DEA relied on a "small and unrepeatable sample group" and its subjective responses, which matched responses to the schedule IV sedative suvorexant. The commenter also contended that there is a disparity in DEA's scheduling treatment for lemborexant (schedule IV) and Rozarem (non-controlled), as these both are sedatives—with the same Food and Drug Administration (FDA)-

approved indication—that exert pharmacological activity by other means than binding to gamma-aminobutyric acid (GABA) receptors. As such, the commenter considered DEA's decision to schedule lemborexant "arbitrary and capricious." This commenter further stated that the placement of lemborexant in schedule IV of the CSA would increase the regulatory restrictions on a drug intended to treat insomnia, thereby causing many to resort to more dangerous and addictive substances such as benzodiazepines and other drugs that bind to the GABA receptor. Lastly, the commenter stated lemborexant is a new molecular entity thus evidence of actual abuse or potential for abuse liability does not exist. Therefore, the commenter asserted that DEA should either not place lemborexant in the same schedule as drugs with proven abuse potential, such as Xanax and Ambien, or delay scheduling lemborexant until evidence of actual abuse data can be produced using the eight-factors stipulated in 21 U.S.C. 811(c).

DEA Response: Regarding the commenter's point concerning the lack of appropriate pharmacological data in support of the abuse potential of lemborexant, DEA asserts that pharmacological data serves as only one portion of the data used to determine abuse potential and abuse liability. As stated in the interim final rule, while lemborexant is highly selective for both the orexin 1 and orexin 2 receptors and has little to no affinity to other central nervous system receptor sites associated with abuse potential, in a clinical HAP study of lemborexant, lemborexant produced statistically significant increases in positive subjective measures in the bipolar visual analog scale (*i.e.*, Drug Liking, Overall Drug Liking, Good Effects, High, Stoned, and Take Drug Again) that were greater than placebo and statistically similar to other sedatives in the same drug class. Thus, in this HAP study, lemborexant showed potential for abuse. Following comprehensive evaluation of all available data, including both preclinical and clinical data as related to the eight-factor analysis pursuant to 21 U.S.C. 811(c), HHS recommended schedule IV for lemborexant. Upon careful consideration of all available data, DEA concurred with HHS' recommendation that lemborexant possesses abuse potential comparable to other schedule IV depressants.

Regarding the commenter's concerns that the control of lemborexant as a schedule IV drug would negatively impact treatment choices and increase addiction risks, DEA contends that there

is no evidence to suggest that such control of lemborexant creates undue regulatory restrictions increasing the risk of addiction. Furthermore, a HAP study of lemborexant was conducted, the results of which indicate that lemborexant has an abuse potential that is greater than placebo and statistically similar to other controlled sedatives in schedule IV of the CSA. Therefore, DEA asserts that by adopting the interim final rule placing lemborexant in schedule IV of the CSA, there is no “risk of restricting its prescribing” and limiting treatment options for insomnia to “more dangerous and addictive molecules.” Rather, lemborexant is being placed in a schedule with other sedative/hypnotics that have similar abuse potential such as benzodiazepines, barbiturates, and muscle relaxants.

Regarding the commenter’s point that lemborexant is a new molecular entity with unknown actual or potential for abuse, and the commenter’s request for DEA to either not place lemborexant in schedule IV or to postpone such scheduling until there is evidence showing the requisite abuse potential, DEA’s determination of the abuse liability of lemborexant in the interim final rule, and again in this final rule, is in agreement with that of HHS. In a clinical HAP study investigating the abuse potential of lemborexant, HHS concluded that lemborexant produced subjective responses that were similar to those for the schedule IV sedative suvorexant. In the context of drug development, HAP studies are conducted as a component of the safety evaluation of a new molecular entity. These studies are utilized by HHS, FDA, and the scientific community. They are accepted as repeatable and follow rigorous scientific guidelines. In effect, the HAP studies are indeed evidence showing the requisite abuse potential of lemborexant; therefore, no additional studies are necessary to prove potential for abuse. Additionally, HHS’ evaluation of a HAP study conducted by the Sponsor concluded that lemborexant produces positive subjective effects and has abuse potential similar to that of schedule IV sedatives, such as suvorexant and zolpidem, which were used as positive controls in the study. DEA asserts that when the evidence of actual abuse is not available, both HHS and DEA rely upon data from preclinical and clinical studies to inform determinations on potential for abuse of a given substance. Therefore, upon evaluation of the above-mentioned clinical studies and other preclinical data, DEA concurred with HHS’ findings that the abuse liability of

lemborexant is similar to other substances placed in schedule IV (*i.e.*, benzodiazepines, barbiturates, and muscle relaxants) and therefore supported—and continues to support through this final rule—placement of lemborexant in schedule IV.

Finally, we address the commenter’s claim that the control of lemborexant is improper because there is another substance, that is not controlled, which the commenter asserts has similar pharmacological properties to those of lemborexant. DEA contends that while both drugs are classified as sedatives with similar FDA-approved indications, they do not share the same pharmacological mechanism of action or abuse liability. Even assuming this assertion were correct, this is not a legal basis to decline to control a substance. The CSA does not require, as a condition of control under 21 U.S.C. 811, that every other substance with similar properties be simultaneously controlled.

Based on the rationale set forth in the interim final rule, DEA adopts the interim final rule without change.

Requirements for Handling Lemborexant

As indicated above, lemborexant has been a schedule IV controlled substance by virtue of the interim final rule issued by DEA in April 2020. Thus, this final rule does not alter the regulatory requirements applicable to handlers of lemborexant that have been in place since that date. Nonetheless, for informational purposes, we re-state here those requirements. Lemborexant is subject to the CSA’s schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule IV substances, including, but not limited to, the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) lemborexant, or who desires to handle lemborexant, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who intends to handle lemborexant, and is not registered with DEA, must submit an application for registration and may not handle lemborexant, unless DEA approves that application for

registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who obtains a schedule IV registration to handle lemborexant but who subsequently does not desire or is not able to maintain such registration must surrender all quantities of lemborexant, or may transfer all quantities of lemborexant to a person registered with DEA in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Lemborexant is subject to schedule III–V security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.93. Non-practitioners handling lemborexant must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of lemborexant must comply with 21 U.S.C. 825 and 958(f), and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of lemborexant was required to keep an inventory of lemborexant on hand, as of April 7, 2020, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for lemborexant, or products containing lemborexant, pursuant to 21 U.S.C. 827 and 958(f), and in accordance with 21 CFR parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for lemborexant or products containing lemborexant must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule IV controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of lemborexant may only be for the legitimate purposes consistent with the drug’s labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act and the CSA.

9. *Importation and Exportation.* All importation and exportation of lemborexant must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving lemborexant not authorized by, or in

violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

This final rule, without change, affirms the amendment made by the interim final rule that is already in effect. Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is: (1) Approved by HHS and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an interim final rule scheduling the drug within 90 days. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause. DEA issued an interim final rule on April 7, 2020, and solicited public comments on that rule. Subsection (j) further states that after giving interested persons the opportunity to comment and to request a hearing, the Attorney General, as delegated to the Administrator of DEA, shall issue a final rule in accordance with the scheduling criteria of 21 U.S.C. 811 (b) through (d) and 812(b). DEA is now responding to the comments submitted by the public and issuing the final rule in accordance with subsection (j).

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a) and (j), this scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This final rule does not have federalism implications warranting the application of E.O. 13132. The final rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This final rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As noted in the above discussion regarding the applicability of the APA, DEA was not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any 1 year.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action does not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This rule will not result in an annual effect on the

economy of \$100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the U.S.-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to the CRA, DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ Accordingly, the interim final rule (85 FR 19387) amending 21 CFR part 1308, which published on April 7, 2020, is adopted as a final rule without change.

D. Christopher Evans,
Acting Administrator.

[FR Doc. 2021–04183 Filed 3–2–21; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 49

[EPA–R01–OAR–2020–0374; FRL–10018–74–Region 1]

Approval and Promulgation of Air Quality Implementation Plan; Mashantucket Pequot Tribal Nation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) approves the Mashantucket Pequot Tribal Nation’s (MPTN or the Tribe) Tribal Implementation Plan (TIP) under the Clean Air Act (CAA) to regulate air pollution within the exterior boundaries of the Tribe’s reservation. The TIP is one of two CAA regulatory programs that comprise the Tribe’s Clean Air Program (CAP). EPA approved the Tribe for treatment in the same manner as a State (Treatment as State or TAS) for purposes of administering New Source Review (NSR) and Title V operating permits under the CAA on July 10, 2008. In this action we act only on those portions of MPTN’s CAP that constitute a TIP containing severable elements of

an implementation plan under CAA section 110(a). The TIP includes permitting requirements for major and minor sources of air pollution. The purpose of the TIP is to enable the Tribe to attain and maintain the National Ambient Air Quality Standards (NAAQS) within the exterior boundaries of its reservation by establishing a federally enforceable preconstruction permitting program.

DATES: This rule is effective on April 2, 2021.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA-R01-OAR-2020-0374. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at <https://www.regulations.gov> or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact 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 legal holidays and facility closures due to COVID-19.

FOR FURTHER INFORMATION CONTACT: Patrick Bird, Air Permits, Toxics and Indoor Programs Branch, U.S. Environmental Protection Agency, Region 1, 5 Post Office Square, Mail Code: 05-2, Boston, MA 02109-0287. Telephone: 617-918-1287. Fax: 617-918-0287. Email: Bird.Patrick@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

Table of Contents

- I. Background and Purpose
- II. Response to Comments
- III. Final Action
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

I. Background and Purpose

On September 9, 2020 (85 FR 55628), EPA published a Notice of Proposed Rulemaking (NPRM) for a TIP submitted by the MPTN for approval under section 110 of the CAA. The TIP addresses attainment and maintenance of the

National Ambient Air Quality Standards (NAAQS) by establishing a federally enforceable preconstruction permitting program within the exterior boundaries of the Tribe's reservation. It also allows for sources that otherwise would have the potential to emit hazardous air pollutants or regulated NSR pollutants in amounts at or above those for major sources to request federally enforceable permit limitations that restrict emissions to below those of a major source.

The MPTN is an Indian Tribe federally recognized in 1983 by Congressional legislation (Pub. L. 98-134, sec. 9, Oct. 1st, 1983 97 Stat 855, Title 25 U.S.C.A. 1751-1760). The Secretary of the Interior recognizes the “Mashantucket Pequot Tribe of Connecticut” (73 FR 18553, 18554, April 4, 2008). MPTN's CAP was established by Tribal Council Resolution in 2005 (TCR102600-01 of 02). On July 10, 2008, EPA determined that the Tribe is eligible for TAS for these purposes.

The MPTN formally submitted the applicable elements of its TIP to EPA Region 1 on December 7, 2018. Having found that the MPTN is eligible for TAS to implement these regulatory programs, EPA is now approving the Tribe's TIP. We intend to act on the Tribe's title V operating permit program in separate notice and comment processes, as appropriate.

The rationale for EPA's proposed approval of the MPTN TIP is explained in the NPRM and will not be restated here. No adverse public comments were received on the NPRM.

II. Response to Comments

EPA received three comments during the comment period, all of which supported EPA's proposed action. As such, these comments do not require further response to finalize the action as proposed.

III. Final Action

EPA is approving the MPTN's TIP under the Clean Air Act to regulate air pollution within the exterior boundaries of the Tribe's reservation. In this action we act only on those portions of MPTN's CAP that constitute a TIP containing severable elements of an implementation plan under CAA section 110(a). The TIP includes permitting requirements for major and minor sources of air pollution. Specifically, we are approving the following sections of the MPTN's air quality regulations. Title 12, Subtitle 12.1, § 2—Applicability (with effective date); Title 12, Subtitle 12.1, § 4—

Definitions; and Title 12, Subtitle 12.2—New Source Review—MPTN TIP.

IV. Incorporation by Reference

In this rule, 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 the MPTN rules discussed in section I. and III. of this preamble. EPA has made, and will continue to make, these documents generally available through <https://www.regulations.gov> and at the EPA Region 1 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a TIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing TIP submissions, EPA's role is to approve tribal choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this final action merely approves tribal law as meeting Federal requirements and does not impose additional requirements beyond those imposed by tribal 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 Clean Air Act; 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 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. Section 804, however, exempts from section 801 the following types of rules: Rules of particular applicability; rules relating to agency management or personnel; and rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties, 5 U.S.C. 804(3). Because this is a rule of particular applicability, EPA is not required to submit a rule report regarding this action under section 801.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 3, 2021. 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 49

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Indians, Intergovernmental relations, Reporting and recordkeeping requirements.

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

Dated: February 10, 2021.

Deborah Szaro,

Acting Regional Administrator, EPA Region 1.

Part 49 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 49—INDIAN COUNTRY: AIR QUALITY PLANNING AND MANAGEMENT

■ 1. The authority citation for part 49 continues to read as follows:

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

Subpart D—Implementation Plans for Tribes—Region 1

■ 2. Subpart D of Part 49 is amended by adding an undesignated center heading and § 49.202, after § 49.201, to read as follows:

Implementation Plan for the Mashantucket Pequot Tribal Nation.

§ 49.202 Identification of Plan

(a) *Purpose and scope.* This section contains the implementation plan for

the Mashantucket Pequot Tribal Nation. This plan consists of permitting requirements for major and minor sources of air pollution submitted by the Tribe on December 7, 2018, applicable to lands within the exterior boundaries of the Mashantucket Pequot Tribal Nation's reservation.

(b) *Incorporation by reference.* (1) Material listed in paragraph (c) of this section was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Material is incorporated as it exists on the date of the approval, and notice of any change in the material will be published in the **Federal Register**. Entries in paragraph (c) of this section with EPA approval dates after January 6, 2021, will be incorporated by reference in the next update to the TIP compilation.

(2) EPA Region 1 certifies that the rules/regulations provided by EPA in the TIP compilation at the addresses in paragraph (b)(3) of this section are an exact duplicate of the officially promulgated tribal rules/regulations which have been approved as part of the Tribal Implementation Plan as of January 6, 2021.

(3) Copies of the materials incorporated by reference may be inspected at the EPA Region 1 Office, 5 Post Office Square, Suite 100, Boston, MA 02109–3912 and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(c) *EPA-approved regulations.*

TABLE 1 TO PARAGRAPH (c)—EPA-APPROVED MASHANTUCKET PEQUOT TRIBAL NATION REGULATIONS

Tribal citation	Title/subject	Tribal effective date	EPA approval date	Explanations
Resolution Number TCR101118–04 of 06 of the Mashantucket Pequot Tribe.	RESOLUTION NUMBER TCR101118–04 of 06 OF THE MASHANTUCKET PEQUOT TRIBAL COUNCIL, THE GOVERNING BODY OF THE MASHANTUCKET PEQUOT TRIBE, Approves the MPTN Air Quality Program, Submission of the Tribal Implementation Plan and Requests Delegation of the Title V Program.	10/11/2018	3/3/2021 [Insert Federal Register citation].	
MPTN Land Use Regulations, Title 12 Air Quality Regulations.	MPTN Land Use Regulations, Title 12 Air Quality Regulations.	10/11/2018	3/3/2021[Insert Federal Register citation].	MPTN only submitted, and EPA only approved, applicable TIP References: Subtitle 12.1, § 2 “Applicability” and § 4 “Definitions”; and Subtitle 12.2 “New Source Review—MPTN TIP.”

[FR Doc. 2021-03124 Filed 3-2-21; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 52****[EPA-R09-OAR-2020-0534; FRL-10020-36-Region 9]****Approval and Promulgation of Air Quality State Implementation Plans; California; Plumas County; Moderate Area Plan for the 2012 PM_{2.5} 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 California to address Clean Air Act (CAA or “Act”) requirements for the 2012 annual fine particulate matter (PM_{2.5}) national ambient air quality standard (NAAQS or “standard”) in the Plumas County Moderate PM_{2.5} nonattainment area (“Portola nonattainment area”). The submitted SIP revision is the State’s “Proposed Portola PM_{2.5} Plan Contingency Measure SIP Submittal” (“PM_{2.5} Plan Revision”), which includes a revised City of Portola ordinance regulating PM_{2.5} emission sources and the State’s demonstration that this submission meets the Moderate area contingency measure requirement for the 2012 annual PM_{2.5} NAAQS in the Portola nonattainment area. The EPA is also taking final action to approve the contingency measure element of the Moderate area attainment plan for the Portola nonattainment area, as revised and supplemented by the PM_{2.5} Plan Revision.

DATES: This rule is effective on April 2, 2021.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-R09-OAR-2020-0534. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for

additional availability information. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: John Ungvarsky, Air Planning Office (AIR-2), EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 972-3963 or ungvarsky.john@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document, “we,” “us,” and “our” refer to the EPA.

Table of Contents

- I. Background
- II. Public Comments and EPA Responses
- III. Final Action
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

I. Background

On January 15, 2013, the EPA strengthened the primary annual NAAQS for particulate matter with a diameter of 2.5 microns or less by lowering the level from 15.0 micrograms per cubic meter (µg/m³) to 12.0 µg/m³ (“2012 PM_{2.5} NAAQS”).¹ The EPA established this standard after considering substantial evidence from numerous health studies demonstrating that serious health effects are associated with exposures to PM_{2.5} concentrations above these levels.

Epidemiological studies have shown statistically significant correlations between elevated levels of PM_{2.5} (particulate matter with a diameter of 2.5 microns or less) and premature mortality. Other important health effects associated with PM_{2.5} exposure include aggravation of respiratory and cardiovascular disease, changes in lung function, and increased respiratory symptoms. Individuals particularly sensitive to PM_{2.5} exposure include older adults, people with heart and lung disease, and children.² PM_{2.5} can be emitted directly into the atmosphere as a solid or liquid particle (“primary PM_{2.5}” or “direct PM_{2.5}”) or can be formed in the atmosphere as a result of various chemical reactions among precursor pollutants such as nitrogen oxides, sulfur oxides, volatile organic compounds, and ammonia (“secondary PM_{2.5}”).³

¹ 78 FR 3086 and 40 CFR 50.18. Unless otherwise noted, all references to the PM_{2.5} NAAQS in this notice are to the 2012 annual NAAQS of 12.0 µg/m³ codified at 40 CFR 50.18.

² 78 FR 3086, 3088 (January 15, 2013).

³ EPA, Air Quality Criteria for Particulate Matter, No. EPA/600/P-99/002aF and EPA/600/P-99/002bF, October 2004.

Following promulgation of a new or revised NAAQS, the EPA is required by CAA section 107(d) to designate areas throughout the nation as attaining or not attaining the NAAQS. The EPA designated and classified the Portola nonattainment area as “Moderate” nonattainment for the 2012 annual PM_{2.5} standards based on ambient monitoring data that showed the area was above 12.0 µg/m³ for the 2011–2013 monitoring period.⁴ For the 2011–2013 period, the annual PM_{2.5} design value for the Portola nonattainment area was 12.8 µg/m³ based on monitored readings at the 161 Nevada Street and 420 Gulling Street monitors.⁵

The Portola nonattainment area includes the City of Portola (“Portola”), which has a population of approximately 2,100 and is located at an elevation of 4,890 feet in an intermountain basin isolated by rugged mountains. For a precise description of the geographic boundaries of the Portola nonattainment area, see 40 CFR 81.305.

The local air district with primary responsibility for developing a plan to attain the 2012 annual PM_{2.5} NAAQS in this area is the Northern Sierra Air Quality Management District (NSAQMD or “District”). The District worked with the California Air Resources Board (CARB) in preparing the PM_{2.5} Plan Revision. Under state law, authority for regulating sources under state jurisdiction in the Portola nonattainment area is split between the District, which has responsibility for regulating stationary and most area sources, and CARB, which has responsibility for regulating most mobile sources.

On February 28, 2017, California submitted the “Portola Fine Particulate Matter (PM_{2.5}) Attainment Plan” (“Portola PM_{2.5} Plan”) to address the CAA’s Moderate area requirements for the 2012 annual PM_{2.5} NAAQS in the Portola nonattainment area. On March 25, 2019, the EPA fully approved the Portola PM_{2.5} Plan, except for the contingency measure element.⁶ As part of the attainment control strategy, the Portola PM_{2.5} Plan relies on “Ordinance No. 344: An Ordinance of the City of Portola, County of Plumas Amending Chapter 15.10 of the City of Portola Municipal Code Providing for Regulation of Wood Stoves and Fireplaces” (“City Ordinance No. 344”) to achieve direct PM_{2.5} emission reductions necessary for attainment by

⁴ 80 FR 2206 (January 15, 2015).

⁵ From 2000 through early 2013, the Portola PM_{2.5} monitoring site was located at 161 Nevada Street. In 2013, the site was relocated to 420 Gulling Street.

⁶ 84 FR 11208.

the December 31, 2021 attainment date. The EPA approved City Ordinance No. 344 into the SIP on March 5, 2018.⁷ The attainment control strategy in the Portola PM_{2.5} Plan also relies on an enforceable state commitment to implement an incentive grant program called the “Greater Portola Woodstove Change-out Program 2016” (“Wood Stove Program”) during the 2016 to 2021 period to fund the replacement of uncertified wood stoves with newer, EPA-certified devices and to educate residents on proper ways to store and burn wood. The EPA approved the Wood Stove Program into the SIP on April 2, 2018.⁸

On October 28, 2020, CARB submitted “Ordinance No. 359: An Ordinance of the City of Portola, County of Plumas Amending Chapter 15.10 of the City of Portola Municipal Code Providing for Regulation of Wood Stoves and Fireplaces and the Prohibition of the Open Burning of Yard Waste” (“City Ordinance No. 359”), together with a document entitled “Proposed Portola PM_{2.5} Plan Contingency Measure SIP Submittal,” October 16, 2020 (hereafter “CARB Staff Report”), to the EPA with a request for approval into the SIP through the EPA’s parallel processing procedures in 40 CFR part 51, appendix V, section 2.3.⁹ We refer to this submission of City Ordinance No. 359 and the CARB Staff Report together as the “Proposed PM_{2.5} Plan Revision.” The Proposed PM_{2.5} Plan Revision contains, among other things, a contingency measure in City Ordinance No. 359 that revises and supplements the contingency measure element of the Portola PM_{2.5} Plan.¹⁰

On December 3, 2020, the EPA proposed to approve the Proposed PM_{2.5} Plan Revision, through parallel processing, and to approve the contingency measure element of the Portola PM_{2.5} Plan, as revised and supplemented by the Proposed PM_{2.5} Plan Revision.¹¹ Specifically, the EPA proposed to find that the contingency measure element of the Portola PM_{2.5} Plan, as revised and supplemented by the Proposed PM_{2.5} Plan Revision, would satisfy the requirements for contingency measures in CAA section 172(c)(9) and 40 CFR 51.1014 for

purposes of the 2012 PM_{2.5} NAAQS in the Portola nonattainment area. Our proposed approval was contingent upon the State’s submission of the final, adopted PM_{2.5} Plan Revision in time for the EPA to finalize this action by March 1, 2021, our court-ordered deadline for taking final action on the contingency measure element of the Portola PM_{2.5} Plan.¹² The EPA also proposed to find that the requirement for contingency measures to address a failure to meet a reasonable further progress (RFP) requirement for the 2019 RFP milestone year was moot as applied to the Portola nonattainment area, because the State and District had adequately demonstrated that the emission reductions needed for RFP had been achieved and that the Portola nonattainment area had met its 2019 quantitative milestone. Finally, the EPA proposed to approve a new prohibition on the open burning of yard waste and related provisions in City Ordinance No. 359 that would strengthen the SIP, excluding paragraph 15.10.060 B. and sections 15.10.100 and 15.10.110 regarding penalties and violations.¹³

On November 19, 2020, CARB adopted the Proposed PM_{2.5} Plan Revision, and on December 29, 2020, CARB submitted the final PM_{2.5} Plan Revision to the EPA as a revision to the California SIP.¹⁴ The SIP submission includes evidence that the State provided adequate public notice and an opportunity for a public hearing, consistent with the EPA’s implementing regulations in 40 CFR 51.102.

II. Public Comments and EPA Responses

The EPA’s proposed action provided a 30-day public comment period that ended on January 4, 2021. During this period, the EPA received one anonymous comment that does not articulate any issue.¹⁵ We do not respond to this comment because it fails to identify any issue that is germane to the EPA’s action.

¹² Order, *Center for Biological Diversity, et al. v. Andrew Wheeler*, Case No. 3:19-cv-02782-EMC (N.D. Cal., February 19, 2020).

¹³ 85 FR 78050.

¹⁴ CARB Resolution 20–26, “Proposed Portola PM_{2.5} Plan Contingency Measure State Implementation Plan Submittal” (November 19, 2020) and letter dated December 28, 2020, from Richard W. Corey, Executive Officer, CARB, to John W. Busterud, Regional Administrator, EPA Region IX, including enclosures (transmitting Proposed Portola PM_{2.5} Plan Contingency Measure State Implementation Plan Submittal).

¹⁵ The comment is available in the docket for this rulemaking at <https://www.regulations.gov/document?D=EPA-R09-OAR-2020-0534-0028>.

III. Final Action

For the reasons discussed in detail in the proposed rule and summarized herein, under CAA section 110(k)(3), the EPA is taking final action to approve the PM_{2.5} Plan Revision and to approve the contingency measure element of the Portola PM_{2.5} Plan, as revised and supplemented by the PM_{2.5} Plan Revision, as meeting the contingency measure requirements of CAA section 172(c)(9) and 40 CFR 51.1014 for the 2012 annual PM_{2.5} NAAQS in the Portola nonattainment area. The EPA is also determining that the requirement for RFP contingency measures for the 2019 milestone date is moot as applied to the Portola nonattainment area, because the State and District have adequately demonstrated that the emission reductions needed for RFP have been achieved and that the 2019 quantitative milestone has been met in the Portola nonattainment area.

Finally, the EPA is approving new provisions in City Ordinance No. 359 concerning open burning of yard wastes and other debris, including related definitions and exemptions. These provisions strengthen the SIP and are consistent with CAA requirements regarding enforceability and SIP revisions. At the State’s and District’s request, we are not acting on paragraph 15.10.060 B., section 15.10.100, or section 15.10.110 of City Ordinance No. 359.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the City of Portola ordinance described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents available through www.regulations.gov and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

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. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA’s role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves, or conditionally approves, state plans as meeting federal

⁷ 83 FR 9213.

⁸ 83 FR 13871.

⁹ Letter dated October 28, 2020, from Richard Corey, Executive Officer, CARB, to John Busterud, Regional Administrator, EPA Region IX, with enclosures.

¹⁰ CARB requested that the EPA entirely replace City Ordinance No. 344 in the SIP with City Ordinance No. 359. NSAQMD, Resolution 2020–09 (October 26, 2020).

¹¹ 85 FR 78050 (December 3, 2020).

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 the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practical and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).
- In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).
- 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. The 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 May 3, 2021. 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, Ammonia, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

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

Dated: February 23, 2021.

Deborah Jordan,

Acting Regional Administrator, Region IX.

Chapter I, title 40 of the Code of Federal Regulations is amended 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 F—California

- 2. Section 52.220 is amended by adding paragraphs (c)(497)(i)(C)(1)(ii), (c)(500)(ii)(A)(2), and (c)(553) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(497) * * *

(i) * * *

(C) * * *

(1) * * *

(ii) Previously approved on March 5, 2018 at (c)(497)(i)(C)(1)(i) of this section

and now deleted with replacement at (c)(553)(i)(B)(1)(i), Ordinance No. 344, Portola Municipal Code, Chapter 15.10, “Wood Stove and Fireplace Ordinance,” adopted June 22, 2016.

* * * * *

(500) * * *

(ii) * * *

(A) * * *

(2) The “Portola Fine Particulate Matter (PM_{2.5}) Attainment Plan,” adopted January 23, 2017, subchapter VI.B (“Contingency Measure”), as supplemented and revised October 26, 2020.

* * * * *

(553) The following additional materials were submitted on December 29, 2020, by the Governor’s designee as an attachment to a letter dated December 28, 2020.

(i) *Incorporation by reference.* (A) Northern Sierra Air Quality Management District.

(1) City of Portola.

(i) Ordinance No. 359, Portola Municipal Code, Chapter 15.10, “Wood Stove and Fireplace Ordinance and the Prohibition of the Open Burning of Yard Waste,” adopted September 9, 2020, except paragraph 15.10.060 B., section 15.10.100, and section 15.10.110.

(ii) [Reserved]

(B) [Reserved]

(ii) *Additional materials.* (A) California Air Resources Board.

(1) Resolution 20–26, “Proposed Portola PM_{2.5} Plan Contingency Measure State Implementation Plan Submittal,” adopted November 19, 2020.

(2) [Reserved]

(B) Northern Sierra Air Quality Management District.

(1) Northern Sierra Air Quality Management District Resolution 2020–09, adopted October 26, 2020.

(2) [Reserved]

[FR Doc. 2021–04351 Filed 3–2–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2020–0196; FRL–10020–45–Region 3]

Air Plan Approval; West Virginia; 1997 8-Hour Ozone National Ambient Air Quality Standard Second Maintenance Plan for the West Virginia Portion of the Huntington-Ashland, WV-KY Area Comprising Cabell and Wayne Counties

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision submitted by the West Virginia Department of Environmental Protection (WVDEP) on behalf of the State of West Virginia (WV). This revision pertains to West Virginia's plan for maintaining the 1997 8-hour ozone national ambient air quality standard (NAAQS) for the West Virginia portion of the Huntington-Ashland, WV-KY area (Huntington Area), comprising Cabell and Wayne Counties. The EPA is approving these revisions to the West Virginia SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on April 2, 2021.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA-R03-OAR-2020-0196. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Keila M. Pagán-Incle, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814-2926. Ms. Pagán-Incle can also be reached via electronic mail at pagan-incle.keila@epa.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

On June 29, 2020 (85 FR 38825), EPA published a notice of proposed rulemaking (NPRM) for the State of West Virginia. In the NPRM, EPA proposed approval of West Virginia's plan for maintaining the 1997 8-hour ozone NAAQS through October 16, 2026, in accordance with CAA section 175A. The formal SIP revision was submitted by WVDEP on December 10, 2019.

II. Summary of SIP Revision and EPA Analysis

On September 15, 2006 (71 FR 54421, effective October 16, 2006), EPA approved a redesignation request (and maintenance plan) from WVDEP for the Huntington Area. Per CAA section 175A(b), at the end of the eighth year after the effective date of the redesignation, the state must also submit a second maintenance plan to ensure ongoing maintenance of the standard for an additional 10 years, and in *South Coast Air Quality Management District v. EPA*,¹ the D.C. Circuit held that this requirement cannot be waived for areas, like the Huntington Area, that had been redesignated to attainment for the 1997 8-hour ozone NAAQS prior to revocation and that were designated attainment for the 2008 ozone NAAQS. CAA section 175A sets forth the criteria for adequate maintenance plans. In addition, EPA has published longstanding guidance that provides further insight on the content of an approvable maintenance plan, explaining that a maintenance plan should address five elements: (1) An attainment emissions inventory; (2) a maintenance demonstration; (3) a commitment for continued air quality monitoring; (4) a process for verification of continued attainment; and (5) a contingency plan.² WVDEP's December 10, 2019 SIP submittal fulfills West Virginia's obligation to submit a second maintenance plan and addresses each of the five necessary elements.

As discussed in the June 29, 2020 NPRM, consistent with longstanding EPA's guidance,³ areas that meet certain criteria may be eligible to submit a limited maintenance plan (LMP) to satisfy one of the requirements of CAA section 175A. Specifically, states may meet CAA section 175A's requirements to "provide for maintenance" by demonstrating that the area's design value⁴ are well below the NAAQS and

¹ 882 F.3d 1138 (D.C. Cir. 2018).

² "Procedures for Processing Requests to Redesignate Areas to Attainment," Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (Calcagni Memo).

³ See "Limited Maintenance Plan Option for Nonclassifiable Ozone Nonattainment Areas" from Sally L. Shaver, Office of Air Quality Planning and Standards (OAQPS), dated November 16, 1994; "Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas" from Joseph Paisie, OAQPS, dated October 6, 1995; and "Limited Maintenance Plan Option for Moderate PM₁₀ Nonattainment Areas" from Lydia Wegman, OAQPS, dated August 9, 2001.

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 nonattainment area

that it has had historical stability attaining the NAAQS. EPA evaluated WVDEP's December 10, 2019 submittal for consistency with all applicable EPA guidance and CAA requirements. EPA found that the submittal met CAA section 175A and all CAA requirements, and proposed approval of the LMP for the Huntington Area, comprising Cabell and Wayne Counties as a revision to the West Virginia SIP. The effect of this action makes certain commitments related to the maintenance of the 1997 8-hour ozone NAAQS federally enforceable as part of the West Virginia SIP.

Other specific requirements of WVDEP's December 10, 2019 submittal and the rationale for EPA's proposed action are explained in the NPRM and will not be restated here.

III. EPA's Response to Comments Received

EPA received four sets of relevant comments on the June 29, 2020 NPRM. Comments 2 and 3 raised concerns about EPA's reliance on the Air Quality Modeling Technical Support Document (TSD) and are summarized and addressed together under Comment 2. All comments received are in the docket for this rulemaking action. A summary of the comments and EPA's responses are provided herein.

Comment 1: The commenter contends that the LMP should not be approved because it is not based on the "the best available science." The commenter asserts that the second maintenance plan does not provide information regarding the prevention and reduction of future impacts of "oil and gas development activity," and does not take into consideration impacts of "installation of oil and gas pipelines in the area." Additionally, the commenter asserts that the LMP "does not have adequate funding to cover the costs and does not comply with other provisions of state policy that make it impossible for it to meet the EPA standards." Further, the commenter claims that the second maintenance plan failed to consider "potential emissions from oil and gas pipelines" including "spills and releases," and these emissions need to be included and mitigated.

Response 1: Commenter contends that EPA's proposed approval of West Virginia's second maintenance plan is not based on "the best available science," but provides no support for its contention. EPA disagrees with the commenter that West Virginia's second maintenance plan is not based on "the

is the highest design value of any monitoring site in the area.

best available science.” As EPA laid out in the NPRM, EPA has interpreted the provision in CAA section 175A that requires states to “provide for maintenance” of the NAAQS to be satisfied when the design values are consistently below 85% of the relevant standard, which in this case means at or below 0.071 parts per million (ppm). At the time of submission, on December 10, 2019, the Huntington Area’s 2016 to 2018 design value was at 0.064 ppm. The 2017 to 2019 period design value fell to 0.062 ppm. As EPA noted in the NPRM the area has maintained design values below 0.065 ppm since 2014. The commenter did not identify what science might provide a better basis for demonstrating maintenance with the ozone NAAQS than what West Virginia relied upon in the second maintenance plan, or that EPA should consider in its evaluation of the plan. The commenter had provided EPA with no basis to change its conclusion that the data and analysis of the data provided by West Virginia in support of the second maintenance plan will result in maintenance of the NAAQS for the remainder of the second maintenance period. See, e.g., *International Fabricare Institute v. E.P.A.*, 972 F.2d 384, 391 (D.C. Cir. 1992). (The Administrative Procedures Act does not require that EPA change its decision based on “comments consisting of little more than assertions that in the opinions of the commenters the agency got it wrong,” when submitted with no accompanying data.)

The commenter further asserts that: (1) The plan did not provide information about prevention and reduction of future impacts of “oil and gas development activity;” (2) the plan did not take into consideration future installation of oil and gas pipelines in the area; and (3) the plan failed to consider “potential emissions from oil and gas pipeline.” We do not agree with the commenter that a demonstration of maintenance under CAA section 175A is required to “prevent” potential future emissions activities in the area, or to consider potential future emissions from sources that do not yet exist. As noted above and in the proposal, under the LMP option, states may demonstrate that areas will maintain the NAAQS by showing that design values in the area in question are stably and significantly below the level of the NAAQS. In this case, the Huntington Area’s most recent design value ⁵ is below 0.065 ppm and

has been since 2014. The design values for the Huntington Area, that includes Cabell County in West Virginia and Boyd County in Kentucky (KY), consistently have been below 0.071 ppm since 2013 through 2019, the last year for which EPA has data.⁶ See Table 1 of this preamble for the design value data in ppm for both counties. Based on these trends, EPA has a high degree of confidence that the Area will be able to continue to maintain the NAAQS.

TABLE 1—REPORTED DESIGN VALUE DATA BETWEEN 2006 AND 2019 FOR CABELL COUNTY, WV AND BOYD COUNTY, KY ⁷

Year	Design value (ppm)	
	Cabell County, WV	Boyd County, KY
2006	0.076	0.076
2007	0.084	0.077
2008	0.080	0.074
2009	0.073	0.070
2010	0.066	0.070
2011	0.067	0.069
2012	0.072	0.072
2013	0.069	0.069
2014	0.065	0.068
2015	0.062	0.066
2016	0.064	0.066
2017	0.064	0.065
2018	0.064	0.064
2019	0.062	0.062

Moreover, in addition to demonstrating maintenance via the LMP option, West Virginia also pointed to EPA’s Air Quality Modeling TSD which projects future design values, including the Huntington Area, in 2023. This modeling takes into consideration all on-the-books control measures and any known future planned projects and sources. The Air Quality Modeling TSD projects that the average design value for the area in 2023 to be 0.058 ppm. This value is so far below the level of the 1997 8-hour ozone NAAQS that even if additional oil and gas sources

is the highest design value of any monitoring site in the area.

⁶ Design values for 2020 are not expected to be available before May 1, 2021. Design values are calculated for the year after states, locals and/or tribes certify their data on May 1st of the following year. Typically, design values are not finalized and posted until July of the following year. Design values are published annually by EPA and currently available through calendar year 2019. For more information on air quality design values visit: <https://www.epa.gov/air-trends/air-quality-design-values>.

⁷ See “EPA Air Quality System—Huntington WV Design Value Report” of WVDEP’s December 10, 2019 submittal, which includes details about the design values from the Huntington Area in WV from 2006 until 2019. Air quality data is also available at: <https://www.epa.gov/outdoor-air-quality-data>.

were to be sited in the Huntington Area (any of which would be subject to applicable CAA controls such as Prevention of Significant Deterioration [PSD]), those emissions increases would be unlikely to cause the area to violate the 1997 8-hour ozone NAAQS. Any emissions increases above the trigger levels specified in the LMP, whatever the cause, will result in West Virginia having to implement contingency measures as described in the NPRM. Moreover, as stated in the NPRM, if there is indeed a violation and the design value exceeds the NAAQS, the contingency plan will be “triggered,” based on the following schedule: (1) Quality assurance procedures must confirm the monitored violation within 45 days of occurrence; (2) a draft rule would be developed by WVDEP for any regulation chosen; (3) WVDEP will adopt the selected control measure(s) as emergency rule(s) which will be implemented within six months after adoption and will file the rule(s) as legislative rule(s) for permanent authorization by the legislature; and (4) for each voluntary measure selected, WVDEP will initiate program development with local governments within the area by the start of the following ozone season. These measures are part of the CAA section 175A requirements for an approvable LMP and West Virginia’s second maintenance plan meets these requirements.

The commenter also contends that the LMP does not present “adequate funding to cover the costs” and fails to “comply with other provisions of state policy,” but provides no further details or explanation. Similar to the comment regarding the alleged failure of West Virginia to use “the best available science,” the commenter has made an allegation without providing any support. The commenter provides no basis for EPA to be able to evaluate whether or not a funding issue exists. With respect to an alleged failure to comply with state policy, no specific policies that “make it impossible for it to meet the EPA standards” are cited by the commenter. Even had the commenter cited specific policies, “[C]omments consisting of little more than assertions that in the opinions of the commenters the agency got it wrong,” when submitted with no accompanying data do not provide sufficient ground for EPA to change its evaluation of a plan that on its face comports with EPA’s governing law and with the Agency’s consistent and long-standing policies for LMPs. See *International Fabricare* at 391. Furthermore, CAA section 175A does

⁵ 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 nonattainment area

not require that maintenance plans identify or provide funding for any costs associated with implementation of the plan. EPA has set forth in the NPRM the criteria relevant to approvability of the LMP. EPA has determined that the December 10, 2019 SIP revision includes adequate information to support approval of West Virginia's LMP. As set forth in the NPRM, EPA has determined that the State provided sufficient assurances in the LMP for EPA to approve West Virginia's 1997 8-hour ozone second maintenance plan for the Huntington Area. EPA's evaluation of the West Virginia's December 10, 2019 SIP revision and the rationale for taking rulemaking action on this submission was discussed in detail in the NPRM. This comment gives EPA no reason to believe that the criteria it applied in the NPRM are either incorrect, incomplete or have been misapplied.

Comment 2: Two commenters assert that the LMP should not be approved because of EPA's reliance on the Air Quality Modeling TSD that was developed for EPA's regional transport rulemaking.

One of the commenters alleged that the TSD does not consider newer EPA policies (*i.e.*, "repealing the MATS rule or removing California's ability to regulate cars, or even the repeal of the Clean Power Plan and replacement with the ACE rule").

Both commenters contend that: (1) The TSD shows maintenance of the area for three years and not 10 years; (2) the modeling was performed for transport purposes across state lines and not to show maintenance of the NAAQS; (3) the modeling was performed for the 2008 and 2015 ozone NAAQS and not the 1997 ozone NAAQS; and (4) the TSD has been "highly contested" by environmental groups, "incorrectly uses assumptions disputed by multiple non-governmental and governmental organizations" and "other states contend EPA's modeling as flawed."

Further, one commenter contends that the TSD does not address a recent court decision that "threw out" EPA's modeling "because it modeled to the wrong attainment year. . . ." Both commenters assert that the TSD is not being used for its intended purpose and EPA should disapprove the LMP due to EPA's reliance on the TSD in the NPRM.

Response 2: EPA does not agree with the commenters that approval of West Virginia's second maintenance plan is not appropriate. The commenters raise concerns about West Virginia and EPA's citation of the Air Quality Modeling TSD, but the commenters ignore that EPA's primary basis for finding that

West Virginia has provided for maintenance of the 1997 8-hour ozone NAAQS in the Huntington Area is the State's demonstration that the criteria for a LMP has been met. See 85 FR 38825, June 29, 2020. Specifically, as stated in the NPRM, for decades EPA has interpreted the provision in CAA section 175A that requires states to "provide for maintenance" of the NAAQS to be satisfied where areas demonstrate that design values are and have been stable and well below the NAAQS—*e.g.*, at 85% of the standard, or in this case at or below 0.071 ppm. EPA calls such demonstration a "limited maintenance plan." The Air Quality Modeling TSD referenced by West Virginia merely provides additional support for the area's continued maintenance of the 1997 8-hour ozone NAAQS.

EPA disagrees that it must disapprove the LMP because the Air Quality Modeling TSD does not consider newer EPA policies like "repealing the MATS (Mercury and Air Toxics Standards) rule, or California's ability to regulate cars, or even the repeal of the Clean Power Plan and replacement with the ACE (Affordable Clean Energy) rule." First, MATS was not repealed. All emission reductions required under MATS remain. See 85 FR 31286, 31312 (May 22, 2020). Second, the 2023 Air Quality Modeling TSD cited by West Virginia in their second maintenance plan submission does not include emission reductions associated with the Clean Power Plan.⁸ (EPA's actions with respect to regulating automobile emissions in California are not relevant to this action).

The modeling cited by the commenters was referenced in West Virginia's submission and as part of EPA's proposed approval as supplementary supporting information, and we do not agree that the commenters' concerns about relying on that modeling are warranted. The commenters contend that the modeling only goes out three years (to 2023) and it needs to go out to 10 years, and therefore may not be relied upon.

⁸ See 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, at 92 ("The projected EGU emissions for 2023el included the Final Mercury and Air Toxics (MATS) rule announced on December 21, 2011, the Cross-State Air Pollution Rule (CSAPR) issued July 6, 2011, the CSAPR Update Rule issued October 26, 2016 and the Clean Power Plan (CPP), while the 2023en emissions [*i.e.*, the emissions inventory used in the updated 2023 modeling] include the other rules but do not include the CPP.")

However, the Air Quality Modeling TSD was only relied upon by EPA to provide additional support to indicate that the area is expected to continue to attain the NAAQS during the relevant period. As noted above, West Virginia primarily met the requirement to demonstrate maintenance of the NAAQS by showing that they met the criteria for an LMP, rather than by modeling or projecting emissions inventories out to a future year. We also do not agree that the State is required to demonstrate maintenance for 10 years; CAA section 175A requires the State to demonstrate maintenance through the 20th year after the area is redesignated, which in this case is 2026.

We also disagree with the commenters' contention that because the Air Quality Modeling TSD was performed to analyze the transport of pollution across state lines with respect to other ozone NAAQS, it cannot be relied upon in this action. We acknowledge that the Air Quality Modeling TSD at issue was performed as part of EPA's efforts to address interstate transport pollution under CAA section 110(a)(2)(D)(i)(I). However, the purpose of the Air Quality Modeling TSD is fully in keeping with the question of whether the Huntington Area is expected to maintain the NAAQS. The Air Quality Modeling TSD projected ozone concentrations at every air quality monitor in the contiguous United States in 2023 in order to identify which monitors might have problems attaining or maintaining the 2008 and 2015 NAAQS for ozone in 2023. Because the Air Quality Modeling TSD results simply provide projected ozone concentration design values, which are expressed as three-year averages of the annual fourth high 8-hour daily maximum ozone concentrations, the modeling results are useful for analyzing attainment and maintenance of any of the ozone NAAQS that are measured using this averaging time; in this case, the 1997, 2008 and 2015 ozone NAAQS. The only difference between the three standards is stringency. Taking the Huntington Area's most recent certified design value as part of the proposal (*i.e.*, for the years 2016–2018), the area's design value was 0.064 ppm. What we can discern from this is that the area is meeting the 1997 ozone NAAQS of 0.080 ppm, the 2008 ozone NAAQS of 0.075 ppm, and the 2015 ozone NAAQS of 0.070 ppm. The same principle applies to projected design values from the Air Quality Modeling TSD. In this case, the interstate transport modeling indicated that in 2023, the Huntington Area's design value is projected to be 0.058

ppm,⁹ which is again, well below all three standards. The fact that the Air Quality Modeling TSD was performed to indicate whether the area will have problems attaining or maintaining the 2015 ozone NAAQS (*i.e.*, 0.070 ppm) does not make the modeling less useful for determining whether the area will also meet the less stringent revoked 1997 standard (*i.e.*, 0.080 ppm).

The commenters' assert that many groups have criticized EPA's transport modeling, alleging that the agency used improper emissions inventories, incorrect contribution thresholds, wrong modeling years, or that EPA has not accounted for local situations or reductions that occurred after the inventories were established. The commenters' also allege that EPA should not rely on its modeling because it "have now been outlawed by multiple courts" and "fails to stand up to the recent court decisions," citing the *Wisconsin v. EPA* D.C. Circuit decision.¹⁰ EPA disagrees that the existence of criticisms of the agency's Air Quality Modeling TSD render it unreliable, and we also do not agree that anything in recent court decisions, including *Wisconsin v. EPA*, suggests that EPA's Air Quality Modeling TSD is technically flawed. We acknowledge that the source apportionment Air Quality Modeling TSD runs cited by the commenters have been at issue in various legal challenges to EPA actions, including the *Wisconsin v. EPA* case. However, in that case, the *only* flaw in EPA's Air Quality Modeling TSD identified by the D.C. Circuit was the fact that its analytic year did not align with the attainment date found in CAA section 181.¹¹ Contrary to the commenters' suggestion, the D.C. Circuit upheld EPA's Air Quality Modeling TSD with respect to the many technical challenges raised by petitioners in the *Wisconsin* case.¹² We therefore think reliance on the interstate transport Air Quality Modeling TSD as supplemental support for showing that the Huntington Area will maintain the 1997 8-hour ozone NAAQS through the end of its 20th year maintenance period is appropriate.

Comment 3: The commenter asserts that EPA should disapprove this maintenance plan because EPA should not allow states to rely on emission programs such as the Cross-State Air Pollution rule (CSAPR) to demonstrate maintenance for the 1997 ozone NAAQS. The commenter alleges that "the CSAP and CSAP Update and CSAP Close-out rules were vacated entirely" by multiple courts and "are now illegal programs providing no legally enforceable emission reductions to any states formerly covered by the rules." The commenter also asserts that nothing restricts "big coal and gas power plants from emitting way beyond there (sic) restricted amounts." The commenter does allow that "If EPA can show that continued maintenance without these rules is possible for the next 10 years then that would be OK but as the plan stands it relies on these reductions and must be disapproved."

Response 3: The commenter has misapprehended the factual circumstances regarding these interstate transport rules. Every rule cited by the commenter that achieves emission reductions from electric generating units (EGUs or power plants)—*i.e.*, the Cross-State Air Pollution Rule and the CSAPR Update—remains in place and continues to ensure emission reductions of nitrogen oxides (NO_x) and sulfur dioxide (SO₂). CSAPR began implementation in 2015 (after it was largely upheld by the Supreme Court) and the CSAPR Update began implementation in 2017. The latter rule was remanded to EPA to address the analytic year issues discussed in the prior comment and response, but the rule remains fully in effect. The commenter is correct that the D.C. Circuit vacated the CSAPR close-out, but we note that that rule was only a determination that no further emission reductions were required to address interstate transport obligations for the 2008 ozone NAAQS; the rule did not itself establish any emission reductions. We therefore disagree that the legal status of these rules presents any obstacle to EPA's approval of West Virginia's submission.

IV. Final Action

EPA is approving the 1997 8-hour ozone NAAQS limited maintenance plan for the Huntington Area, comprising Cabell and Wayne Counties as a revision to the West Virginia SIP.

V. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 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. Accordingly, 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because it is not a significant regulatory action under Executive Order 12866;
- 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).

In addition, this rule does not have tribal implications as specified by

⁹ The June 29, 2020 NPRM for this action recited 0.060 ppm as the Projected 2023 design value in Table 2—Huntington Area 8-hour Ozone Design Value in Parts Per Million. Through this final action we clarify that the correct Projected 2023 design value that was included in the State's submission, is 0.058 ppm. The inclusion of the slightly higher but incorrect figure in the NPRM is a harmless error that does not alter EPA's proposal to approve this LMP.

¹⁰ *Wisconsin*, 938 F.3d 303 (D.C. Cir. 2019).

¹¹ *Wisconsin*, 938 F.3d at 313.

¹² *Wisconsin*, 938 F.3d at 323–331.

Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

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).

C. Petitions for Judicial Review

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 May 3, 2021. 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 pertaining to West Virginia’s limited maintenance plan for the Huntington Area, comprising Cabell and Wayne Counties 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, Nitrogen dioxide, Ozone, Volatile organic compounds.

Dated: February 18, 2021.

Diana Esher,

Acting Regional Administrator, Region III.

For the reasons stated in the preamble, the 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 XX—West Virginia

■ 2. In § 52.2520, the table in paragraph (e) is amended by adding an entry for “1997 8-Hour Ozone National Ambient Air Quality Standard Second Maintenance Plan for the West Virginia Portion of the Huntington-Ashland, WV-KY Area Comprising Cabell and Wayne Counties” at the end of the table to read as follows:

§ 52.2520 Identification of plan.

* * * * *

(e) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
* * *	* * *	* * *	* * *	* * *
1997 8-Hour Ozone National Ambient Air Quality Standard Second Maintenance Plan for the West Virginia Portion of the Huntington-Ashland, WV-KY Area Comprising Cabell and Wayne Counties.	Huntington-Ashland WV-KY, West Virginia Area Comprising Cabell and Wayne Counties.	12/10/19	3/3/21, [insert Federal Register citation].	

[FR Doc. 2021-04107 Filed 3-2-21; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R05-OAR-2020-0388; FRL-10020-89-Region 5]

Air Plan Approval; Ohio; Base Year Emission Inventories and Emissions Statement Rule Certification for the 2015 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving, under the Clean Air Act (CAA), a revision to the State Implementation Plan (SIP) submitted by the Ohio Environmental Protection Agency on July 24, 2020. The

CAA establishes emission inventory requirements for all ozone nonattainment areas. The revision addresses the emission inventory requirements for the Cleveland, Ohio (OH) ozone nonattainment area and the Ohio portion of the Cincinnati, Ohio-Kentucky (Cincinnati) ozone nonattainment area, as designated under the 2015 ozone National Ambient Air Quality Standard (NAAQS or standard). EPA is also confirming that Ohio’s stationary annual emissions statement regulation, which has been previously approved by EPA under a prior ozone standard, satisfies the CAA emissions statement rule requirement for the Cleveland and Cincinnati nonattainment areas under the 2015 ozone NAAQS.

DATES: This final rule is effective on April 2, 2021.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-R05-OAR-2020-0388. 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 (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either through www.regulations.gov or at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID-19. We recommend that you telephone Charles Hatten, Environmental Engineer, at (312) 886-6031 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT:

Charles Hatten, Environmental Engineer, Control Strategies Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-6031, hatten.charles@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA.

I. What is being addressed in this document?

This rule approves Ohio’s July 24, 2020 submission to address the ozone-related emissions inventory requirements and emissions statement requirements for the Cleveland and Cincinnati ozone nonattainment areas for the 2015 ozone NAAQS. An explanation of the CAA requirements, a detailed analysis of the revisions, and EPA’s reasons for proposing approval were provided in EPA’s notice of proposed rulemaking (NPRM), dated November 5, 2020 (85 FR 70554), and will not be restated here.

II. What comments did we receive on the proposed rule?

In the NPRM, EPA provided a 30-day review and comment period for the proposed rule. The comment period ended on December 7, 2020. We received no comments on the proposed rule.

III. What action is EPA taking?

EPA is approving Ohio’s July 24, 2020 SIP revision as addressing the ozone-related emission inventory requirements for the Cleveland and Cincinnati ozone nonattainment areas for the 2015 ozone NAAQS. We are approving the emission inventories for these areas because they contain comprehensive, accurate, and current inventories of actual emissions of oxides of nitrogen (NO_x) and volatile organic compounds (VOC) for all relevant sources in accordance with CAA sections 172(c)(3) and 182(a). We are also approving Ohio’s certification that the state has an acceptable and enforceable stationary annual emission statement rule in its SIP for NO_x and VOC stationary sources in the Cleveland and Cincinnati ozone nonattainment areas for the 2015 ozone NAAQS, in accordance with the CAA section 182(a)(3)(B).

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

CAA and applicable Federal regulations. 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. Accordingly, 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).

In addition, 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 and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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 Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 3, 2021. 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, Nitrogen dioxide, Ozone, Volatile organic compounds.

Dated: February 24, 2021.

Cheryl Newton,

Acting Regional Administrator, Region 5.

For the reasons stated in the preamble, EPA amends title 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 § 52.1870, the table in paragraph (e) is amended under the sub-heading Summary of Criteria Pollutant Attainment Plans by adding two entries for “Ozone (8-Hour, 2015)” before the entry “PM_{2.5} (2012)” to read as follows:

§ 52.1870 Identification of plan.

*	*	*	*	*
(e)	*	*	*	*

EPA-APPROVED OHIO NONREGULATORY AND QUASI-REGULATORY PROVISIONS

Title	Applicable geographical or non-attainment area	State date	EPA approval	Comments
*	*	*	*	*
Summary of Criteria Pollutant Attainment Plans				
Ozone (8-Hour, 2015)	Cincinnati	7/24/2020	3/3/2021, [INSERT Federal Register CITATION].	EPA is approving only the 2014 base year emissions inventory and emissions statement elements.
Ozone (8-Hour, 2015)	Cleveland	7/24/2020	3/3/2021, [INSERT Federal Register CITATION].	EPA is approving only the 2014 base year emissions inventory and emissions statement elements.
*	*	*	*	*

* * * * *

[FR Doc. 2021-04246 Filed 3-2-21; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[EPA-HQ-OW-2019-0583; FRL-10019-70-OW]

RIN 2040-AF93

Announcement of Final Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Regulatory determinations.

SUMMARY: The U.S. Environmental Protection Agency (EPA or Agency) is announcing final regulatory determinations for eight of the 109 contaminants listed on the Fourth Contaminant Candidate List. Specifically, the Agency is making final determinations to regulate perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) and to not regulate 1,1-dichloroethane, acetochlor, methyl bromide (bromomethane), metolachlor, nitrobenzene, and RDX. The Safe Drinking Water Act (SDWA), as amended in 1996, requires EPA to make regulatory determinations every five years on at least five unregulated contaminants. A regulatory determination is a decision about whether or not to begin the process to propose and promulgate a national primary drinking water regulation for an unregulated contaminant.

DATES: For purposes of judicial review, the determinations not to regulate in

this document are issued as of March 3, 2021.

FOR FURTHER INFORMATION CONTACT: Richard Weisman, Standards and Risk Management Division, Office of Ground Water and Drinking Water, Office of Water (Mail Code 4607M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564-2822; email address: weisman.richard@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

These final regulatory determinations will not impose any requirements on anyone. Instead, this action notifies interested parties of EPA's final regulatory determinations for eight unregulated contaminants and provides a summary of the major comments received on the March 10, 2020, preliminary determinations (USEPA, 2020a).

B. How can I get copies of this document and other related information?

Docket: EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2019-0583. Publicly available docket materials are available either electronically at <http://www.regulations.gov> or in hard copy at the Water Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426.

Electronic Access: You may access this **Federal Register** document electronically from the Government Printing Office under the "**Federal Register**" listings at <http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR>.

Table of Contents

- I. General Information
 - A. Does this action apply to me?
 - B. How can I get copies of this document and other related information?
- II. Purpose and Background
 - A. What is the purpose of this action?
 - B. What are the statutory requirements for the Contaminant Candidate List (CCL) and regulatory determinations?
 - C. What contaminants did EPA consider for regulation?
- III. What process did EPA use to make the regulatory determinations?
 - A. How EPA Identified and Evaluated Contaminants for the Fourth Regulatory Determination
 - B. Consideration of Public Comments
- IV. EPA's Findings on Specific Contaminants
 - A. PFOS and PFOA
 - 1. Description
 - 2. Agency Findings
 - a. Adverse Health Effects
 - b. Occurrence
 - c. Meaningful Opportunity
 - d. Summary of Public Comments on PFOA and PFOS and Agency Responses
 - 3. Considerations for Additional PFAS
 - a. Summary of Public Comments on Considerations for Additional PFAS and Agency Responses
 - b. Summary of Public Comments on Potential PFAS Monitoring Approaches and Agency Responses
 - B. 1,1-Dichloroethane
 - 1. Description
 - 2. Agency Findings
 - a. Adverse Health Effects
 - b. Occurrence
 - c. Meaningful Opportunity
 - d. Summary of Public Comments on 1,1-Dichloroethane and Agency Responses
 - C. Acetochlor
 - 1. Description
 - 2. Agency Findings
 - a. Adverse Health Effects
 - b. Occurrence
 - c. Meaningful Opportunity
 - d. Summary of Public Comments on Acetochlor and Agency Responses
 - D. Methyl Bromide
 - 1. Description
 - 2. Agency Findings

- a. Adverse Health Effects
- b. Occurrence
- c. Meaningful Opportunity
- d. Summary of Public Comments on Methyl Bromide and Agency Responses
- E. Metolachlor
 - 1. Description
 - 2. Agency Findings
 - a. Adverse Health Effects
 - b. Occurrence
 - c. Meaningful Opportunity
 - d. Summary of Public Comments on Metolachlor and Agency Responses
- F. Nitrobenzene
 - 1. Description
 - 2. Agency Findings
 - a. Adverse Health Effects
 - b. Occurrence
 - c. Meaningful Opportunity
 - d. Summary of Public Comments on Nitrobenzene and Agency Responses
- G. RDX
 - 1. Description
 - 2. Agency Findings
 - a. Adverse Health Effects
 - b. Occurrence
 - c. Meaningful Opportunity
 - d. Summary of Public Comments on RDX and Agency Responses
- H. Strontium
- I. 1,4-Dioxane
- J. 1,2,3-Trichloropropane
- V. Next Steps
- VI. References

II. Purpose and Background

A. What is the purpose of this action?

The purpose of this action is to present a summary of EPA's final regulatory determinations for eight contaminants listed on the Fourth Contaminant Candidate List (CCL 4) (USEPA, 2016a). The eight contaminants are: Perfluorooctanesulfonic acid (PFOS), perfluorooctanoic acid (PFOA), 1,1-dichloroethane, acetochlor, methyl bromide (bromomethane), metolachlor, nitrobenzene, and Royal Demolition eXplosive (RDX). The Agency is making final determinations to regulate two contaminants (PFOS and PFOA) and to not regulate the remaining six contaminants (1,1-dichloroethane, acetochlor, methyl bromide (bromomethane), metolachlor, nitrobenzene, and RDX). The Agency is not making any determination at this time on any other CCL contaminants, including strontium, 1,4-dioxane, and 1,2,3-trichloropropane. This action summarizes the statutory requirements for targeting drinking water contaminants for regulatory determination, provides an overview of the contaminants that the Agency considered for regulation, and describes the approach used to make the final regulatory determinations. In addition, this action summarizes the public comments received on the Agency's preliminary determinations

announcement and the Agency's responses to those comments.

B. What are the statutory requirements for the Contaminant Candidate List (CCL) and regulatory determinations?

Section 1412(b)(1)(B)(i) of SDWA requires EPA to publish the CCL every five years after public notice and an opportunity to comment. The CCL is a list of contaminants which are not subject to any proposed or promulgated National Primary Drinking Water Regulations (NPDWRs) but are known or anticipated to occur in public water systems (PWSs) and may require regulation under SDWA. SDWA section 1412(b)(1)(B)(ii) directs EPA to determine, after public notice and an opportunity to comment, whether to regulate at least five contaminants from the CCL every five years.

Under Section 1412(b)(1)(A) of SDWA, EPA makes a determination to regulate a contaminant in drinking water if the Administrator determines that:

- (a) The contaminant may have an adverse effect on the health of persons;
- (b) The contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

(c) In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

If after considering public comment on a preliminary determination, the Agency makes a determination to regulate a contaminant, EPA will initiate the process to propose and promulgate an NPDWR. In that case, the statutory time frame provides for Agency proposal of a regulation within 24 months and action on a final regulation within 18 months of proposal. When proposing and promulgating drinking water regulations, the Agency must conduct a number of analyses.

C. What contaminants did EPA consider for regulation?

On March 10, 2020, EPA published preliminary regulatory determinations for eight contaminants on the fourth Contaminant Candidate List (CCL 4) (85 FR 14098) (USEPA, 2020a). The eight contaminants are PFOS, PFOA, 1,1-dichloroethane, acetochlor, methyl bromide, metolachlor, nitrobenzene, and RDX. The Agency is making final regulatory determinations to regulate two contaminants (*i.e.*, PFOS and PFOA) and to not regulate six

contaminants (*i.e.*, 1,1-dichloroethane, acetochlor, methyl bromide, metolachlor, nitrobenzene, and RDX).

Information on the eight contaminants with regulatory determinations can be found in the *Final Regulatory Determination 4 Support Document* (USEPA, 2021a). More information is available in the Public Docket at www.regulations.gov (Docket ID No. EPA-HQ-OW-2019-0583) and also on EPA's Regulatory Determination 4 website at <https://www.epa.gov/ccl/regulatory-determination-4>.

III. What process did EPA use to make the regulatory determinations?

A. How EPA Identified and Evaluated Contaminants for the Fourth Regulatory Determination

This section summarizes the process the Agency followed to identify and evaluate contaminants for the Fourth Regulatory Determination. For more detailed information on the process and the analyses performed, please refer to the "Protocol for the Regulatory Determination 4" found in Appendix E of the *Final Regulatory Determination 4 Support Document* (USEPA, 2021a) and the **Federal Register** publication for the preliminary regulatory determinations (USEPA, 2020a).

The CCL 4 identified 109 contaminants that are currently not subject to any proposed or promulgated national drinking water regulation, are known or anticipated to occur in public water systems, and may require regulation under SDWA (USEPA, 2016a). Since some of the CCL 4 contaminants do not have adequate health and/or occurrence data to evaluate against the three statutory criteria (see section II.B of this document), as when EPA evaluated the previous CCLs, the Agency used a three-phase process to identify which of the contaminants are candidates for regulatory determinations. Priority was given to identifying contaminants known to occur or with substantial likelihood to occur at frequencies and levels of public health concern.

Because the regulatory determination process includes consideration of human health effects, the Agency's Policy on Evaluating Health Risks to Children (USEPA, 1995a) reaffirmed by Administrator Wheeler in a memorandum dated October 11, 2018 to Agency staff (USEPA, 2018a), applies to this document. The policy requires EPA to consistently and comprehensively address children's unique vulnerabilities. We have explicitly considered children's health in the RD 4 process by reviewing all the available

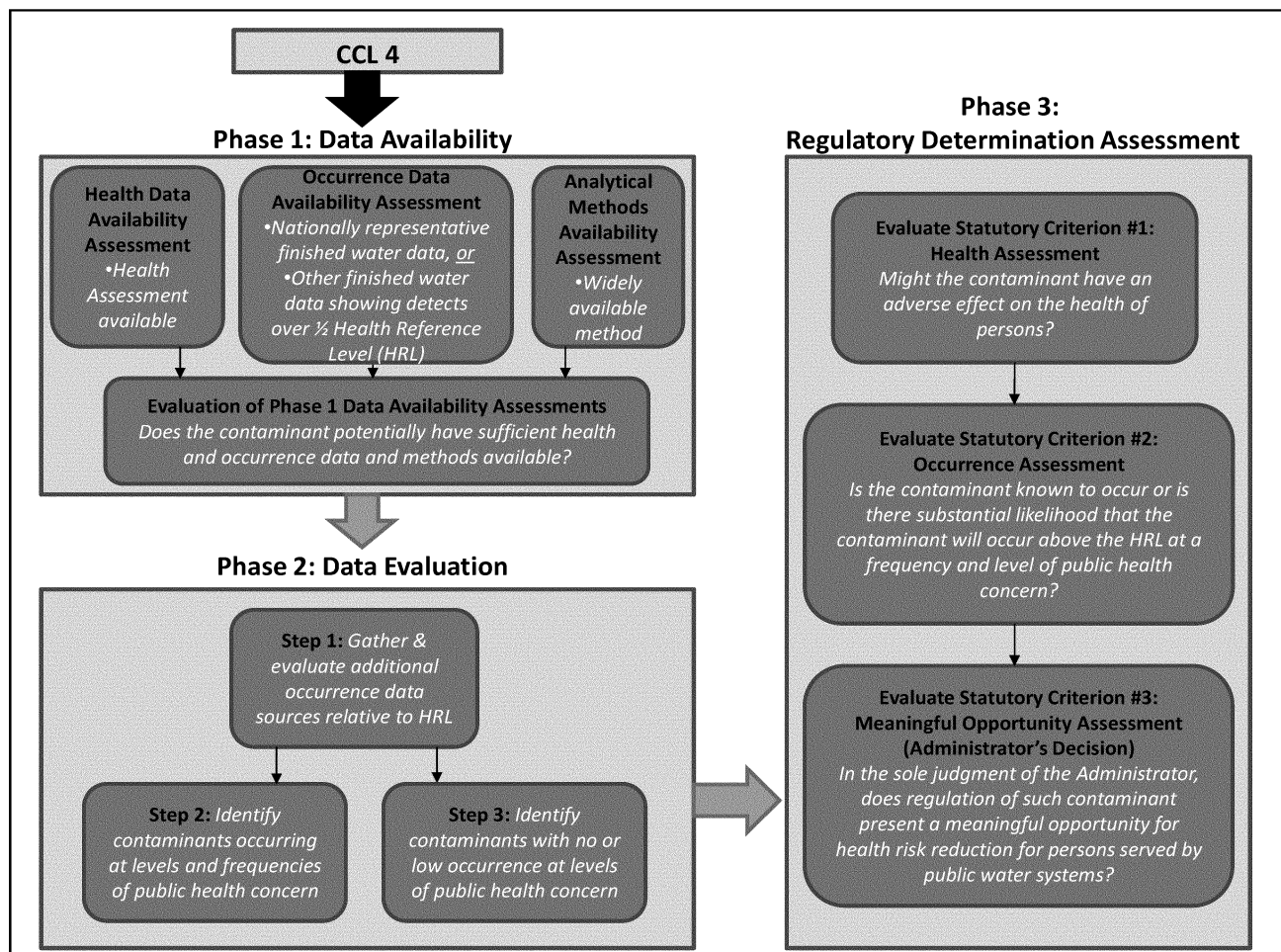
children's exposure and health effects information.

The three phases of the Fourth Regulatory Determination process are

(1) the *Data Availability Phase*, (2) the *Data Evaluation Phase* and (3) the *Regulatory Determination Assessment*

Phase. The overall process is displayed in Exhibit 1.

Exhibit 1: The Three Phases of the Regulatory Determination 4 Process



The purpose of the first phase, the *Data Availability Phase*, is to screen out contaminants that clearly do not have sufficient data to support a regulatory determination. The Agency applies criteria to ensure that any contaminant that potentially has sufficient data to characterize the health effects and known or likely occurrence in drinking water will proceed to the *Data Evaluation Phase*, the second phase of the regulatory determination process. From the 109 CCL 4 contaminants, the Agency identified 25 CCL 4 contaminants to further evaluate in the second phase. These are known as the “short list.”

During the second phase, the Agency evaluates the contaminants on the short list in greater depth and detail to identify those that have sufficient data (or are expected to have sufficient data

within the timeframe allotted for the second phase) for EPA to assess the three statutory criteria. As part of the second phase, the Agency specifically focuses its efforts on identifying those contaminants or contaminant groups that are occurring or have substantial likelihood to occur at levels and frequencies of public health concern, based on the best available peer reviewed data. If, during the first or second phase, the Agency finds that sufficient data are not available or not likely to be available to evaluate the three statutory criteria, then the contaminant is not considered a candidate for making a regulatory determination.

If sufficient data are available for a contaminant to characterize the potential health effects and known or likely occurrence in drinking water, the

contaminant is evaluated against the three statutory criteria in the *Regulatory Determination Assessment Phase*, which is the third phase of the process. Of the 25 contaminants that were evaluated under Phase 2, 10 were designated for evaluation against the three statutory criteria in Phase 3.

Of the 10 CCL4 contaminants that were evaluated in Phase 3, the Agency did not make preliminary regulatory determinations for two contaminants (1,4-dioxane and 1,2,3-trichloropropane); see Section IV of this document for discussion about these contaminants. Additionally, in Section IV of this document, EPA discusses continuing with its previous 2016 decision to defer a final determination for strontium (a CCL3 contaminant for which the Agency made a preliminary positive determination in the third

regulatory determination (RD 3)) in order to further consider additional studies related to strontium exposure.

Of the eight remaining CCL 4 contaminants (PFOS, PFOA, 1,1-dichloroethane, acetochlor, methyl bromide, metolachlor, nitrobenzene, and RDX) evaluated in Phase 3 against the three statutory criteria, including an evaluation of level and frequency of occurrence in drinking water, the size of the population exposed to concentrations of health concern, and information on sensitive populations and lifestyles¹ (e.g., pregnant women, infants and children), the Agency made preliminary regulatory determinations to regulate PFOS and PFOA and to not regulate the remaining six contaminants. These preliminary determinations, with their supporting analyses and documentation, were published in the **Federal Register** on March 10, 2020, for public comment (USEPA, 2020a). The public comment period was initially intended to run through May 11, 2020. In response to stakeholder requests, on April 30, 2020, EPA extended the comment period by 30 days to June 10, 2020.

B. Consideration of Public Comments

EPA received comments from approximately 11,600 organizations and individuals on the March 10, 2020, **Federal Register** document including 12 states (California, Colorado, Connecticut, Indiana, Massachusetts, Michigan, Missouri, New Hampshire, New Mexico, South Carolina, West Virginia, and Wisconsin). Comments on specific contaminants, and EPA's responses, are briefly summarized in the sections below. The Agency prepared a response-to-comments document for this action (USEPA, 2021b) that is available in the Public Docket at www.regulations.gov under Docket ID No. EPA-HQ-OW-2019-0583. The response-to-comments document is organized in a manner similar to this document and generally contains more detailed responses to the public comments received than those found in this document.

IV. EPA's Findings on Specific Contaminants

After considering the public comments, EPA is making final regulatory determinations to regulate PFOS and PFOA and to not regulate 1,1-dichloroethane, acetochlor, methyl

bromide, metolachlor, nitrobenzene, and RDX.

This document provides a brief description of the Agency findings on these contaminants. Details on the background, health and occurrence information, and analyses used to evaluate and make final determinations for these contaminants can be found in the *Final Regulatory Determination 4 Support Document* (USEPA, 2021a) and the **Federal Register** publication for the preliminary regulatory determination (USEPA, 2020a).

For each contaminant, the Agency reviewed the available human and toxicological data, derived a health reference level (HRL),² analyzed data on occurrence in drinking water, and estimated the population likely exposed to concentrations of the contaminant at levels of health concern in public water systems. The Agency also considered whether information was available on sensitive populations. The Agency used the findings to evaluate the contaminants against the three SDWA statutory criteria. Table 1 gives a summary of the health and occurrence information for the eight contaminants with final determinations under RD 4.

TABLE 1—SUMMARY OF THE HEALTH AND OCCURRENCE INFORMATION AND THE FINAL DETERMINATIONS FOR THE EIGHT CONTAMINANTS RECEIVING A FINAL DETERMINATION UNDER RD 4

RD 4 contaminant	Health reference level (HRL), µg/L	Occurrence findings from primary data sources					Final determination
		Primary database	PWSs with at least 1 detection > ½ HRL	Population served by PWSs with at least 1 detection > ½ HRL	PWSs with at least 1 detection > HRL	Population served by PWSs with at least 1 detection > HRL	
PFOS	0.07	UCMR 3 AM	95/4,920 (1.93%)	10,427,193/241 M (4.32%)	46/4,920 (0.93%)	3,789,831/241 M (1.57%)	Regulate.
PFOA	0.07	UCMR 3 AM	53/4,920 (1.07%)	3,652,995/241 M (1.51%)	13/4,920 (0.26%)	490,480/241 M (0.20%)	Regulate.
1,1-Dichloroethane	1,000	UCMR 3 AM	0/4,916 (0.00%) ...	0/241 M (0.00%)	0/4,916 (0.00%) ...	0/241 M (0.00%)	Do not regulate. Do not regulate.
Acetochlor	100	UCMR 1 AM	0/3,869 (0.00%)— UCMR 1.	0/226 M (0.00%)— UCMR 1.	0/3,869 (0.00%)— UCMR 1.	0/226 M (0.00%)— UCMR 1.	
		UCMR 2 SS	0/1,198 (0.00%)— UCMR 2.	0/157 M (0.00%)— UCMR 2.	0/1,198 (0.00%)— UCMR 2.	0/157 M (0.00%)— UCMR 2.	
Methyl Bromide (Bromomethane)	100	UCMR 3 AM	0/4,916 (0.00%) ...	0/241 M (0.00%)	0/4,916 (0.00%) ...	0/241 M (0.00%)	Do not regulate.
Metolachlor	300	UCMR 2 SS	0/1,198 (0.00%) ...	0/157 M (0.00%)	0/1,198 (0.00%) ...	0/157 M (0.00%)	Do not regulate. Do not regulate.
Nitrobenzene	10	UCMR 1 AM	2/3,861 (0.05%) ...	255,358/226 M (0.11%)	2/3,861 (0.05%) ...	255,358/226 M (0.11%)	
RDX	30 (noncancer) ... 0.4 (cancer)	UCMR 2 AM	0/4,139 (0.00%) ... >15 µg/L	0/229 M (0.00%) ... >15 µg/L	0/4,139 (0.00%) ... >30 µg/L	0/229 M (0.00%) ... >30 µg/L ...	Do not regulate.
			3/4,139 (0.07%) ... >0.2 µg/L	96,033/229 M (0.04%) ... >0.2 µg/L	3/4,139 (0.07%) ... >0.4 µg/L	96,033/229 M (0.04%) ... >0.4 µg/L ...	

¹ <https://www.epa.gov/children/childhood-lifestyles-relating-childrens-environmental-health>.

² An HRL is a health-based concentration against which the Agency evaluates occurrence data when

making decisions about preliminary regulatory determinations. An HRL is not a final determination on establishing a protective level of a contaminant in drinking water for a particular population; it is derived prior to development of a complete health

and exposure assessment and can be considered a screening value. See Section E.5.1 of the *Final Regulatory Determination 4 Support Document* for information about how HRLs are derived (USEPA, 2021a).

A. PFOS and PFOA

1. Description

Per- and polyfluoroalkyl substances (PFAS) are a class of synthetic chemicals that have been manufactured and in use since the 1940s (AAAS, 2020; USEPA, 2018b). PFAS are most commonly used to make products resistant to water, heat, and stains and are consequently found in industrial and consumer products like clothing, food packaging, cookware, cosmetics, carpeting, and fire-fighting foam (AAAS, 2020). PFAS manufacturing and processing facilities, facilities using PFAS in production of other products, airports, and military installations have been associated with PFAS releases into the air, soil, and water (USEPA 2016b; USEPA 2016c). People may potentially be exposed to PFAS through the use of certain consumer products, through occupational exposure, and/or through consuming contaminated food or contaminated drinking water (Domingo and Nadal, 2019; Fromme et al. 2009).

Perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) are part of a subset of PFAS referred to as perfluorinated alkyl acids (PFAA) and are two of the most widely studied and longest-used PFAS. Due to their widespread use and persistence in the environment, most people have been exposed to PFAS, including PFOA and PFOS (USEPA 2016b; USEPA 2016c). PFOA and PFOS have been detected in up to 98% of serum samples taken in biomonitoring studies that are representative of the U.S. general population (CDC, 2019). Following the voluntary phase-out of PFOA by eight major chemical manufacturers and processors in the United States under EPA's 2010/2015 PFOA Stewardship Program and reduced manufacturing of PFOS (last reported in 2002 under Chemical Data Reporting), serum concentrations have been declining. The National Health and Nutrition Examination Survey (NHANES) data exhibited that 95th-percentile serum PFOS concentrations have decreased over 75%, from 75.7 µg/L in the 1999–2000 cycle to 18.3 µg/L in the 2015–2016 cycle (CDC, 2019; Jain, 2018; Calafat et al., 2007; Calafat et al., 2019).

2. Agency Findings

The Agency is making a determination to regulate PFOA and PFOS with a NPDWR. EPA has determined that PFOA and PFOS may have adverse health effects; that PFOA and PFOS occur in public water systems with a frequency and at levels of public health concern; and that, in the sole judgment of the Administrator,

regulation of PFOA and PFOS presents a meaningful opportunity for health risk reduction for persons served by public water systems.

(a) Adverse Health Effects

The Agency finds that PFOA and PFOS may have adverse effects on the health of persons. In 2016, EPA published health assessments (Health Effects Support Documents or HESDs) for PFOA and PFOS based on the Agency's evaluation of the peer reviewed science available at that time. The lifetime Health Advisory (HA) of 0.07 µg/L is used as the HRL for Regulatory Determination 4 and reflect concentrations of PFOA and PFOS in drinking water at which adverse health effects are not anticipated to occur over a lifetime. Studies indicate that exposure to PFOA and/or PFOS above certain exposure levels may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants (e.g., low birth weight, accelerated puberty, skeletal variations), cancer (e.g., testicular, kidney), liver effects (e.g., tissue damage), immune effects (e.g., antibody production and immunity), and other effects (e.g., cholesterol changes). Both PFOA and PFOS are known to be transmitted to the fetus via the placenta and to the newborn, infant, and child via breast milk. Both compounds were also associated with tumors in long-term animal studies (USEPA, 2016d; USEPA, 2016e; NTP, 2020). For specific details on the potential for adverse health effects and approaches used to identify and evaluate information on hazard and dose-response, please see (USEPA, 2016b; USEPA, 2016c; USEPA, 2016d; USEPA, 2016e).

(b) Occurrence

EPA has determined that PFOA and PFOS occur with a frequency and at levels of public health concern at PWSs based on the Agency's evaluation of available occurrence information. In accordance with SDWA 1412(b)(1)(B)(ii)(II), EPA has determined monitoring data from the third Unregulated Contaminant Monitoring Rule (UCMR 3) are the best available occurrence information for PFOA and PFOS regulatory determinations. UCMR 3 monitoring occurred between 2013 and 2015 and are currently the only nationally representative finished water dataset for PFOA and PFOS. Under UCMR 3, 36,972 samples from 4,920 PWSs were analyzed for PFOA and PFOS. The minimum reporting level (MRL) for PFOA was 0.02 µg/L and the MRL for PFOS was 0.04 µg/L. A total of

1.37% of samples had reported detections (greater than or equal to the MRL) of at least one of the two compounds. To examine the occurrence of PFOS and PFOA in aggregate, EPA summed the concentrations detected in the same sample to calculate a total PFOS/PFOA concentration. EPA notes that the reference doses (RfDs) for both PFOA and PFOS are based on similar developmental effects and are numerically identical; when these two chemicals co-occur at the same time and location in drinking water sources, EPA has recommended considering the sum of the concentrations (USEPA, 2016d; USEPA, 2016e) and has done so for this regulatory determination. The maximum summed concentration of PFOA and PFOS was 7.22 µg/L and the median summed value was 0.05 µg/L. Summed PFOA and PFOS concentrations exceeded one-half the HRL (0.035 µg/L) at a minimum of 2.4% of PWSs (115 PWSs) and exceeded the HRL (0.07 µg/L) at a minimum of 1.3% of PWSs (63 PWSs³). Since UCMR 3 monitoring occurred, certain sites where elevated levels of PFOA and PFOS were detected may have installed treatment for PFOA and PFOS, may have chosen to blend water from multiple sources, or may have otherwise remediated known sources of contamination. Those 63 PWSs serve a total population of approximately 5.6 million people and are located in 25 states, tribes, or U.S. territories (USEPA, 2019a). Data from more recent state monitoring (discussed below) demonstrate occurrence in multiple geographic locations consistent with UCMR 3 monitoring and support the Agency's final determination that PFOA and PFOS occur with a frequency and at levels of public health concern in finished drinking water across the United States. The *Final Regulatory Determination 4 Support Document* presents a sample-level summary of the results for PFOA and PFOS individually and includes discussion on state monitoring efforts as well as uncertainties in occurrence data (USEPA, 2021a).

Consistent with the Agency's commitment in the PFAS Action Plan (the Agency's first multi-media, multi-program, national research, management, and risk communication plan to address a challenge like PFAS) to present information about additional sampling efforts for PFAS in water systems, the Agency has supplemented its Unregulated Contaminant Monitoring Regulation (UCMR) data

³ Sum of PFOA + PFOS results rounded to 2 decimal places in those cases where a laboratory reported more digits.

with data collected by states who have made their data publicly available at this time (USEPA, 2019b). A summary of these occurrence data were presented in the preliminary Regulatory Determination 4 **Federal Register** document. Subsequent to the preliminary announcement, based on comments and information received on the proposed determination, the Agency collected additional data from additional states. The finished water data available from fifteen states collected since UCMR 3 monitoring showed that there were at least 29 PWSs where the summed concentrations of PFOA and PFOS exceeded the EPA HRL. The Agency notes that some of these data are from targeted sampling efforts and thus may not be representative of levels found in all PWSs within the state or represent occurrence in other states. The state data demonstrate occurrence in multiple geographic locations and support EPA's finding that PFOA and PFOS occur with a frequency and at levels of public health concern in drinking water systems across the United States. The Final Regulatory Determination 4 Support Document presents a detailed discussion of state PFOA and PFOS occurrence information (USEPA, 2021a). EPA acknowledges that there may be other states with occurrence data available and that additional states have or intend to conduct monitoring of finished drinking water. As such, EPA will consider any new or additional state data to inform the development of the proposed NPDWR for PFOA and PFOS.

(c) Meaningful Opportunity

Considering the population exposed to PFOA and PFOS including sensitive populations and lifestages, the potential adverse human health impacts of these contaminants, the environmental persistence of these substances, the persistence in the human body and potential for bioaccumulation of these substances, the availability of validated methods to measure and treatment technologies to remove PFOA and PFOS, the detections that exceeded the HRL and $\frac{1}{2}$ the HRL, and significant public concerns (particularly those expressed in comments submitted by state and local government agencies) on the challenges that these contaminants pose for communities nationwide, the Agency has determined that regulation of PFOA and PFOS presents a meaningful opportunity for health risk reduction for persons served by PWSs, including sensitive populations such as infants, children, and pregnant and nursing women.

PFOA and PFOS are both generated as degradation products of other perfluorinated compounds (e.g., fluorotelomer alcohols), and due to their strong carbon-fluorine bonds, are resistant to metabolic and environmental degradation (USEPA, 2016b; USEPA, 2016c). Due to this underlying chemical structure, PFOA and PFOS are extremely persistent in the environment, including resistance to chemical, biological, and physical degradation processes. While most U.S. manufacturers have voluntarily phased out production and manufacturing of both PFOS and PFOA, their environmental persistence and formation as degradation products from other compounds may still contribute to their release in the environment. Upon exposure to the human body, there is a potential for bioaccumulation and toxicity at environmentally relevant concentrations as studies show it can take years to leave the human body (NIEHS, 2020; USEPA, 2016b; USEPA, 2016c).

Adverse effects observed following exposures to PFOA and PFOS include effects in humans on serum lipids, birth weight, and serum antibodies. Some of the animal studies show common effects on the liver, neonate development, and responses to immunological challenges. Both compounds were also associated with tumors in long-term animal studies (USEPA, 2016d; USEPA, 2016e). In determining that regulation of PFOA and PFOS presents a meaningful opportunity for health risk reduction for sensitive populations, EPA noted that both PFOA and PFOS are associated with developmental toxicity in animals, with reduced birth weight in humans, and have been shown to be transmitted to the fetus via the placenta and to the newborn, infant, and child via breast milk (USEPA, 2016b; USEPA, 2016c).

Drinking water analytical methods are available to measure PFOA, PFOS, and other PFAS in drinking water. EPA has published validated drinking water laboratory methods for detecting a total of 29 unique PFAS in drinking water, including EPA Method 537.1 (18 PFAS) and EPA Method 533 (25 PFAS).

Available treatment technologies for removing PFAS from drinking water have been evaluated and reported in the literature (e.g., Dickenson and Higgins, 2016). EPA's Drinking Water Treatability Database (USEPA, 2020b) summarizes available technical literature on the efficacy of treatment technologies for a range of priority drinking water contaminants, including PFOA and PFOS. In summary, conventional treatment (comprised of the unit processes coagulation,

flocculation, clarification, and filtration) is not considered effective for the removal of PFOA and PFOS. Granular activated carbon (GAC), anion exchange resins, reverse osmosis and nanofiltration are considered effective for the removal of PFOA and PFOS.

(d) Summary of Public Comments on PFOA and PFOS and Agency Responses

EPA received many comments on the Agency's evaluation of the first statutory criterion under section 1412(b)(1)(A) of SDWA. Most commenters agreed with EPA's finding that PFOA and PFOS may have adverse effects on the health of persons. Most commenters also state that there is "strong evidence" and "substantial scientific evidence" for EPA's finding of adverse health effects of PFOA and PFOS. One commenter disagreed with EPA's evaluation of the first statutory criterion, arguing that the body of scientific evidence does not show adverse effects from PFAS in humans. EPA also received numerous comments relating to the Agency's 2016 Lifetime Health Advisory for PFOA and PFOS, the corresponding HESD and the HRL used to support the preliminary regulatory determination. Numerous commenters encouraged EPA to update and "improve its health reference level" and "revise the PFOA and PFOS hazard assessments" prior to making a final regulatory determination.

EPA acknowledges commenters' suggestions to consider and evaluate newer studies; however, EPA disagrees with recommendations to establish new HRLs prior to a final regulatory determination. Consistent with SDWA section 1412(b)(3)(A)(i), EPA is using the 2016 PFOA and PFOS Lifetime Health Advisory as the basis in deriving an HRL which the Agency has concluded represent the best available peer reviewed scientific assessment at this time. Based upon the 2016 EPA HESDs for PFOA and PFOS, and other supporting studies cited in the record, EPA finds that PFOA and PFOS may have an adverse effect on the health of persons. Consistent with commenters' recommendations, EPA has initiated the first steps of a systematic literature review of peer-reviewed scientific literature for PFOA and PFOS published since 2013 with the goal of identifying any new studies that may be relevant to human health assessment. An annotated bibliography of the identified relevant studies as well as the protocol used to identify the relevant publications can be found in Appendix D of the Final Regulatory Determination 4 Support Document (USEPA, 2021a), available in the docket for this document. Additional analyses of these new

studies is needed to confirm relevance, extract the data to assess the weight of evidence, and identify critical studies in order to inform future decision making.

EPA also received comments on the Agency's evaluation of the second statutory criterion under section 1412(b)(1)(A) of SDWA. Many commenters supported EPA's preliminary determination that PFOA and PFOS meet the second statutory occurrence criterion under SDWA. Several commenters stated that while they are supportive of using UCMR 3 data as the basis of nationwide drinking water occurrence for PFOA and PFOS, solely relying on these monitoring data may be an inaccurate reflection of PFOA and PFOS exposure. The Agency also received comments and information on actions taken by a number of states to monitor PFOA, PFOS, and other PFAS in PWSs, particularly in locations that were not previously required to conduct UCMR monitoring. Some commenters suggested that PFOA and PFOS UCMR 3 occurrence information used by EPA in making the Preliminary Determination for PFOA and PFOS is not reflective of the actual occurrence of PFOS and PFOS within public water systems. These commenters stated that UCMR 3 monitoring excludes small public water systems and was conducted with high minimum reporting levels. Three commenters did not support EPA's preliminary determination that PFOA and PFOS meet the second statutory criterion under SDWA. These commenters expressed concern that the data EPA relied upon are outdated, are skewed, and overestimate current PFOA and PFOS occurrence. These commenters suggest that EPA should revise its occurrence analysis with more recent data prior to making a final determination.

EPA disagrees with those commenters who assert that UCMR 3 are not the best available occurrence data. EPA also disagrees that the UCMR 3 excludes small water systems and disagrees that the minimum reporting levels were too high. The UCMR 3 assured a nationally representative sample of 800 small drinking water systems and established minimum reporting levels based upon laboratory performance data that are lower than the HRLs for PFOA and PFOS. The UCMR 3 data are the best available information to assess the frequency and level of occurrence of PFOA and PFOS in the nation's public water systems. After considering the public comments and additional occurrence data provided by commenters, EPA continues to find that PFOA and PFOS meet the second

statutory criterion for regulatory determinations under Section 1412(b)(1)(A) of SDWA that "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern." Nonetheless, EPA agrees with commenters who recommend that the Agency consider other existing available occurrence data to inform its final regulatory determination and PFOA and PFOS rulemaking. As discussed previously, the Final Regulatory Determination 4 Support Document presents a detailed discussion of state PFOA and PFOS occurrence information that were analyzed and used to further support the Agency's finding that PFOA and PFOS occur in public water systems with a frequency and at levels of public health concern (USEPA, 2021a).

EPA also received many comments on the Agency's evaluation of the third statutory criterion under section 1412(b)(1)(A) of SDWA. Many commenters, including multiple state regulators and organizations representing states, agree with EPA's evaluation that regulation of PFOA and PFOS presents a meaningful opportunity for health risk reduction for persons served by PWSs. These commenters highlight the extensive amount of work associated with developing their own drinking water standards for several PFAS compounds. These commenters also noted the need for a consistent national standard for use in states where a state-specific standard has not yet been developed. Many commenters have also noted that although some states have developed or are in the process of developing their own state-level PFAS drinking water standards, regulatory standards currently vary across states. These commenters expressed concern that absence of a national drinking water standard has resulted in risk communication challenges with the public and disparities with PFAS exposure. Some commenters noted there are populations particularly sensitive or vulnerable to the health effects of PFAS, including newborns, infants and children. One commenter did not support EPA's evaluation of the third statutory criterion, noting that in their opinion, the toxicity assessment for PFOA and PFOS and existing occurrence data do not suggest that establishing drinking water standards presents a meaningful opportunity for health risk reduction.

EPA acknowledges commenter concerns regarding sensitive and vulnerable subpopulations and notes

that the Agency has been particularly mindful that PFOA and PFOS are known to be transmitted to the fetus via cord blood and to the newborn, infant and child via breast milk. EPA agrees with commenters that there is a need for protective drinking water regulations across the United States and that moving forward with a national-level regulation for PFOA and PFOS would provide improved national consistency in protecting public health and may reduce regulatory uncertainty for stakeholders across the country. The Agency disagrees with the commenter's assertion that PFOA and PFOS health and occurrence information are insufficient to justify a drinking water standard, and the Agency finds that there is a meaningful opportunity for health risk reduction potential based upon consideration the population exposed to PFOA and PFOS including sensitive populations and lifestages, such as newborns, infants and children.

3. Considerations for Additional PFAS

As EPA begins the process to promulgate the NPDWR for PFOA and PFOS, the Agency recognizes that there is additional information to consider regarding a broader range of PFAS, including new monitoring and occurrence data, and ongoing work developing toxicity assessments by EPA, other federal agencies, state governments, international organizations, industry groups, and other stakeholders. While the Agency is not making regulatory determinations for additional PFAS at this time, the Agency remains committed to filling information gaps, including those identified in the PFAS Action Plan, by completing peer reviewed toxicity assessments and collecting nationally representative occurrence data for additional PFAS to support future regulatory determinations as part of the UCMR monitoring program (see discussion below).

EPA committed in the PFAS Action Plan to characterize potential health impacts and develop more drinking water occurrence data for a broader set of PFAS (USEPA, 2019b). EPA has followed through on its commitments and as a result expects to have peer-reviewed health assessments and national occurrence data for more PFAS becoming available over the next few years. EPA notes that although SDWA does not require the Agency to complete regulatory determinations for the contaminants from the fifth CCL until 2026, because of the significant progress related to developing new high-quality PFAS information, combined with the Agency's commitment in the PFAS

Action Plan to assist states and communities with PFAS contaminated drinking water, EPA will continue to prioritize regulatory determinations of additional PFAS in drinking water. The Agency is committing to making regulatory determinations in advance of the next SDWA deadline for additional PFAS for which the Agency has a peer reviewed health assessment, has nationally representative occurrence data in finished drinking water, and has sufficient information to determine whether there is a meaningful opportunity for health risk reduction for persons served by public water systems.

EPA is currently developing scientifically rigorous toxicity assessments for seven PFAS chemicals. The chemicals currently undergoing assessment include PFBS, PFBA, PFHxS, PFHxA, PFNA, PFDA, and HFPO-DA (GenX chemicals), all of which are currently scheduled to be completed by 2023. These assessments all include public comment periods, independent scientific external peer review, and a robust interagency review process. Furthermore, these toxicity assessments will provide critical health information for PFAS with varying chain lengths and functional groups. When complete, these assessments will summarize available scientific information regarding the anticipated human dose-response relationship for these chemicals, which is a key information need for informing a variety of Agency decisions.

To inform EPA's understanding of PFAS occurrence in drinking water as discussed in EPA's PFAS Action Plan (USEPA, 2019b), the Agency is also leading efforts to gather additional monitoring data for 29 PFAS contaminants in finished drinking water. EPA recently announced its proposal for nationwide drinking water monitoring for PFAS under the next UCMR monitoring cycle (UCMR 5) utilizing Methods 537.1 and 533 to detect more PFAS chemicals and at lower reporting limits than previously possible.

EPA is also generating new PFAS toxicology data for a much larger set of less-studied PFAS through new approach methods (NAMs)⁴ such as high throughput screening, computational toxicology tools, and chemical informatics for chemical prioritization, screening, and risk assessment. EPA will continue research

on methods for using these data to support risk assessments using NAMs such as read-across (*i.e.*, an effort to predict biological activity based on similarity in chemical structure) and transcriptomics (*i.e.*, a measure of changes in gene expression in response to chemical exposure or other external stressors), and to make inferences about the toxicity of PFAS mixtures that commonly occur in real world exposures. This research can inform a more complete understanding of PFAS toxicity for the large set of PFAS chemicals without conventional toxicity data and can allow prioritization of actions to potentially address groups of PFAS. For additional information on the NAMs for PFAS toxicity testing, please visit: <https://www.epa.gov/chemical-research/pfas-chemical-lists-and-tiered-testing-methods-descriptions>. These EPA actions, in addition to other research, may provide useful information for future EPA evaluations of additional PFAS.

(a) Summary of Public Comments on Considerations for Additional PFAS and Agency Responses

EPA requested comment on potential regulatory constructs the Agency may consider for PFAS chemicals including PFOA and PFOS. EPA specifically requested input on a regulatory approach to evaluate PFAS by different grouping approaches.

EPA received multiple comments on how the Agency could consider additional PFAS for potential future rulemaking. Many commenters support a class-based approach for regulating PFAS based on one or more characteristics such as chain length, functional group, treatment processes, health effects, toxicity, common analytical methods, and/or shared occurrence with other contaminants within a group. Additionally, many commenters also urge EPA to make additional regulatory determinations for PFAS that have a proposed or final drinking water standard in at least one state; PFAS that have been measured in water systems through monitoring programs such as UCMR; and/or PFAS for which EPA or the Agency for Toxic Substances and Disease Registry (ATSDR) has established a toxicity value. Some commenters suggest that EPA should make positive regulatory determinations for PFHxS and PFNA as well as in combination with PFOA, PFOS, and other PFAS such as PFBS. Many commenters recommend EPA consider various grouping and treatment technique approaches for PFAS beyond PFOA and PFOS that may not have sufficient health and occurrence data.

Some of these commenters recommend approaches that consider acute and chronic health effects, long-term compared to short-term exposures, exposures during sensitive lifestages, and type of water systems and vulnerable populations such as vulnerable workers. Many commenters stated that the data may not be robust enough for each PFAS and therefore support a class-based approach for regulating PFAS in drinking water. In contrast, two commenters did not support a class-based approach for regulating PFAS. In summary, these commenters suggest that regulation without assessing each chemical's individual traits "would be contrary to the intent of SDWA" and that the Agency should address outstanding data and knowledge gaps regarding PFAS of concern prior to determining a regulatory grouping approach.

With respect to comments received on regulatory determinations for additional PFAS compounds other than PFOA and PFOS, EPA remains committed to filling information gaps by completing peer reviewed health assessments where appropriate and collecting nationally representative occurrence data. As discussed above, in response to public comments advocating timely regulation of additional PFAS in drinking water, where sufficient information is available, EPA intends to make regulatory determinations for additional PFAS prior to the fifth Regulatory Determination's statutory deadline (2026).

The Agency acknowledges many commenters' support for a class-based approach for regulating PFAS and appreciates commenter recommendations regarding potential regulatory constructs. EPA acknowledges commenters' recommendations to evaluate whether PFAS can be regulated as groups, and the Agency is developing the science necessary to consider whether such regulation is necessary and appropriate for PFAS. Regarding commenters' assertions that regulation without assessing each chemical's individual traits "would be contrary to the intent of SDWA," the Agency notes that the Safe Drinking Water Act establishes a robust scientific and public participation process that guide EPA's development of regulations for unregulated contaminants that may present a risk to public health. Regulation by groups is a regulatory strategy that is already used for certain regulated contaminants like disinfection byproducts, polychlorinated biphenyls, and radionuclides. EPA will continue to use best available science and available

⁴New approach methods (NAMs) refer to any technologies, methodologies, approaches, or combinations thereof that can be used to provide information on chemical hazard and potential human exposure that can avoid or significantly reduce the use of testing on animals.

statutory authorities to guide Agency decision making with respect to how the Agency evaluates and potentially regulates additional PFAS.

(b) Summary of Public Comments on Potential PFAS Monitoring Approaches and Agency Responses

As part of the proposed preliminary regulatory determination for PFOA and PFOS, EPA solicited comment on potential monitoring approaches if the Agency were to finalize a positive regulatory determination for these contaminants. EPA presented two monitoring approaches in the Agency's preliminary Regulatory Determination for CCL 4 contaminants. Under the Standardized Monitoring Framework (SMF) for synthetic organic chemicals, monitoring schedules are based around the detection levels of the regulated contaminants, and state primacy agencies can also issue waivers for monitoring. The Agency also presented an alternative monitoring approach to allow state primacy agencies to require monitoring at PWSs where information indicates potential PFAS contamination, such as proximity to facilities with historical or on-going uses of PFAS.

Many commenters supported the Agency's goal of reducing potential monitoring burden for PWSs without compromising public health protection. While there were differing views among commenters regarding which monitoring approach is best for PFAS, many urged EPA to keep evaluating different approaches as the Agency promulgates the NPDWR for PFOA and PFOS.

The Agency appreciates commenter recommendations on monitoring approaches. As the Agency promulgates the regulatory standard for PFOA and PFOS, EPA will continue to work to establish monitoring requirements in the rule that minimize burden while ensuring public health protection.

B. 1,1-Dichloroethane

1. Description

1,1-Dichloroethane is a halogenated alkane. It is an industrial chemical and is used as a solvent and a chemical intermediate. 1,1-Dichloroethane is expected to have moderate to high persistence in water (USEPA, 2021a).

2. Agency Findings

The Agency is making a determination not to regulate 1,1-dichloroethane with an NPDWR. It does not occur with a frequency and at levels of public health concern. As a result, the Agency finds that an NPDWR does not present a meaningful opportunity for health risk reduction.

(a) Adverse Health Effects

The Agency finds that 1,1-dichloroethane may have adverse effects on the health of persons. Based on a 13-week gavage study in rats (Muralidhara et al., 2001), the kidney was identified as a sensitive target for 1,1-dichloroethane, and no-observed-adverse-effect level (NOAEL) and lowest-observed-adverse-effect level (LOAEL) values of 1,000 and 2,000 mg/kg/day, respectively, were identified based on increased urinary enzyme markers for renal damage and central nervous system (CNS) depression (USEPA, 2006a).

The only available reproductive or developmental study with 1,1-dichloroethane is an inhalation study where pregnant rats were exposed on days 6 through 15 of gestation (Schwetz et al., 1974). No effects on the fetuses were noted at 3,800 ppm. Delayed ossification of the sternum without accompanying malformations was reported at a concentration of 6,000 ppm.

A cancer assessment for 1,1-dichloroethane is available on IRIS (USEPA, 1990a). That assessment classifies the chemical, according to EPA's 1986 Guidelines for Carcinogenic Risk Assessment (USEPA, 1986), as Group C, a possible human carcinogen. This classification is based on no human data and limited evidence of carcinogenicity in two animal species (rats and mice), as shown by increased incidences of hemangiosarcomas and mammary gland adenocarcinomas in female rats and hepatocellular carcinomas and benign uterine polyps in mice (NCI, 1978). The data were considered inadequate to support quantitative assessment. The close structural relationship between 1,1-dichloroethane and 1,2-dichloroethane, which is classified as a B2 probable human carcinogen and produces tumors at many of the same sites where marginal tumor increases were observed for 1,1-dichloroethane, supports the suggestion that the 1,1-isomer could possibly be carcinogenic to humans. Mixed results in initiation/promotion studies and genotoxicity assays are consistent with this classification. On the other hand, the animals from the 1,1-dichloroethane National Cancer Institute (NCI, 1978) study were housed with animals being exposed to 1,2-dichloroethane providing opportunities for possible co-exposure impacting the 1,1-dichloroethane results. The following groups of individuals may have an increased risk from exposure to 1,1-dichloroethane (NIOSH, 1978; ATSDR, 2015):

- Those with chronic respiratory disease,
- Those with liver diseases that impact hepatic microsomal cytochrome P-450 functions,
- Individuals with impaired renal function and vulnerable to kidney stones
- Individuals with skin disorders vulnerable to irritation by solvents like 1,1-dichloroethane,
- Those who consume alcohol or use pharmaceuticals (e.g., phenobarbital) that alter the activity of cytochrome P-450s.

A provisional chronic RfD was derived from the 13-week gavage study in rats based on a NOAEL of 1,000 mg/kg/day administered for five days/week and adjusted to 714.3 mg/kg/day for continuous exposure (an increase in urinary enzymes was the adverse impact on the kidney). The chronic oral RfD of 0.2 mg/kg/day was derived by dividing the normalized NOAEL of 714.3 mg/kg/day in male Sprague-Dawley rats by a combined UF of 3,000. The combined UF includes factors of 10 for interspecies extrapolation, 10 for extrapolation from a subchronic study, 10 for human variability, and 3 for database deficiencies (including lack of reproductive and developmental toxicity tests by the oral route). This assessment noted several limitations in the critical study and database as a whole. Specifically, that the reporting of the results in the critical study were marginally adequate and that the database lacks information on reproductive and developmental and nervous system toxicity.

EPA calculated an HRL for 1,1-dichloroethane of 1,000 µg/L, based on EPA oral RfD of 0.2 mg/kg/day, using 2.5 L/day drinking water ingestion, 80 kg body weight and a 20% relative source contribution (RSC) factor.

(b) Occurrence

EPA has determined that 1,1-dichloroethane does not occur with a frequency and at levels of public health concern at PWSs based on the Agency's evaluation of available occurrence information. The primary occurrence data for 1,1-dichloroethane are the 2013–2015 nationally representative drinking water monitoring data generated through EPA's UCMR 3. 1,1-Dichloroethane was not detected in any of the 36,848 UCMR 3 samples collected by 4,916 PWSs (serving ~ 241 million people) at levels greater than ½ the HRL (500 µg/L) or the HRL (1,000 µg/L). 1,1-Dichloroethane was detected in about 2.3% samples at or above the MRL (0.03 µg/L) (USEPA, 2019a; USEPA, 2021a).

Other supplementary sources of finished water occurrence data from UCM Rounds 1 and 2 indicate that the occurrence of 1,1-dichloroethane in PWSs is likely to be low to non-existent (USEPA, 2021a). 1,1-Dichloroethane occurrence data for ambient water from NAWQA and NWIS are consistent with those for finished water (USEPA, 2021a).

(c) Meaningful Opportunity

The Agency has determined that regulation of 1,1-dichloroethane does not present a meaningful opportunity for health risk reduction for persons served by PWSs based on the estimated exposed populations, including sensitive populations. UCMR 3 findings indicate that the estimated population exposed to 1,1-dichloroethane at levels of public health concern is 0%, based on lack of detections at levels greater than $\frac{1}{2}$ the HRL (500 $\mu\text{g/L}$) or the HRL (1,000 $\mu\text{g/L}$). As a result, the Agency finds that an NPDWR for 1,1-dichloroethane does not present a meaningful opportunity for health risk reduction.

(d) Summary of Public Comments on 1,1-Dichloroethane and Agency Responses

EPA received several comments on the Agency's evaluation of 1,1-dichloroethane under section 1412(b)(1)(A) of SDWA, all of which were in support of its preliminary determination not to regulate 1,1-dichloroethane. EPA agrees with the comments that are in support of the negative regulatory determination.

C. Acetochlor

1. Description

Acetochlor is a chloroacetanilide pesticide that is used as an herbicide for pre-emergence control of weeds. It is registered for use on corn crops (field corn and popcorn) and has been approved for use on cotton as a rotational crop. Synonyms for acetochlor include 2-chloro-2'-methyl-6-ethyl-N-ethoxymethylacetanilide (USEPA, 2021a). Acetochlor is expected to have low to moderate persistence in water due to its biodegradation half-life, as well as susceptibility to photolysis (USEPA, 2021a).

2. Agency Findings

The Agency is making a determination not to regulate acetochlor with an NPDWR. Acetochlor does not occur with a frequency and at levels of public health concern. As a result, the Agency finds that an NPDWR does not present a meaningful opportunity for health risk reduction.

(a) Adverse Health Effects

The Agency finds that acetochlor may have adverse effects on the health of persons. Subchronic and chronic oral studies have demonstrated adverse effects on the liver, thyroid (secondary to the liver effects), nervous system, kidney, lung, testes, and erythrocytes in rats and mice (USEPA, 2006b; USEPA, 2018c). There was evidence of carcinogenicity in studies conducted with acetochlor in rats and mice and a non-mutagenic mode of action was demonstrated for nasal and thyroid tumors in rats (USEPA, 2006b). Cancer effects include nasal tumors and thyroid tumors in rats, lung tumors and histiocytic sarcomas in mice, and liver tumors in both rats and mice (Ahmed and Seely, 1983; Ahmed et al., 1983; Amyes, 1989; Hardisty, 1997a; Hardisty, 1997b; Hardisty, 1997c; Naylor and Ribelin, 1986; Ribelin, 1987; USEPA, 2004b; USEPA, 2006b; and Virgo and Broadmeadow, 1988). No biologically sensitive human subpopulations have been identified for acetochlor. Developmental and reproductive toxicity studies do not indicate increased susceptibility to acetochlor exposure at early life stages in test animals (USEPA, 2006b).

The study used to derive the oral RfD is a 1-year oral chronic feeding study conducted in beagle dogs. This study describes a NOAEL of 2 mg/kg/day, and a LOAEL of 10 mg/kg/day, based on the critical effects of increased salivation; increased levels of alanine aminotransferase (ALT) and ornithine carbamoyl transferase (OTC); increased triglyceride levels; decreased blood glucose levels; and alterations in the histopathology of the testes, kidneys, and liver of male beagle dogs (USEPA, 2018c; ICI, Inc., 1988). The UF applied was 100 (10 for intraspecies variation and 10 for interspecies extrapolation). The EPA OPP RfD for acetochlor of 0.02 mg/kg/day, based on the NOAEL of 2 mg/kg/day from the 1-year oral chronic feeding study in beagle dogs, is expected to be protective of both noncancer and cancer effects.

EPA calculated an HRL of 100 $\mu\text{g/L}$ based on the EPA OPP RfD for non-cancer effects for acetochlor of 0.02 mg/kg/day (USEPA, 2018c) using 2.5 L/day drinking water ingestion, 80 kg body weight, and a 20% RSC factor.

(b) Occurrence

EPA has determined that acetochlor does not occur with a frequency and at levels of public health concern at PWSs based on the Agency's evaluation of available occurrence information. The primary occurrence data for acetochlor

are from the first Unregulated Contaminant Monitoring Regulation (UCMR 1) assessment monitoring (AM) (2001–2003) and the second Unregulated Contaminant Monitoring Regulation (UCMR 2) screening survey (SS) (2008–2010). Acetochlor was not detected at levels greater than $\frac{1}{2}$ the HRL (50 $\mu\text{g/L}$), the HRL (100 $\mu\text{g/L}$), or the MRL (2 $\mu\text{g/L}$) in any of the 33,778 UCMR 1 assessment monitoring samples from 3,869 PWSs (USEPA, 2008; USEPA, 2021a) or in any of the 11,193 UCMR 2 screening survey samples from 1,198 PWSs (USEPA, 2015; USEPA, 2021a).

Findings from the available ambient water data for acetochlor are consistent with the results in finished water. Ambient water data in NAWQA show that acetochlor was detected in between 13% and 23% of samples from between 3% and 10% of sites. While maximum values in NAWQA Cycle 2 (2002–2012) and Cycle 3 (2013–2017) monitoring exceeded the HRL (215 $\mu\text{g/L}$ in 2004 and 137 $\mu\text{g/L}$ in 2013) (only one sample in each of those two cycles exceeded the HRL), 90th percentile levels of acetochlor remained below 1 $\mu\text{g/L}$. More than 10,000 samples were collected in each cycle. Non-NAWQA NWIS data (1991–2016), which included limited finished water data in addition to the ambient water data, show no detected concentrations greater than the HRL (USEPA, 2021a).

(c) Meaningful Opportunity

The Agency has determined that regulation of acetochlor does not present a meaningful opportunity for health risk reduction for persons served by PWSs based on the estimated exposed populations, including sensitive populations. The estimated population exposed to acetochlor at levels of public health concern is 0% based on UCMR 1 finished water data gathered from 2001 to 2003 and UCMR 2 finished water data gathered from 2008 to 2010. As a result, the Agency finds that an NPDWR for acetochlor does not present a meaningful opportunity for health risk reduction.

(d) Summary of Public Comments on Acetochlor and Agency Responses

EPA received several comments on the Agency's evaluation of acetochlor under section 1412(b)(1)(A) of SDWA, all of which were in support of its preliminary determination not to regulate acetochlor. EPA agrees with the comments that are in support of the negative regulatory determination.

D. Methyl Bromide

1. Description

Methyl bromide is a halogenated alkane and occurs as a gas. Methyl bromide has been used as a fumigant fungicide applied to soil before planting, to crops after harvest, to vehicles and buildings, and for other specialized purposes. Use of the chemical in the United States was phased out in 2005, except for specific critical use exemptions and quarantine and pre-shipment exemptions in accordance with the Montreal Protocol. Critical use exemptions have included strawberry cultivation and production of dry cured pork. Synonyms for methyl bromide include bromomethane, monobromomethane, curafume, Meth-O-Gas, and Brom-O-Sol. Methyl bromide is expected to have moderate persistence in water due to its susceptibility to hydrolysis (USEPA, 2021a).

2. Agency Findings

The Agency is making a determination not to regulate methyl bromide with an NPDWR. Methyl bromide does not occur with a frequency and at levels of public health concern. As a result, the Agency finds that an NPDWR does not present a meaningful opportunity for health risk reduction.

(a) Adverse Health Effects

The Agency finds that methyl bromide may have adverse effects on the health of persons. The limited number of studies investigating the oral toxicity of methyl bromide indicate that the route of administration influences the toxic effects observed (USEPA, 2006c). The forestomach of rats (forestomachs are not present in humans) appears to be the most sensitive target of methyl bromide when it is administered orally by gavage (ATSDR, 1992). Acute and subchronic oral gavage studies in rats identified stomach lesions (Kaneda et al., 1998), hyperemia (excess blood) (Danse et al., 1984), and ulceration (Boorman et al., 1986; Danse et al., 1984) of the forestomach. However, forestomach effects were not observed in rats and stomach effects were not observed in dogs that were chronically exposed to methyl bromide in the diet, potentially because methyl bromide degrades to other bromide compounds in the food (Mertens, 1997). Decreases in food consumption, body weight, and body weight gain were noted in the chronic rat study when methyl bromide was administered in capsules (Mertens, 1997).

In a subchronic (13-week) rat study (Danse et al., 1984), a NOAEL of 1.4 mg/kg/day (a time weighted average, $\frac{5}{7}$ days, of the 2 mg/kg/day dose group) was selected in the EPA IRIS assessment based on severe hyperplasia of the stratified squamous epithelium in the forestomach, in the next highest dose group of 7.1 mg/kg/day (USEPA, 1989). In ATSDR's Toxicological Profile (ATSDR, 1992), a lower dose of 0.4 mg/kg/day is selected as the NOAEL because "mild focal hyperemia" was observed at the 1.4 mg/kg/day dose level. It is worth noting that authors of this study reported neoplastic changes in the forestomach. However, EPA and others (USEPA, 1985; Schatzow, 1984) re-evaluated the histological results, concluding that the lesions were hyperplasia and inflammation, not neoplasms. ATSDR notes that histological diagnosis of epithelial carcinomas in the presence of marked hyperplasia is difficult (Wester and Kroes 1988; ATSDR 1992). Additionally, the hyperplasia of the forestomach observed after 13 weeks of exposure to bromomethane regressed when exposure ended (Boorman et al. 1986; ATSDR 1992).

EPA selected an OPP Human Health Risk Assessment from 2006 as the basis for developing the HRL for methyl bromide (USEPA, 2006c). As described in the OPP document, the study was of chronic duration (two years) with four groups of male rats and four groups of female rats treated orally via encapsulated methyl bromide. In the OPP assessment (USEPA, 2006c), Mertens (1997) was identified as the critical study and decreased body weight, decreased rate of body weight gain, and decreased food consumption were the critical effects in rats orally exposed to methyl bromide (USEPA, 2006c). The NOAEL was 2.2 mg/kg/day and the LOAEL was 11.1 mg/kg/day. The RfD derived in the 2006 OPP Human Health Assessment is 0.022 mg/kg/day, based on the point of departure (POD) of 2.2 mg/kg/day (the NOAEL) and a combined uncertainty factor (UF) of 100 for interspecies variability (10) and intraspecies variability (10). No benchmark dose modeling was performed.

Neurological effects reported after inhalation exposures have not been reported after oral exposures, indicating that route of exposure may influence the most sensitive adverse health endpoint (USEPA, 1988).

Limited data are available regarding the developmental or reproductive toxicity of methyl bromide, especially via the oral route of exposure. ATSDR (1992) found no information on

developmental effects in humans with methyl bromide exposure. An oral developmental toxicity study of methyl bromide in rats (doses of 3, 10, or 30 mg/kg/day) and rabbits (doses of 1, 3, or 10 mg/kg/day) found that there were no treatment-related adverse effects in fetuses of the treated groups of either species (Kaneda et al., 1998). ATSDR's 1992 Toxicological Profile also did not identify any LOAELs for rats or rabbits in this study. In rats exposed to 30 mg/kg/day, there was an increase in fetuses having 25 presacral vertebrae; however, ATSDR notes that there were no significant differences in the number of litters with this variation and the effect was not exposure-related (ATSDR, 1992). No significant alterations in resorptions or fetal deaths, number of live fetuses, sex ratio, or fetal body weights were observed in rats and no alterations in the occurrence of external, visceral, or skeletal malformations or variations were observed in the rabbits. Some inhalation studies reported no effects on development or reproduction, but other inhalation studies show adverse developmental effects. For example, Hardin et al. (1981) and Sikov et al. (1980) conducted studies in rats and rabbits and found no developmental effects, even when maternal toxicity was severe (ATSDR, 1992). However, another inhalation study of rabbits found increased incidence of gallbladder agenesis, fused vertebrae, and decreased fetal body weights in offspring (Breslin et al., 1990). Decreased pup weights were noted in a multigeneration study in rats exposed to 30 ppm (Enloe et al., 1986). Reproductive effects were noted in intermediate-duration inhalation studies in rats and mice (Eustis et al., 1988; Kato et al., 1986), which indicated that the testes may undergo degeneration and atrophy at high exposure levels.

In the OPP HHRA for methyl bromide (USEPA, 2006c), methyl bromide is classified as "not likely to be carcinogenic to humans". In 2007, EPA published a PPRTV report which stated that there is "inadequate information to assess the carcinogenic potential" of methyl bromide in humans (USEPA, 2007a). The PPRTV assessment agrees with earlier National Toxicology Program (NTP) conclusions that the available data indicate that methyl bromide can cause genotoxic and/or mutagenic changes. The PPRTV assessment states that the results in studies by Vogel and Nivard (1994) and Gansewendt et al. (1991) clearly indicate methyl bromide is distributed throughout the body and is capable of methylating DNA *in vivo*. However, the

PPRTV assessment also summarizes the results of several studies in mice and rats that have not demonstrated evidence of methyl bromide-induced carcinogenic changes (USEPA, 2007a; NTP, 1992; Reuzel et al. 1987; ATSDR, 1992). In 2012, an epidemiology study was published that concluded there was a significant monotonic exposure-dependent increase in stomach cancer risk among 7,814 applicators of methyl bromide (Barry et al., 2012). In OPP's Draft HHRA for Methyl Bromide, OPP reviews all the epidemiological studies for methyl bromide, including the Barry et al. (2012) Agricultural Health Study. OPP concludes that "based on the review of these studies, there is insufficient evidence to suggest a clear associative or causal relationship between exposure to methyl bromide and carcinogenic or non-carcinogenic health outcomes."

According to ATSDR (1992) and the EPA OPP assessment (USEPA, 2006c), no studies suggest that a specific subpopulation may be more susceptible to methyl bromide, though there is little information about susceptible lifestyles or subpopulations when exposed via the oral route. Because the critical effects of decreased body weight, decreased rate of body weight gain, and decreased food consumption in this study are not specific to a sensitive subpopulation or life stage, the target population of the general adult population was selected in deriving the HRL for regulatory determination. EPA's OPP assessment conducted additional exposure assessments for lifestyles that may increase exposure to methyl bromide and concluded that no lifestyles have expected exposure greater than 10% of the chronic population-adjusted dose (cPAD), including children.

EPA calculated an HRL of 100 µg/L (rounded from 140.8 µg/L) based on an EPA OPP assessment cPAD of 0.022 mg/kg/day and using 2.5 L/day drinking water ingestion, 80 kg body weight, and a 20% RSC factor (USEPA, 2006d; USEPA, 2011, Table 8–1 and 3–33).

(b) Occurrence

EPA has determined that methyl bromide does not occur with a frequency and at levels of public health concern at PWSs based on the Agency's evaluation of available occurrence information. The primary data occurrence data for methyl bromide are the 2013–2015 nationally representative drinking water monitoring data generated through EPA's UCMR 3. Methyl bromide was not detected in any of the 36,848 UCMR 3 samples collected by 4,916 PWSs (serving ~ 241 million people) at levels greater than ½ the HRL

(50 µg/L) or the HRL (100 µg/L). Methyl bromide was detected in about 0.3% samples at or above the MRL (0.2 µg/L) (USEPA, 2019a; USEPA, 2021a).

Findings from the available ambient water data for methyl bromide are consistent with the results in finished water. Ambient water data in NAWQA show that methyl bromide was detected in fewer than 1% of samples from fewer than 2% of sites. No detections were greater than the HRL in any of the three cycles. The median concentration among detections were 0.5 µg/L and 0.8 µg/L in Cycle 1 and Cycle 3, respectively. There were no detections in Cycle 2. The results of the NWIS analysis show that methyl bromide was detected in approximately 0.1% of samples at approximately 0.1% of sites. The median concentration among detections was 0.6 µg/L.

(c) Meaningful Opportunity

The Agency has determined that regulation of methyl bromide does not present a meaningful opportunity for health risk reduction for persons served by PWSs based on the estimated exposed populations, including sensitive populations. UCMR 3 findings indicate that the estimated population exposed to methyl bromide at levels of public health concern is 0%. As a result, the Agency finds that an NPDWR for methyl bromide does not present a meaningful opportunity for health risk reduction.

(d) Summary of Public Comments on Methyl Bromide and Agency Responses

EPA received several comments on the Agency's evaluation of methyl bromide under section 1412(b)(1)(A) of SDWA, including several comments in support of its preliminary determination not to regulate methyl bromide. Three anonymous members of the public opposed the negative determination of methyl bromide because of their perceptions about its production and use. Specifically, commenters appear to be seeking to prohibit the production and use of methyl bromide.

EPA agrees with the comments that are in support of the negative regulatory determination. Regarding comments that oppose the negative determination because of methyl bromide's production and use; the production, importation, use, and disposal of specific chemicals are not regulated by SDWA and therefore are not relevant to this determination. As discussed above, methyl bromide was not found above ½ the HRL in drinking water in any UCMR 3 samples. Furthermore, commenters did not provide any data or other information that suggested that their

concerns had impacts on the occurrence of methyl bromide in drinking water or discuss any other methyl bromide issues that specifically related to drinking-water. Hence, commenters concerns are not addressable by this decision not to regulate methyl bromide under SDWA.

E. Metolachlor

1. Description

Metolachlor is a chloroacetanilide pesticide that is used as an herbicide for weed control. Initially registered in 1976 for use on turf, metolachlor has more recently been used on corn, cotton, peanuts, pod crops, potatoes, safflower, sorghum, soybeans, stone fruits, tree nuts, non-bearing citrus, non-bearing grapes, cabbage, certain peppers, buffalograss, guymon bermudagrass for seed production, nurseries, hedgerows/fencerows, and landscape plantings. Synonyms for metolachlor include dual and bicep (USEPA, 2021a). Metolachlor is expected to have moderate to high persistence in water due to its biodegradation half-life (USEPA, 2021a).

2. Agency Findings

The Agency is making a determination not to regulate metolachlor with an NPDWR. Metolachlor does not occur with a frequency and at levels of public health concern. As a result, the Agency finds that an NPDWR does not present a meaningful opportunity for health risk reduction.

(a) Adverse Health Effects

The Agency finds that metolachlor may have adverse effects on the health of persons. The existing toxicological database includes studies evaluating both metolachlor and S-metolachlor. When combined with the toxicology database for metolachlor, the toxicology database for S-metolachlor is considered complete for risk assessment purposes (USEPA, 2018d). In subchronic (metolachlor and S-metolachlor) (USEPA, 1995b; USEPA, 2018d) and chronic (metolachlor) (Hazelette, 1989; Tisdell, 1983; Page, 1981; USEPA, 2018d) toxicity studies in dogs and rats, decreased body weight was the most commonly observed effect. Chronic exposure to metolachlor in rats also resulted in increased liver weight and microscopic liver lesions in both sexes (USEPA, 2018d). No systemic toxicity was observed in rabbits when metolachlor was administered dermally, though dermal irritation was observed at lower doses (USEPA, 2018d). Portal of entry effects (e.g., hyperplasia of the squamous epithelium and mucous cell)

occurred in the nasal cavity at lower doses in a 28-day inhalation study in rats (USEPA, 2018d). Systemic toxicity effects were not observed in this study. Immunotoxicity effects were not observed in mice exposed to S-metolachlor (USEPA, 2018d).

While some prenatal developmental studies in the rat and rabbit with both metolachlor and S-metolachlor revealed no evidence of a qualitative or quantitative susceptibility in fetal animals, decreased pup body weight was observed in a two-generation study (Page, 1981, USEPA, 2018d). Though there was no evidence of maternal toxicity, decreased pup body weight in the F1 and F2 litters was observed, indicating developmental toxicity (Page, 1981; USEPA, 1990b). Therefore, sensitive lifestages to consider include infants, as well as pregnant women and their fetus, and lactating women.

Although treatment with metolachlor did not result in an increase in treatment-related tumors in male rats or in mice (both sexes), metolachlor caused an increase in liver tumors in female rats (USEPA, 2018d). There was no evidence of mutagenic or cytogenetic effects *in vivo* or *in vitro* (USEPA, 2018d). In 1994 (USEPA, 1995b), EPA classified metolachlor as a Group C possible human carcinogen, in accordance with the 1986 Guidelines for Carcinogen Risk Assessment (USEPA, 1986). In 2017 (USEPA, 2018d), EPA reassessed the cancer classification for metolachlor in accordance with EPA's final Guidelines for Carcinogen Risk Assessment (USEPA, 2005), and reclassified metolachlor/S-metolachlor as "Not Likely to be Carcinogenic to Humans" at doses that do not induce cellular proliferation in the liver. This classification was based on convincing evidence of a constitutive androstane receptor (CAR)-mediated mitogenic MOA for liver tumors in female rats that supports a nonlinear approach when deriving a guideline that is protective for the tumor endpoint (USEPA, 2018d).

A recent OPP HHRA identified a two-generation reproduction study in rats as the critical study (USEPA, 2018d). OPP proposed an RfD for metolachlor of 0.26 mg/kg/day, derived from a NOAEL of 26 mg/kg/day for decreased pup body weight in the F1 and F2 litters. A combined UF of 100 was used based on interspecies extrapolation (10), intraspecies variation (10), and an FQPA Safety Factor of 1. This RfD is considered protective of carcinogenic effects as well as effects observed in chronic toxicity studies (USEPA, 2018d). The decreased F1 and F2 litter pup body weights in the absence of maternal toxicity were considered

indicative of increased susceptibility to the pups. Therefore, a rate of 0.15 L/kg/day was selected from the Exposure Factors Handbook (USEPA, 2011) to represent the consumers-only estimate of DWI based on the combined direct and indirect community water ingestion at the 90th percentile for bottle fed infants. This estimate is more protective than the estimate for pregnant women (0.033 L/kg/day) or lactating women (0.054 L/kg/day). DWI and BW parameters are further outlined in the Exposure Factors Handbook (USEPA, 2011).

EPA OW calculated an HRL for metolachlor of 300 µg/L (rounded from 0.347 mg/L). The HRL was derived from the oral RfD of 0.26 mg/kg/day for bottle fed infants ingesting 0.15 L/kg/day water, with the application of a 20% RSC.

(b) Occurrence

EPA has determined that metolachlor does not occur with a frequency and at levels of public health concern at PWSs based on the Agency's evaluation of available occurrence information. The primary occurrence data for metolachlor are from the UCMR 2 screening survey. A total of 11,192 metolachlor samples were collected from 1,198 systems. Of these systems, three (0.25%) had metolachlor detections (1 µg/L) and none of the detections were greater than ½ the HRL (150 µg/L) or the HRL (300 µg/L) (USEPA, 2015; USEPA, 2021a).

Supplementary sources of finished water occurrence data from UCM Round 2 indicate that the occurrence of metolachlor in PWSs is likely to be low to non-existent (USEPA, 2021a). Metolachlor occurrence data for ambient water from NAWQA and NWIS are consistent with those for finished water (USEPA, 2021a).

(c) Meaningful Opportunity

The Agency has determined that regulation of metolachlor does not present a meaningful opportunity for health risk reduction for persons served by PWSs based on the estimated exposed populations, including sensitive populations. UCMR 2 findings indicate that the estimated population exposed to metolachlor at levels of public health concern is 0%. As a result, the Agency finds that an NPDWR for metolachlor does not present a meaningful opportunity for health risk reduction.

(d) Summary of Public Comments on Metolachlor and Agency Responses

EPA received several comments on the Agency's evaluation of metolachlor under section 1412(b)(1)(A) of SDWA,

all of which were in support of its preliminary determination not to regulate metolachlor. EPA agrees with the comments that are in support of the negative regulatory determination.

F. Nitrobenzene

1. Description

Nitrobenzene is a synthetic aromatic nitro compound and occurs as an oily, flammable liquid. It is commonly used as a chemical intermediate in the production of aniline and drugs such as acetaminophen. Nitrobenzene is also used in the manufacturing of paints, shoe polishes, floor polishes, metal polishes, aniline dyes, and pesticides. Nitrobenzene is expected to have a moderate to high likelihood of partitioning to water and moderate persistence in water (USEPA, 2021a).

2. Agency Findings

The Agency is making a determination not to regulate nitrobenzene with an NPDWR. Nitrobenzene does not occur with a frequency and at levels of public health concern. As a result, the Agency finds that an NPDWR does not present a meaningful opportunity for health risk reduction.

(a) Adverse Health Effects

The Agency finds that nitrobenzene may have adverse effects on the health of persons. NTP (1983) conducted a 90-day oral gavage study of nitrobenzene in F344 rats and B6C3F1 mice. The rats were more sensitive to the effects of nitrobenzene exposure than the mice, and changes in absolute and relative organ weights, hematologic parameters, splenic congestion, and histopathologic lesions in the spleen, testis, and brain were reported. Based on statistically significant changes in absolute and relative organ weights, splenic congestion, and increases in reticulocyte count and methemoglobin (metHb) concentration, a LOAEL of 9.38 mg/kg/day was identified for the subchronic oral effects of nitrobenzene in F344 male rats (USEPA, 2009). This was the lowest dose studied, so a NOAEL was not identified. The mice were treated with higher doses and were generally more resistant to nitrobenzene toxicity, the toxic endpoints were similar in both species.

The testis, epididymis, and seminiferous tubules of the male reproductive system are targets of nitrobenzene toxicity in rodents. In male rats (F344/N and CD) and mice (B6C3F1), nitrobenzene exposure via the oral and inhalation routes results in histopathologic lesions of the testis and

seminiferous tubules, testicular atrophy, a large decrease in sperm count, and a reduction of sperm motility and/or viability, which contribute to a loss of fertility (NTP, 1983; Bond et al., 1981; Koida et al., 1995; Matsuura et al., 1995; Kawashima et al., 1995). These data suggest that nitrobenzene is a male-specific reproductive toxicant (USEPA, 2009).

Under the Guidelines for Carcinogen Risk Assessment (USEPA, 2005), nitrobenzene is classified as “likely to be carcinogenic to humans” by any route of exposure (USEPA, 2009). A two-year inhalation cancer bioassay in rats and mice (Cattley et al., 1994; CIIT, 1993) reported an increase in several tumor types in both species. However, the lack of available data, including a physiologically based biokinetic or model that might predict the impact of the intestinal metabolism on serum levels of nitrobenzene and its metabolites following oral exposures, precluded EPA’s IRIS program from deriving an oral CSF (USEPA, 2009). Additionally, a metabolite of nitrobenzene, aniline, is classified as a probable human carcinogen (B2) (USEPA, 1988).

Nitrobenzene has been shown to be non-genotoxic in most studies and was classified as, at most, weakly genotoxic in the 2009 USEPA IRIS assessment (ATSDR, 1990; USEPA, 2009).

Of the available animal studies with oral exposure to nitrobenzene, the 90-day gavage study conducted by NTP (1983) is the most relevant study for deriving an RfD for nitrobenzene. This study used the longest exposure duration and multiple dose levels. Benchmark dose software (BMDS) (version 1.4.1c; USEPA, 2007b) was applied to estimate candidate PODs for deriving an RfD for nitrobenzene. Data for splenic congestion and increases in reticulocyte count and methHb concentration were modeled. The POD derived from the male rat increased methHb data with a benchmark response (BMR) of 1 standard deviation (SD) was selected as the basis of the RfD (see USEPA, 2009 for additional detail). Therefore, the benchmark dose level (BMDL) used as the POD is a BMDL1SD of 1.8 mg/kg/day.

In deriving the RfD, EPA’s IRIS program applied a composite UF of 1,000 to account for interspecies extrapolation (10), intraspecies variation (10), subchronic-to-chronic study extrapolation (3), and database deficiency (3) (USEPA, 2009). Thus, the RfD calculated in the 2009 IRIS assessment is 0.002 mg/kg/day. The overall confidence in the RfD was medium because the critical effect is

supported by the overall database and is thought to be protective of reproductive and immunological effects observed at higher doses; however, there are no chronic or multigenerational reproductive/developmental oral studies available for nitrobenzene.

Because the critical effect in this study (increased methHb in the adult rat) is not specific to a sensitive subpopulation or lifestage, the general adult population was selected in deriving the HRL for regulatory determination.

EPA calculated an HRL for the noncancer effects of nitrobenzene of 10 µg/L (rounded from 12.8 µg/L), based on the RfD of 0.002 mg/kg/day, using 2.5 L/day drinking water ingestion, 80 kg body weight, and a 20% RSC factor.

(b) Occurrence

EPA has determined that nitrobenzene does not occur with a frequency and at levels of public health concern at PWSs based on the Agency’s evaluation of available occurrence information. The primary occurrence data for nitrobenzene are nationally representative finished water monitoring data generated through EPA’s UCMR 1 a.m. (2001–2003). UCMR 1 collected 33,576 finished water samples from 3,861 PWSs (serving ~226 million people) for nitrobenzene and it was detected in only a small number of those samples (0.01%) above the HRL (10 µg/L), which is the same as the MRL (10 µg/L).

Findings from the available ambient water data for nitrobenzene are consistent with the results in finished water. Ambient water data in NAWQA show that nitrobenzene was not detected in any of the samples collected under any of the three monitoring cycles, while NWIS data show that nitrobenzene was detected in approximately 1% of samples.

(c) Meaningful Opportunity

The Agency has determined that regulation of nitrobenzene does not present a meaningful opportunity for health risk reduction for persons served by PWSs based on the estimated exposed populations, including sensitive populations. UCMR 1 data indicate that the estimated population exposed to nitrobenzene above the HRL is 0.1%. The Agency finds that an NPDWR for nitrobenzene does not present a meaningful opportunity for health risk reduction.

(d) Summary of Public Comments on Nitrobenzene and Agency Responses

EPA received several comments on the Agency’s evaluation of nitrobenzene under section 1412(b)(1)(A) of SDWA,

all of which were in support of its preliminary determination not to regulate nitrobenzene. EPA agrees with the comments that are in support of the negative regulatory determination.

G. RDX

1. Description

RDX is a nitrated triazine and is an explosive. The name RDX is an abbreviation of “Royal Demolition eXplosive.” The formal chemical name is hexahydro-1,3,5-trinitro-1,3,5-triazine. RDX is expected to have a moderate to high likelihood of partitioning to water and low to moderate persistence in water (USEPA, 2021a).

2. Agency Findings

The Agency is making a determination not to regulate RDX with an NPDWR. RDX does not occur with a frequency and at levels of public health concern. As a result, the Agency finds that an NPDWR does not present a meaningful opportunity for health risk reduction.

(a) Adverse Health Effects

The Agency finds that RDX may have adverse effects on the health of persons. Available health effects assessments include an IRIS toxicological review (USEPA, 2018e), and older assessments including an ATSDR toxicological profile (ATSDR, 2012) and an OW assessment published in the 1992 Drinking Water Health Advisory: Munitions (USEPA, 1992). The EPA IRIS assessment (2018e) presents an RfD of 0.004 mg/kg/day based on convulsions as the critical effect observed in a subchronic study in F-344 rats by Crouse et al. (2006). The POD for the derivation was a BMDL_{0.05} of 1.3 mg/kg/day derived using a pharmacokinetic model that identified the human equivalent dose (HED) based on arterial blood concentrations in the rats as the dose metric. A 300-fold UF (3 for extrapolation from animals to humans, 10 for interindividual differences in human susceptibility, and 10 for uncertainty in the database) was applied in determination of the RfD.

Additionally, the EPA IRIS assessment (USEPA, 2018e) classified data from the Lish et al. (1984) chronic study in B6C3F1 as providing suggestive evidence of carcinogenic potential following EPA (USEPA, 2005) guidelines. The slope factor was derived from the lung and liver tumors’ dose-response in the Lish et al. (1984) study. The POD for the slope factor was the BMDL₁₀ allometrically scaled to a HED

yielding a slope factor of 0.08 per mg/kg/day.

In mice fed doses of 0 to 35 mg/kg/day for 24 months in the Lish et al. (1984) study, there were dose-dependent increases in adenomas or carcinomas of the lungs and liver in males and females (USEPA, 2018e). The formulation used contained 3 to 10% HMX, another munition ingredient. EPA assessed the toxicity of HMX (USEPA, 1988). No chronic-duration studies were available to evaluate the carcinogenicity of HMX (USEPA, 1988). HMX is classified as Group D, or not classifiable as to human carcinogenicity (USEPA, 1992; USEPA, 1988). In the Levine et al. (1983) RDX dietary exposure study with Fischer 344 rats, a statistically significant increase in the incidence of hepatocellular carcinomas was observed in males but not in females (USEPA, 2018e). Although evidence of carcinogenicity included dose-dependent increases in two experimental animal species, two sexes, and two systems (liver and lungs), evidence supporting carcinogenicity in addition to the B6C3F1 mouse study was not robust; this factor contributed to the suggestive evidence of carcinogenic potential classification. EPA considered both the Lish et al. (1984) and Levine et al. (1983) studies to be suitable for dose-response analysis because they were well conducted, using similar study designs with large numbers of animals at multiple dose levels (USEPA, 2018e). EPA (2018e) concluded that insufficient information was available to evaluate male reproductive toxicity from experimental animals exposed to RDX. In addition, EPA (2018e) concluded that inadequate information was available to assess developmental effects from experimental animals exposed to RDX. EPA selected the 2018 EPA IRIS assessment to derive two HRLs for RDX: The RfD-derived HRL (based on Crouse et al., 2006) and the oral cancer slope factor-derived HRL (based on Lish et al., 1984). EPA has generally derived HRLs for “possible” or Group C carcinogens using the RfD approach in past Regulatory Determinations. However, for RDX, EPA decided to show both an RfD-derived and oral-cancer-slope-factor-derived HRL since the mode of action for liver tumors is unknown and the 1×10^{-6} cancer risk level provides a more health protective HRL to evaluate the occurrence information.

The RfD-derived HRL for RDX was calculated using the RfD of 0.004 mg/kg/day based on a subchronic study in F-344 rats by Crouse et al. (2006) with convulsions as the critical effect (USEPA, 2018e). The point of departure for the RfD calculation was a human

equivalent BMDL_{0.05} of 1.3 mg/kg/day. The HED was derived using a pharmacokinetic model based on arterial blood concentrations in the rats as the dose metric. A 300-fold uncertainty factor (3 for extrapolation from animals to humans, 10 for interindividual differences in human susceptibility, and 10 for uncertainty in the database) was applied in determination of the RfD. EPA calculated a RfD-derived HRL of 30 µg/L (rounded from 25.6 µg/L), for the noncancer effects of RDX based on the RfD of 0.004 mg/kg/day, using 2.5 L/day drinking water ingestion, 80 kg body weight, and a 20% RSC factor.

The oral-cancer-slope-factor-derived HRL for RDX was also based on values presented in the 2018 EPA IRIS assessment. The slope factor is derived from the dose-response for lung and liver tumors in the Lish et al. (1984) study, with elimination of the data for the high dose group due to high mortality. The point of departure for the slope factor of 0.08 (mg/kg/day)-1 was the BMDL₁₀ which was allometrically scaled to a HED. EPA calculated an oral cancer slope factor-derived HRL of 0.4 µg/L for RDX based on the cancer slope factor of 0.08 (mg/kg/day)-1, using 2.5 L/day drinking water ingestion, 80 kg body weight, and a 1 in a million cancer risk level.

EPA’s (USEPA, 2018e) derivation of an oral slope factor for cancer is in accordance with the Guidelines for Carcinogen Risk Assessment (USEPA, 2005) while RDX is classified as having “suggestive evidence of carcinogenic potential.” Specifically, the guidelines state “when the evidence includes a well-conducted study, quantitative analyses may be useful for some purposes, for example, providing a sense of the magnitude and uncertainty of potential risks, ranking potential hazards, or setting research priorities” (USEPA, 2005). The EPA IRIS assessment concluded that the database for RDX contains well-conducted carcinogenicity studies (Lish et al., 1984; Levine et al., 1983) suitable for dose response and that the quantitative analysis may be useful for providing a sense of the magnitude and uncertainty of potential carcinogenic risk (USEPA, 2018e). Therefore, EPA felt it was important to evaluate the occurrence information against both the RfD-derived HRL and the oral cancer slope factor-derived HRL.

(b) Occurrence

EPA has determined that RDX does not occur with a frequency and at levels of public health concern at PWSs based on the Agency’s evaluation of available

occurrence information. The primary data for RDX are nationally representative drinking water monitoring data generated through EPA’s UCMR 2 AM (2008–2010). UCMR 2 collected 32,150 finished water samples from 4,139 PWSs (serving ~229 million people) for RDX and it was detected in only a small number of those samples (0.01%) at or above the MRL. The detections occurred in three large surface water systems; the maximum detected concentration of RDX was 1.1 µg/L. The MRL is 1 µg/L, which is about 2.5 times higher than the oral cancer slope factor-derived HRL (0.4 µg/L). The RfD-derived HRL (30 µg/L) is 30 times higher than the MRL and 75 times higher than the cancer slope factor-derived HRL.

Findings from the available ambient water data for RDX in ambient water, available from NWIS, show that RDX was detected in approximately 46% of samples and at approximately 29% of sites; RDX data are not available from the NAWQA program.

(c) Meaningful Opportunity

The Agency has determined that regulation of RDX does not present a meaningful opportunity for health risk reduction for persons served by PWSs based on the estimated exposed populations, including sensitive populations. UCMR 2 findings indicate that the estimated population exposed to RDX at or above the MRL is 0.04%. There were no detections greater than the non-cancer HRL (30 µg/L) or the one-half the non-cancer HRL (15 µg/L). Because the MRL of 1 µg/L is higher than the cancer HRL of 0.4 µg/L, the population exposed relative to the cancer HRL and ½ the cancer HRL is not presented here. As a result, the Agency finds that an NPDWR for RDX does not present a meaningful opportunity for health risk reduction. Based on the small number of samples measured at or marginally above the MRL, EPA does not believe that there would be enough occurrence in the narrow range between the HRL and the MRL to change the meaningful opportunity determination.

(d) Summary of Public Comments on RDX and Agency Responses

EPA received several comments on the Agency’s evaluation of RDX under section 1412(b)(1)(A) of SDWA, all of which were in support of its preliminary determination not to regulate RDX. EPA agrees with the comments that are in support of the negative regulatory determination.

Summary of Public Comments on Strontium, 1,4-Dioxane, and 1,2,3-Trichloropropane, and the Agency's Responses

H. Strontium

Strontium is an alkaline earth metal. On October 20, 2014 the Agency published its preliminary regulatory determination to regulate strontium and requested public comment on the determination and supporting technical information (USEPA, 2014). Informed by the public comments received, rather than making a final determination for strontium in 2016, EPA delayed the final determination to consider additional data, and to decide whether there is a meaningful opportunity for health risk reduction by regulating strontium in drinking water (USEPA, 2016f). Specifically, the publication on the delayed final determination mentioned that EPA would evaluate additional studies on strontium exposure and health studies related to strontium exposure. Since 2016, EPA has worked to identify and evaluate published studies on health effects associated with strontium exposure, sources of exposure to strontium, and treatment technologies to remove strontium from drinking water. In its March 10, 2020 document (USEPA, 2020a), EPA clarified that it is continuing with its previous 2016 decision (USEPA, 2016f) to delay a final determination for strontium in order to further consider additional studies related to strontium exposure.

The Agency received several comments in support of a continued evaluation of strontium and not making a final determination for strontium in this action. One commenter requested that EPA complete its evaluation of strontium in a more timely manner. EPA agrees with the comments that are in support of the continued evaluation prior to making a final regulatory determination for strontium. Regarding making a regulatory determination for strontium in this rulemaking, EPA notes that there continues to be a need for additional information and analyses before a regulatory determination can be made for strontium. While EPA determined in 2014 that strontium may have adverse effects on the health of persons including children, the Agency continues to consider additional data, consult existing assessments (such as Health Canada's Drinking Water Guideline from 2018), and evaluate whether there is a meaningful opportunity for health risk reduction by regulating strontium in drinking water. Additionally, EPA understands that strontium may co-occur with beneficial

calcium in some drinking water systems and treatment technologies that remove strontium may also remove calcium. The Agency is evaluating the effectiveness of treatment technologies under different water conditions, including calcium concentrations. EPA intends to make a determination after these data needs have been resolved as part of its regulatory determination process.

I. 1,4-Dioxane

1,4-Dioxane is used as a solvent in cellulose formulations, resins, oils, waxes, and other organic substances; also used in wood pulping, textile processing, degreasing; in lacquers, paints, varnishes, and stains; and in paint and varnish removers.

While the health effects data suggest that 1,4-dioxane may have an adverse effect on human health and the occurrence data indicate that 1,4-dioxane is occurring in finished drinking water above the current HRL in some systems, EPA has not made a preliminary determination for 1,4-dioxane, as the Agency has not determined whether 1,4-dioxane occurs in public water systems with a frequency and at levels of public health concern and whether there is a meaningful opportunity for public health risk reduction by establishing an NPDWR for 1,4-dioxane (USEPA, 2020a). The *Final Regulatory Determination 4 Support Document* (USEPA, 2021a) and the *Occurrence Data from the Third Unregulated Contaminant Monitoring Rule (UCMR 3)* (USEPA, 2019a) present additional information and analyses supporting the Agency's evaluation of 1,4-dioxane.

The Agency received several comments in support of a continued evaluation and not making a 1,4-dioxane determination at this time. One commenter provided information summarizing their belief that 1,4 dioxane has a non-linear mode of action. Another commenter requested that EPA complete its evaluation of 1,4-dioxane in a more-timely manner. EPA agrees with the comments that are in support of the continued evaluation. Regarding making a regulatory determination for 1,4-dioxane today, EPA notes that there is a need for additional information and analyses before a regulatory determination can be made for 1,4-dioxane. Based on UCMR 3 data, EPA derived a national estimate of less than two baseline cancer cases per year attributable to 1,4-dioxane in drinking water (USEPA, 2021a). However, while the number of baseline cancer cases is relatively low, other adverse health effects following

exposure to 1,4-dioxane may also contribute to potential risk to public health, and these analyses under SDWA have not yet been completed. The Agency recently completed its new TSCA risk evaluation for 1,4-dioxane by the Office of Chemical Safety and Pollution Prevention (OCSPP) (USEPA, 2020c) and intends to consider it and the Canadian guideline technical document, once finalized, (Health Canada, 2018) and other relevant new science relevant to drinking water contamination prior to making a regulatory determination. This evaluation may provide clarity as to whether a new HRL is appropriate for evaluating the occurrence of 1,4-dioxane and whether there is a meaningful opportunity for an NPDWR to reduce public health risk.

J. 1,2,3-Trichloropropane

1,2,3-Trichloropropane is a man-made chemical used as an industrial solvent, cleaning and degreasing agent, and synthesis intermediate.

While the UCMR 3 data indicated 1,2,3-trichloropropane occurrence was relatively low at concentrations above the MRL, the MRL (0.03 µg/L) is more than 75 times the HRL (0.0004 µg/L) for 1,2,3-trichloropropane. This discrepancy allows for a broad range of potential contaminant concentrations that could be in exceedance of the HRL but below the MRL. EPA did not make a preliminary determination for 1,2,3-trichloropropane due to these analytical method-based limitations. The Agency noted that it needs additional lower-level occurrence information prior to making a preliminary regulatory determination for 1,2,3-trichloropropane. The *Final Regulatory Determination 4 Support Document* (USEPA, 2021a) and the *Occurrence Data from the Third Unregulated Contaminant Monitoring Rule (UCMR 3)* (USEPA, 2019a) present additional information and analyses supporting the Agency's evaluation of 1,2,3-trichloropropane.

The Agency received several comments in support of a continued evaluation and not making a 1,2,3-trichloropropane determination at this time. In addition, EPA notes that several comments requested that EPA find solutions to the analytical method limitations and collect additional monitoring data with an MRL adequate to support decision-making. EPA agrees with the comments that are in support of the continued evaluation. EPA also agrees that further evaluation of 1,2,3-trichloropropane is warranted when new methods or other tools are available to do so.

V. Next Steps

As required by SDWA, EPA will initiate the process to propose a NPDWR for PFOA and PFOS within 24 months of the publication of this document in the **Federal Register**. For this rulemaking effort, in addition to using the best available science, the Agency will seek recommendations from the EPA Science Advisory Board and consider public comment on the proposed rule. Therefore, EPA anticipates further scientific review of new science and an opportunity for additional public input prior to the promulgation of the regulatory standard for PFOA and PFOS. Additionally, the Agency will continue to collect and review additional state and other occurrence information during the development of the proposed NPDWR for PFOA and PFOS. The Agency will not be taking any further regulatory action under SDWA for the six negative determinations at this time.

VI. References

- American Association for the Advancement of Science (AAAS). 2020. Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water. Available on the internet at: <https://www.aaas.org/programs/epi-center/pfas>.
- Ahmed, F.E. and J.C. Seely. 1983. Acetochlor: Chronic Feeding Toxicity and Oncogenicity Study in the Rat. Pharmacopathics Research Laboratories, Inc., Laurel, MD. Study No. PR-80-006. May 20, 1983. Unpublished report (as cited in USEPA, 2006b).
- Ahmed, F.E., A.S. Tegeris, and J.C. Seely. 1983. MON 097: 24-Month Oncogenicity Study in the Mouse. Pharmacopathics Research Laboratories, Inc., Laurel, MD. Report No. PR-80-007. May 4, 1983. Unpublished report (as cited in USEPA, 2006b).
- Agency for Toxic Substances and Disease Registry (ATSDR). 1990. *Toxicological Profile for Nitrobenzene*. U.S. Department of Health and Human Services, Public Health Service. Available on the internet at: <https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=532&tid=95>.
- ATSDR. 1992. *Toxicological Profile for Bromomethane*. U.S. Department of Health and Human Services, Public Health Service.
- ATSDR. 2012. *Toxicological Profile for RDX*. U.S. Department of Health and Human Services, Public Health Service. Available on the internet at: <https://www.atsdr.cdc.gov/ToxProfiles/tp.asp?id=412&tid=72>.
- ATSDR. 2015. *Toxicological Profile for 1,1-Dichloroethane*. U.S. Department of Health and Human Services, Public Health Service. Available on the internet at: <https://www.atsdr.cdc.gov/ToxProfiles/tp133.pdf>.
- Barry, K.H., S. Koutros, J. Lupin, H.B. Coble, F. Barone-Adesi, L.E. Beane Freeman, D.P. Sandler, J.A. Hoppin, X. Ma, T. Zheng, and M.C.R. Alavanja. 2012. Methyl bromide exposure and cancer risk in the Agricultural Health Study. *Cancer Causes Control* 23:807–818.
- Bond, J.A., J.P. Chism, D.E. Rickert, et al. 1981. Induction of hepatic and testicular lesions in Fischer 344 rats by single oral doses of nitrobenzene. *Fundam Appl Toxicol* 1:389–394 (as cited in USEPA, 2009).
- Boorman, G.A., H.L. Hong, C.W. Jameson, et al. 1986. Regression of methyl bromide induced forestomach lesions in the rat. *Toxicol Appl Pharmacol* 86:131–139.
- Breslin, W.J., C.L. Zublotny, G.J. Bradley, et al. 1990. Methyl bromide inhalation teratology study in New Zealand white rabbits with cover letter and attachment (declassified). Dow Chemical Company. Submitted to the U.S. Environmental Protection Agency under TSCA Section 8E. OTS0522340–3 (as cited in ATSDR, 1992).
- Calafat, A.M., L-Y Wong, Z. Kuklenyik, J.A. Reidy, and L.L. Needham. 2007. Polyfluoroalkyl Chemicals in the U.S. Population: Data from the National Health and Nutrition Examination Survey (NHANES) 2003–2004 and Comparisons with NHANES 1999–2000. *Environ Health Perspect* 115(11):1596–1602.
- Calafat, A.M., K. Kato, K. Hubbard, et al. 2019. Legacy and alternative per and polyfluoroalkyl substances in the U.S. general population: Paired serum-urine data from the 2013–2014 National Health and Nutrition Examination Survey. *Environ Health International* 131:105048.
- Cattley, R.C., J.I. Everitt, E.A. Gross, et al. 1994. Carcinogenicity and toxicity of inhaled nitrobenzene in B6C3F1 mice and F344 and CD rats. *Fundam Appl Toxicol* 22:328–340 (as cited in USEPA, 2009).
- Centers for Disease Control and Prevention (CDC). 2019. *Fourth National Report on Human Exposure to Environmental Chemicals, Updated Tables, January 2019, Volume 1*. Department of Health and Human Services, Centers for Disease Control and Prevention. Available on the internet at: https://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Volume1_Jan2019-508.pdf.
- Chemical Industry Institute of Toxicology (CIIT). 1993. Initial submission: A chronic inhalation toxicity study of nitrobenzene in B6C3F1 mice, Fischer 344 rats and Sprague-Dawley (CD) rats. Chemical Industry Institute of Toxicology. Research Triangle Park, NC. EPA Document No. FYI-OTS-0794–0970; NTIS No. OTS0000970 (as cited in USEPA, 2009).
- Crouse, L.C.B., M.W. Michie, M. Major, M.S. Johnson, R.B. Lee, and H.I. Paulus. 2006. Subchronic oral toxicity of RDX in rats. (Toxicology Study No. 85–XC–5131–03). Aberdeen Proving Ground, MD: U.S. Army Center for Health Promotion and Preventive Medicine.
- Danse, L.H., F.L. van Velsen, and C.A. Van Der Heljden. 1984. Methylbromide: Carcinogenic effects in the rat forestomach. *Toxicol Appl Pharmacol* 72:262–271 (as cited in ATSDR, 1992).
- Dickenson, E.R.V. and C. Higgins. 2016. *Treatment Mitigation Strategies for Poly- and Perfluoroalkyl Substances*. Web Report #4322. Water Research Foundation. Denver, CO.
- Domingo, J.L., and M. Nadal. 2019. Human exposure to per- and polyfluoroalkyl substances (PFAS) through drinking water: A review of the recent scientific literature. *Environmental Research* 177: 108648.
- Enloe, P.V., C.M. Salamon, and S.V. Becker. 1986. Two-generation reproduction study via inhalation in albino rats using methyl bromide. American Biogenics Corp. Submitted to the U.S. Environmental Protection Agency under TSCA Section 8d. OTS0515364. EPA Doc. ID 86–870000926 (as cited in ATSDR, 1992).
- Eustis, S.L., S.B. Haber, R.T. Drew, et al. 1988. Toxicology and pathology of methyl bromide in F344 rats and B6C3F1 mice following repeated inhalation exposure. *Fundam Appl Toxicol* 11:594–610 (as cited in ATSDR, 1992).
- Fromme H, Tittlemier SA, Volkel W, Wilhelm M, Twardella D. 2009. Perfluorinated Compounds—Exposure Assessment for the General Population in Western Countries. *International Journal of Hygiene and Environmental Health* 212: 239–270, doi: 10.1016/j.ijheh.2008.04.007.
- Ganewendt, B., U. Foest, D. Xu et al. 1991. Formation of DNA adducts in F-344 rats after oral administration or inhalation of [14C] methyl bromide. *Food Chem. Toxicol* 29:557–563.
- Hardin, B.D., G.P. Bond, M.R. Sikov, et al. 1981. Testing of selected workplace chemicals for teratogenic potential. *Scand J Work Environ Health* 7:66–75 (as cited in ATSDR, 1992).
- Hardisty, J.F. 1997a. Pathology Working Group Peer Review of Histiocytic Sarcoma in Female Mice from Two Long-Term Studies with Acetochlor. Experimental Pathology Laboratories, Inc., Research Triangle Park, NC. Laboratory Project ID CTL/C/3196, February 11, 1997. Unpublished report (as cited in USEPA, 2006b).
- Hardisty, J.F. 1997b. Pathology Working Group Peer Review of Hepatocellular Neoplasms in the Liver of Rats and Mice from Five Long-Term Studies with Acetochlor. Experimental Pathology Laboratories, Inc., Research Triangle Park, NC. Laboratory Project ID CTL/C/3197, February 11, 1997. Unpublished report (as cited in USEPA, 2006b).
- Hardisty, J.F. 1997c. Pathology Working Group Peer Review of Neoplastic Lesions in the Lung of Male and Female Mice from Two Long-Term Studies with Acetochlor. Experimental Pathology Laboratories, Inc., Research Triangle Park, NC. Laboratory Project ID CTL/C/3198, February 11, 1997. Unpublished report (as cited in USEPA, 2006b).
- Hazelette, J. 1989. Metolachlor Technical: Chronic Toxicity Study in Dogs: Study

- No. 862253. Unpublished study prepared by Ciba-Geigy Corp. 758 p. MRID: 4098070 (as cited in USEPA, 2018d).
- Health Canada. 2018. 1,4-Dioxane in Drinking Water—Guideline Technical Document for Public Consultation. Available on the internet at: <https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-1-4-dioxane-drinking-water/pub-eng.pdf>.
- ICI, Inc. 1988. MRID No. 41565118; HED Doc No. 008478. (or Broadmeadow, A. 1988). SC-5676: Toxicity Study by Oral (Capsule) Administration to Beagle Dogs for 52 Weeks. Life Science Research, Ltd., Suffolk, England. Study No.: LSR Report 88/SUC018/0136; December 2, 1988 (as cited in USEPA, 1993).
- Jain, R.B. 2018. Time trends over 2003–2014 in the concentrations of selected perfluoroalkyl substance among U.S. adults aged ≥ 20 years: Interpretational issues. *Science of the Total Environment* 645:946–957.
- Kaneda, M., H. Hojo, S. Teramoto, et al. 1998. Oral teratogenicity studies of methyl bromide in rats and rabbits. *Food Chem Toxicol.* 36(5):421–427.
- Kato, N., S. Morinobu, and S. Ishizu. 1986. Subacute inhalation experiment for methyl bromide in rats. *Ind Health* 24(2):87–103 (as cited in ATSDR, 1992).
- Kawashima, K., M. Usami, K. Sakemi, et al. 1995. Studies on the establishment of appropriate spermatogenic endpoints for male fertility disturbance in rodent induced by drugs and chemicals. I. Nitrobenzene. *J Toxicol Sci* 20:15–22 (as cited in USEPA, 2009).
- Koida, M., T. Nakagawa, K. Irimura, et al. 1995. Effects on the sperm and testis of rats treated with nitrobenzene: Age and administration period differences. *Teratology* 52:39B (as cited in USEPA, 2009).
- Levine, B.S., P.M. Lish, E.M. Furedi, V.S. Rac, and J.M. Sagartz. 1983. Determination of the chronic mammalian toxicological effects of RDX (twenty-four-month, chronic toxicity/ carcinogenicity study of hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX) in the Fischer 344 rat): Final report—phase V. Chicago, IL: IIT Research Institute. (As cited in ATSDR, 2012; USEPA, 2018e; USEPA, 1992.)
- Lish, P.M., B.S. Levine, E.M. Furedi, J.M. Sagartz, and V.S. Rac. 1984. Determination of the chronic mammalian toxicological effects of RDX: Twenty-four-month, chronic toxicity/ carcinogenicity study of hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX) in the B6C3F1 hybrid mouse (Volumes 1–3). (ADA181766. DAMD17–79–C-9161). Fort Detrick. (As cited in ATSDR, 2012; USEPA, 2018e; USEPA, 1992.)
- Matsuura, I., N. Hoshino, Y. Wako, et al. 1995. Sperm parameter studies on three testicular toxicants in rats. *Teratology* 52:39B (as cited in USEPA, 2009).
- Mertens, J.J.W.M. 1997. A 24-month chronic dietary study of methyl bromide in rats. WIL Research Laboratories, Inc., 1407 George Road, Ashland, OH 44805–9281, Laboratory Study No. WIL–49014, December 9, 1997, MRID 44462501. Unpublished.
- Muralidhara, S., R. Ramanathan, S.M. Mehta, L.H. Lash, D. Acosta, and J.V. Bruckner. 2001. Acute, subacute, and subchronic oral toxicity studies of 1,1-dichloroethane in rats: Application to risk evaluation. *Toxicol. Sci.* 64:135–145.
- Naylor, M.W. and W.E. Ribelin. 1986. Chronic Feeding Study of MON 097 in Albino Rats. Monsanto Environmental Health Laboratory, St. Louis, MO. Laboratory Project ID EHL–83107 (Report No. MSL–6119). September 25, 1986. Unpublished report (as cited in USEPA, 2006b).
- National Cancer Institute (NCI). 1978. *Bioassay of 1,1-Dichloroethane for Possible Carcinogenicity*. Bethesda, MD: National Cancer Institute. NCI Carcinogenesis Technical Report Series No. 66 (NCI–CG–TR–66). DHEW Publication No. (NIH) 78–1316. Available on the internet at: http://ntp.niehs.nih.gov/ntp/htdocs/LT_rpts/tr066.pdf.
- National Institute of Environmental Health Services (NIEHS). 2020. *Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)*. Available on the internet at: <https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm>.
- National Institute for Occupational Safety and Health (NIOSH). 1978. *Occupational health guidelines for 1,1-dichloroethane. Occupational health guidelines for chemical hazards*. Washington, DC: US Department of Labor, National Institute for Occupational Safety and Health, 1–4.
- National Toxicology Program (NTP). 1983. Report on the subchronic toxicity via gavage of nitrobenzene (C60082) in Fischer 344 rats and B6C3F1 mice [unpublished]. National Toxicology Program, prepared by the EG&G Mason Research Institute, Worcester, MA, for the National Toxicology Program, National Institute of Environmental Health Services, Public Health Service, U.S. Department of Health and Human Services, Research Triangle Park, NC; MRI–NTP 08–83–19 (as cited in USEPA, 2009).
- NTP. 1992. Toxicology and carcinogenesis studies of methyl bromide (CAS NO. 74–83–9) in B6C3F1 mice (inhalation studies). U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health.
- NTP. 2020. Technical report on the toxicology and carcinogenesis studies of perfluorooctanoic acid (CASRN 335–67–1) administered in feed to Sprague Dawley (Hsd: Sprague Dawley® SD®) rats. U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health.
- Page, J.G. 1981. Two-Generation Reproduction Study in Albino Rats with Metolachlor Technical. Toxicogenics, Decatur, IL. Study Number 450–0272, August 31, 1981. Unpublished. MRID: 00080897 (cited as “Smith et al. 1981” in USEPA 1995b, cited as “Ciba-Geigy 1981” in USEPA 1990b, cited as “Page 1981” in USEPA 2018d).
- Reuzel, P.G., C.F. Kuper, H.C. Dreef-Van Der Meulen, et al. 1987. Initial submission: Chronic (29-month) inhalation toxicity and carcinogenicity study of methyl bromide in rats with cover letter dated 081092. DuPont Chem Co. Submitted to the U.S. EPA under TSCA Section ECP. OTS0546338. EPA Doc. 88–920008788 (as cited in ATSDR, 1992).
- Ribelin, W.E. 1987. Histopathology Findings in Noses of Rats Administered MON 097 in a Lifetime Feeding Study. Tegeris Laboratories, Laurel, MD and Monsanto Environmental Health Laboratory, St. Louis, MO. Laboratory Project No. ML–86–44/EHL 86027. November 4, 1987. Unpublished report (as cited in USEPA, 2006b).
- Schatzow, S. 1984. Memorandum to D. Clay, November 9, 1984. FXI–OTS–1184–0327. Supplement, Sequence D (as cited in USEPA, 2007a).
- Schwetz, B.A., B.K. Leong, and P.J. Gehring. 1974. Embryo- and fetotoxicity of inhaled carbon tetrachloride, 1,1-dichloroethane, and methyl ethyl ketone in rats. *Toxicol Appl Pharmacol.* 28: 452–464 (as cited in CalEPA, 2003).
- Sikov M.R., W.C. Cannon, and D.B. Carr. 1980. *Teratologic Assessment of Butylene Oxide, Styrene Oxide and Methyl Bromide*. Cincinnati, OH: National Institute for Occupational Safety and Health. PBS1168510 (as cited in ATSDR, 1992).
- Tisdell, M., T. Jackson, P. MacWilliams, et al. 1983. Two-year Chronic Oral Toxicity and Oncogenicity Study with Metolachlor in Albino Rats: Study No. 80030. Final rept. (Unpublished study received May 24, 1983 under 100–587; prepared by Hazleton Raltech, Inc., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL: 250369–A; 250370; 250371; 250372; 250373; 250374; 250375) (cited as MRID 00129377 in USEPA, 2018d).
- United States Environmental Protection Agency (USEPA). 1985. *Chemical Hazard Information Profile. Draft Report. Methyl Bromide*. Rev. February 20, 1985. USEPA, OTS, Washington, DC (as cited in ATSDR, 1992).
- USEPA. 1986. *Guidelines for Carcinogen Risk Assessment*. EPA 630–R–00–004.
- USEPA. 1988. *Chemical Assessment Summary Information for Octahydro-1,3,5,7-tetranitro-1,3,5,7-tetrazocine (HMX) on the Integrated Risk Information System (IRIS)*. National Center for Environmental Assessment, Washington, DC. Available on the internet at: https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=311.
- USEPA. 1989. Bromomethane (CASRN 74–83–9). Integrated Risk Information System. Carcinogenicity assessment verification date March 1, 1989. U.S. Environmental Protection Agency, Office of Research and Development, Washington, DC.
- USEPA. 1990a. Integrated Risk Information System (IRIS) on 1,1-Dichloroethane. Available on the internet at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0409_summary.pdf.

- USEPA. 1990b. Integrated Risk Information System (IRIS) on Metolachlor. Available on the internet at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0074_summary.pdf.
- USEPA. 1992. Health Advisory for Hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX). In Roberts, WC and WR Hartley eds. *Drinking Water Health Advisory: Munitions*. Boca Raton FL: Lewis Publishers, pp 133–180.
- USEPA. 1993. Integrated Risk Information System (IRIS) Chemical Assessment Summary. Acetochlor; CASRN 34256–82–1. National Center for Environmental Assessment. September 1, 1993. Available on the internet at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0521_summary.pdf.
- USEPA. 1995a. Policy on Evaluating Health Risks to Children. October 20, 1995. Science Policy Council, Washington, DC. Available on the internet at: https://www.epa.gov/sites/production/files/2014-05/documents/1995_childrens_health_policy_statement.pdf; Cover memo at: https://www.epa.gov/sites/production/files/2014-05/documents/health_policy_cover_memo.pdf.
- USEPA. 1995b. *Reregistration Eligibility Decision (RED)—Metolachlor*. EPA 738–R–95–006. Office of Prevention, Pesticides and Toxic Substances. Available on the internet at: https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-108801_1-Dec-94.pdf.
- USEPA. 2004b. Cancer Assessment Document. Evaluation of the Carcinogenic Potential of Acetochlor (Fourth Evaluation). Final Report. Cancer Assessment Review Committee (CARC), Health Effects Division Office of Pesticide Programs. EPA–HQ–OPP–2005–0227–0016. Available on the internet at: <https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/121601/121601-2004-08-31a.pdf>.
- USEPA. 2005. *Guidelines for Carcinogen Risk Assessment*. EPA–630–P–03–001F. Available on the internet at: https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.
- USEPA. 2006a. *Provisional Peer Reviewed Toxicity Values for 1,1-Dichloroethane (CASRN 75–34–3)*. Superfund Health Risk Technical Support Center, National Center for Environmental Assessment, Office of Research and Development. 9–27–2006. Available on the internet at: https://hhprrtv.ornl.gov/issue_papers/Dichloroethane11.pdf.
- USEPA. 2006b. Acetochlor Revised HED Chapter of the Tolerance Reassessment Eligibility Decision (TRED) Document, EPA–HQ–OPPTS, PC Code: 121601, DP Barcode: D292336. Available on the internet at: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2005-0227-0024>.
- USEPA. 2006c. *Methyl Bromide: Phase 5 Health Effects Division (HED) Human Health Risk Assessment for Commodity Uses*. PC Code 053201, DP Barcode D304623. Office of Prevention, Pesticides and Toxic Substances.
- USEPA. 2006d. *Report of Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision (TRED) for Methyl Bromide, and Reregistration Eligibility Decision (RED) for Methyl Bromide's Commodity Uses*. Office of Prevention, Pesticides and Toxic Substances. EPA 738–R–06–026. Available on the internet at: https://archive.epa.gov/pesticides/reregistration/web/pdf/methyl_bromide_tred.pdf.
- USEPA. 2007a. Provisional Peer Reviewed Toxicity Values for Bromomethane (CASRN 74–83–9). Superfund Health Risk Technical Support Center, National Center for Environmental Assessment, Office of Research and Development, U.S. Environmental Protection Agency, Cincinnati, OH. https://hhprrtv.ornl.gov/issue_papers/Bromomethane.pdf.
- USEPA. 2007b. Benchmark dose software (BMDS) version 1.4.1c (last modified November 9, 2007).
- USEPA. 2008. *The Analysis of Occurrence Data from the First Unregulated Contaminant Monitoring Regulation (UCMR 1) in Support of Regulatory Determinations for the Second Drinking Water Contaminant Candidate List*. EPA 815–R–08–012. June 2008.
- USEPA. 2009. *Toxicological Review of Nitrobenzene (CAS No. 98–95–3) in Support of Summary Information on the Integrated Risk Information System (IRIS)*. National Center for Environmental Assessment, Washington, DC. EPA 635–R–08–004F.
- USEPA. 2011. *Exposure Factors Handbook 2011 Edition (Final Report)*. EPA 600–R–09–052F.
- USEPA. 2014. Announcement of Preliminary Regulatory Determinations for Contaminants on the Third Drinking Water Contaminant Candidate List. **Federal Register** 79 FR 62715, October 20, 2014.
- USEPA. 2015. *Occurrence Data from the Second Unregulated Contaminant Monitoring Regulation (UCMR 2)*. EPA 815–R15–013. December 2015.
- USEPA. 2016a. Drinking Water Contaminant Candidate List 4—Final. **Federal Register** 81 FR 81099, November 17, 2016.
- USEPA. 2016b. *Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS)*. EPA 822–R–16–004. Available on the internet at: https://www.epa.gov/sites/production/files/2016-05/documents/pfos_health_advisory_final_508.pdf.
- USEPA. 2016c. *Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)*. EPA 822–R–16–005. Available on the internet at: https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final_508.pdf.
- USEPA. 2016d. *Health Effects Support Document for Perfluorooctane Sulfonate (PFOS)*. EPA 822–R–16–002. Office of Water. Available on the internet at: https://www.epa.gov/sites/production/files/2016-05/documents/pfos_hesd_final_508.pdf.
- USEPA. 2016e. *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)*. Office of Water. EPA 822–R–16–003. Available on the internet at: https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_hesd_final_508.pdf.
- USEPA. 2016f. Announcement of Final Regulatory Determinations for Contaminants on the Third Drinking Water Contaminant Candidate List. **Federal Register** 81 FR 13, January 4, 2016.
- USEPA. 2018a. Reaffirmation of EPA's 1995 Policy on Evaluating Health Risks to Children. October 11, 2018. Available on the internet at: https://www.epa.gov/sites/production/files/2018-10/documents/childrens_health_policy_reaffirmation_memo.10.11.18.pdf.
- USEPA. 2018b. Basic Information on PFAS. Available on the internet at: <https://www.epa.gov/pfas/basic-information-pfas>.
- USEPA. 2018c. *Acetochlor Human Health Risk Assessment for Proposed New Use on Alfalfa and Related Animal Commodities*. Office of Chemical Safety and Pollution Prevention. April 4, 2018. Available on the internet at: <https://beta.regulations.gov/docket/EPA-HQ-OPP-2017-0235/document>.
- USEPA. 2018d. S-Metolachlor: Human Health Risk Assessment for (1) Establishment of Tolerances for New Uses on Chicory, Stevia and Swiss Chard; (2) Tolerance Translations from Table Beet Tops, Turnip Greens, and Radish Tops to Crop Group 2 (Leaves of Root and Tuber Vegetables), except Sugar Beets; (3) Tolerance Conversions (i) from Crop Subgroup 4B to Crop Subgroup 22B (Leaf Petiole Vegetable), (ii) from Crop Subgroup 5A to Crop Group 5–16 (Brassica, Head and Stem Vegetable) and (iii) from Crop Subgroup 5B to Crop Subgroup 4–16B (Brassica Leafy Greens); and (4) Tolerance Expansions of Representative Commodities to (i) Cottonseed Vegetable 20C, and (ii) Stalk and Stem Vegetable Subgroup 22A, except Kohlrabi. Human Health Risk Assessment. EPA–HQ–OPP–2017–0465. September.
- USEPA. 2018e. *Integrated Risk Information System (IRIS). Toxicological Review of Hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX)*. EPA 635–R–18–211Fa. Available on the internet at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0313tr.pdf.
- USEPA. 2019a. Occurrence Data from the Third Unregulated Contaminant Monitoring Rule (UCMR 3). EPA 815–R–19–007.
- USEPA. 2019b. EPA's Per- and Polyfluoroalkyl Substances Action Plan. EPA 823–R–18–004.
- USEPA. 2020a. Announcement of Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List. **Federal Register** 85 FR 14098, March 10, 2020.

- USEPA. 2020b. Drinking Water Treatability Database. <https://iaspub.epa.gov/tdb/pages/general/home.do>. Last updated March 2020.
- USEPA. 2020c. Final Risk Evaluations for 1,4-Dioxane. EPA Document # EPA-740-R1-8007. December 2020. <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-14-dioxane#riskevaluation>.
- USEPA. 2021a. *Final Regulatory Determination 4 Support Document*. EPA 815-R-21-001.
- USEPA. 2021b. *Responses to Public Comments on Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List*. EPA 815-R-21-002.
- Virgo, D.M. and A. Broadmeadow. 1988. SC-5676: Combined Oncogenicity and Toxicity Study in Dietary Administration to CD Rats for 104 Weeks. Life Science Research Ltd., Suffolk, England. Study No. 88/SUC017/0348. March 18, 1988. Unpublished report (as cited in USEPA, 2006b).
- Vogel, E.W. and M.J.M. Nivard. 1994. The subtlety of alkylating agents in reactions with biological macromolecules. *Mutat. Res.* 305: 13-32 (as cited in USEPA, 2007a).
- Wester, P.W. and R. Kroes, 1988. Forestomach carcinogens: pathology and relevance to man. *Toxicologic Pathology* 16(2): 165-71 (as cited in ATSDR, 1992).

Signing Statement

This document of the Environmental Protection Agency was signed on January 15, 2021, by Andrew Wheeler, Administrator, pursuant to the statutory requirements of the Safe Drinking Water Act, Section 1412(b). That document with the original signature and date is maintained by EPA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned EPA Official re-signs the document for publication, as an official document of the Environmental Protection Agency. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Jane Nishida,

Acting Administrator.

[FR Doc. 2021-04184 Filed 3-2-21; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042-8884-02; RTID 0648-XA714]

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; closure of the General category January fishery for 2021.

SUMMARY: NMFS closes the Atlantic bluefin tuna (BFT) General category fishery for the January subquota period. The intent of this closure is to prevent overharvest of the adjusted January subquota.

DATES: Effective 11:30 p.m., local time, February 27, 2021, through May 31, 2021.

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin, sarah.mclaughlin@noaa.gov, 978-281-9260, Nicholas Velseboer, nicholas.velseboer@noaa.gov, 978-675-2168, or Larry Redd, Jr., larry.redd@noaa.gov, 301-427-8503.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Atlantic Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006) and amendments, and in accordance with implementing regulations.

Under § 635.28(a)(1), NMFS files a closure notice with the Office of the Federal Register for publication when a BFT quota (or subquota) is reached or is projected to be reached. Retaining, possessing, or landing BFT under that quota category is prohibited on and after the effective date and time of a closure notice for that category, for the remainder of the fishing year, until the

opening of the subsequent quota period or until such date as specified.

The base quota for the General category is 555.7 mt. See § 635.27(a). Each of the General category time periods (January, June through August, September, October through November, and December) is allocated a subquota or portion of the annual General category quota. Although it is called the “January” subquota, the regulations allow the General category fishery under this quota to continue until the subquota is reached or March 31, whichever comes first. The baseline subquotas for each time period are as follows: 29.5 mt for January; 277.9 mt for June through August; 147.3 mt for September; 72.2 mt for October through November; and 28.9 mt for December. Any unused General category quota rolls forward from one time period to the next and is available for use in subsequent time periods within the fishing year. Effective January 1, 2021, NMFS transferred 19.5 mt of the 28.9-mt General category quota allocated for the December 2021 period to the January 2021 period, resulting in an adjusted subquota of 49 mt for the January period and a subquota of 9.4 mt for the December 2021 period (85 FR 83832, December 23, 2020). Effective February 8, 2021, NMFS transferred an additional 26 mt from the Reserve category to the General category, in the same notice as NMFS made the annual reallocation of Purse Seine category quota to the Reserve category, resulting in an adjusted subquota of 75 mt for the General category 2021 January subquota period and 168 mt for the Reserve category (86 FR 8717, February 9, 2021).

Closure of the January 2021 General Category Fishery

Based on the best available General category BFT Landings information (*i.e.*, 57.7 mt landed as of February 25, 2021), as well as average catch rates and anticipated fishing conditions, NMFS projects that the adjusted General category January 2021 subquota of 75 mt will be reached shortly, and that the General category fishery should be closed. Therefore, retaining, possessing, or landing large medium or giant BFT by persons aboard vessels permitted in the Atlantic Tunas General category and the Atlantic HMS Charter/Headboat category (while fishing commercially) must cease at 11:30 p.m. local time on February 27, 2021. The General category will reopen automatically on June 1, 2021, for the June through August 2021 subquota period. This action applies to those vessels permitted in the General category, as well as to those HMS Charter/Headboat permitted vessels

with a commercial sale endorsement when fishing commercially for BFT, and is taken consistent with the regulations at § 635.28(a)(1). The intent of this closure is to prevent overharvest of the available January subquota.

Fishermen may catch and release (or tag and release) BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. All BFT that are released must be handled in a manner that will maximize their survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the "Careful Catch and Release" brochure available at <https://www.fisheries.noaa.gov/resource/outreach-and-education/careful-catch-and-release-brochure/>.

Monitoring and Reporting

NMFS will continue to monitor the BFT fisheries closely. Dealers are required to submit landings reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustment, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement,

General and HMS Charter/Headboat category vessel owners are required to report the catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing hmspermits.noaa.gov, using the HMS Catch Reporting app, or calling (888) 872-8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional adjustments are necessary to ensure available subquotas are not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (978) 281-9260, or access hmspermits.noaa.gov, for updates on quota monitoring and inseason adjustments.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is consistent with regulations at 50 CFR part 635, which were issued pursuant to section 304(c) of the Magnuson-Stevens Act and the Atlantic Tunas Convention Act, and is exempt from review under Executive Order 12866.

The Assistant Administrator for NMFS finds that pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice of, and an opportunity for public comment on, for the following reasons: The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason retention limit adjustments and fishery closures to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. This fishery is currently underway and delaying this action would be contrary to the public interest as it could result in BFT landings exceeding the January 2021 subquota, which could result in the need to reduce quota for the General category later in the year and thus could affect later fishing opportunities. For all of the above reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: February 26, 2021.

Jennifer M. Wallace,

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

[FR Doc. 2021-04400 Filed 2-26-21; 4:15 pm]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 86, No. 40

Wednesday, March 3, 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 AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 149

[Docket No. APHIS–2020–0065]

RIN 0579–AE59

Elimination of the Voluntary Trichinae Certification Program

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to eliminate the Animal and Plant Health Inspection Service (APHIS) Voluntary Trichinae Certification Program and remove the regulations associated with the program. This action would also notify the public that APHIS will no longer maintain any activity associated with the program, such as training for qualified accredited veterinarians, on-farm audits, or any other administrative process associated with program maintenance and support. We are proposing to eliminate the program because it generates little producer participation. This action would allow APHIS to direct APHIS resources to areas of greater need.

DATES: We will consider all comments that we receive on or before May 3, 2021.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov. Enter APHIS–2020–0065 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0065, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at regulations.gov or in

our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. María Celia Antognoli, Swine Health Senior Staff Officer, Aquaculture, Swine, Equine and Poultry Health Center, Strategy and Policy, VS, APHIS, 2150 Centre Ave., Bldg. B, Fort Collins, CO 80526–8117; (970) 494–7304; celia.antognoli@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Trichinella are parasitic nematodes (roundworms) that are found in many warm-blooded carnivores and omnivores, including swine. There are eight known species of *Trichinella* nematodes: *Trichinella britovi*, *Trichinella murrelli*, *Trichinella nativa*, *Trichinella nelsoni*, *Trichinella papuae*, *Trichinella pseudospiralis*, *Trichinella spiralis*, and *Trichinella zimbabwensis*. Trichinae is a generic term that refers to all species of *Trichinella*.

In a final rule¹ published in the **Federal Register** on October 10, 2008 (73 FR 60463–60488; Docket No. APHIS–2006–0089), we established regulations for the Voluntary Trichinae Certification Program by adding 9 CFR part 149. These regulations provide for the certification of pork production sites that follow certain prescribed management practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella* spp. Participation in the program is voluntary. As stated in § 149.2, a producer's initial enrollment and continued participation in the Trichinae Certification Program requires that the producer adhere to all of the good production practices set out in the regulations, as confirmed by periodic site audits, and comply with other recordkeeping and program requirements provided in part 149.

Producer participation in this voluntary program has decreased since the program began. Only two producers re-enrolled in the past 3 years. The lack

of producer interest and involvement has become problematic for a number of reasons. Maintaining the program places demands on limited Animal and Plant Health Inspection Service (APHIS) funding and human resources that could be better directed elsewhere. In addition, the existence of a program that producers have little interest in has had trade implications. Trading partners have questioned our ability to certify freedom of trichinae in exported products, given that the vast majority of the products are not produced under the auspices of the Trichinae Certification Program.

We are therefore proposing to eliminate the program by removing part 149 from the regulations. Eliminating this program should benefit the swine industry by reducing possible confusion about the trichinae-free status of exported products. APHIS would also no longer incur the costs associated with program administration and payments to auditors.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Regulations.gov website (see **ADDRESSES** above for instructions for accessing Regulations.gov).

APHIS is proposing to eliminate the Voluntary Trichinae Certification Program and remove its associated regulations from title 9 of the Code of Federal Regulations.

Producer participation in the Voluntary Trichinae Certification program has decreased significantly since this voluntary program began in 2007. Only two producers with 23 audit sites re-enrolled in the past 3 years. Continuation of the voluntary program, given the lack of producer participation, is difficult to justify. Furthermore, a voluntary certification program that does not attract producer participation could negatively affect APHIS' and the pork industry's credibility, especially

¹ To view the final rule and supporting documents, go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2006-0089>.

during trade negotiations. Minimal program participation can lead trading partners to question APHIS' ability to certify exported products as trichinae-free, even though certification is not a requirement for U.S. pork exportation.

Preserving APHIS' credibility is crucial in supporting the U.S. pork industry and its exports, which have increased substantially in recent years. Since 2007, U.S. pork exports have more than doubled in value (110 percent increase) and in quantity (109 percent increase).

The Small Business Administration (SBA) small business size standard for hog and pig farming is annual revenue of not more than \$1 million. According to the 2017 Agricultural Census, 64,871 hog and pig farms sold over 235 million hogs and pigs with total sales of \$26.3 billion in 2017. Average annual sales per farm was 3,267 head valued at \$404,907, well below the SBA small-entity standard.

When the census data are divided into two categories—the largest producers, with 5,000 or more hogs and pigs sold, and the remaining farms—the prevalence of small-scale producers becomes clear. Farms with fewer than 5,000 hogs and pigs sold accounted for 57,084 farms (88 percent of the total). However, the number and value of hogs and pigs sold by these farms, 15,157,702 head valued at \$2.4 billion, represent only 6 percent and 9 percent, respectively, of total sales. The average number and value of hogs and pigs sold per farm in 2017 by these smaller farms was 266 head valued at \$42,078. Clearly, hog and pig farms are predominantly small.

Because the Voluntary Trichinae Certification Program did not progress beyond the pilot stage, the participating producers have not borne program costs.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) State and local laws and regulations will not be preempted; (2)

no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and will reduce those currently approved by the Office of Management and Budget under control number 0579–0323.

List of Subjects in 9 CFR Part 149

Animal diseases, Laboratories, Meat and meat products, Meat inspection, Reporting and recordkeeping requirements, Swine.

Accordingly, for the reasons stated in the preamble, and under the authority of 7 U.S.C. 8301 *et seq.*, the Animal and Plant Health Inspection Service is proposing to amend 9 CFR chapter I by removing part 149.

Done in Washington, DC, this 18th day of February, 2021.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–03772 Filed 3–2–21; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0126; Project Identifier MCAI–2020–00266–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH (AHD) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for Airbus Helicopters Deutschland GmbH (AHD) Model MBB–BK 117 D–2 helicopters. This proposed AD was prompted by a report of a broken Titanium (Ti) bolt. This proposed AD would require removing certain Ti-bolts from service and prohibit installing these Ti-bolts in a critical area. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by April 19, 2021.

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

- **Federal eRulemaking Portal:** Go to <https://www.regulations.gov>. Follow the instructions for submitting comments.

- **Fax:** (202) 493–2251.

- **Mail:** U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

- **Hand Delivery:** Deliver to Mail address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at <https://www.airbus.com/helicopters/services/technical-support.html>. You may view the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at <https://www.regulations.gov> by searching for and locating Docket No. FAA–2021–0126; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the European Union Aviation Safety Agency (EASA) AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Matt Fuller, AD Program Manager, General Aviation & Rotorcraft Unit, Airworthiness Products Section, Operational Safety Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email matthew.fuller@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include “Docket No. FAA–2021–0126; Project Identifier MCAI–2020–00266–R” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include

supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Matt Fuller, AD Program Manager, General Aviation & Rotorcraft Unit, Airworthiness Products Section, Operational Safety Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5110; email matthew.fuller@faa.gov. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD No. 2019-0258, dated October 18, 2019, to correct an unsafe condition for Airbus Helicopters Deutschland GmbH (AHD), formerly Eurocopter Deutschland GmbH, Model MBB-BK117 D-2 helicopters. EASA advises of a report of a broken Ti-bolt. Subsequent investigation revealed that an improper heat treatment process was accomplished on a batch of Ti-bolts, which can lead to hydrogen embrittlement. Hydrogen embrittlement can make high-strength bolts susceptible to stress corrosion, pitting, and failure.

EASA states that this condition, if not detected and corrected, could lead to

failure of an affected Ti-bolt installed in a critical location, possibly resulting in reduced control of the helicopter. Accordingly, the EASA AD requires a one-time inspection for Ti-bolt part number (P/N) EN3740-060022F marked with manufacturer monogram "D" or with an illegible manufacturer monogram installed on the aft connection of the tail rotor ball bearing control (ball bearing control) and, depending on findings, contacting AHD for corrective action. The EASA AD also prohibits the (re)installation of these Ti-bolts.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all known relevant information and determining that an unsafe condition is likely to exist or develop on other helicopters of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Airbus Helicopters Alert Service Bulletin (ASB) No. ASB MBB-BK117 D-2-00A-001, Revision 1, dated October 16, 2019 (ASB MBB-BK117 D-2-00A-001 Rev 1), which specifies replacing each Ti-bolt P/N EN3740-060022F that is marked with manufacturer monogram "D" or if the manufacturer monogram cannot be identified with an airworthy Ti-bolt in both locations of the aft connection of ball bearing control and both HF antenna bracket locations.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Proposed AD Requirements

This proposed AD would require removing any Ti-bolt P/N EN3740-060022F marked with manufacturer monogram "D" or with an illegible manufacturer monogram installed on the aft connection of the ball bearing control from service. This proposed AD would also prohibit installing an affected Ti-bolt on the aft connection of the ball bearing control of any helicopter.

Differences Between This Proposed AD and the EASA AD

The EASA AD applies to Model MBB-BK117 D-2 helicopters and requires inspecting for Ti-bolt P/N

EN3740-060022F marked with manufacturer monogram "D" or with an illegible manufacturer monogram installed on the aft connection of the ball bearing control. This proposed AD applies to Model MBB-BK 117 D-2 helicopters with a Ti-bolt P/N EN3740-060022F marked with manufacturer monogram "D" or with an illegible manufacturer monogram installed on the aft connection of the ball bearing control instead. The EASA AD requires contacting AHD for approved instructions if an affected Ti-bolt is found, whereas this proposed AD would require removing an affected Ti-bolt from service instead.

Costs of Compliance

The FAA estimates that this AD if adopted as proposed, would affect 29 helicopters of U.S. Registry. Labor rates are estimated at \$85 per work-hour. Based on these numbers, the FAA estimates that operators may incur the following costs in order to comply with this proposed AD.

Replacing a Ti-bolt would take about 2 work-hours and parts would cost about \$100 for an estimated cost of \$270 per Ti-bolt.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Helicopters Deutschland GmbH

(AHD): Docket No. FAA–2021–0126;

Project Identifier MCAI–2020–00266–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by April 19, 2021.

(b) Affected ADs

None.

(c) Applicability

This airworthiness directive (AD) applies to Airbus Helicopters Deutschland GmbH (AHD) Model MBB–BK 117 D–2 helicopters, certificated in any category, with a Titanium (Ti) bolt part number EN3740–060022F marked with manufacturer monogram “D” or with an illegible manufacturer monogram, installed on the aft connection of the tail rotor ball bearing control.

(d) Subject

Joint Aircraft System Component (JASC) Codes: 1430, Fasteners; and 6720, Tail Rotor Control System.

(e) Unsafe Condition

This AD defines the unsafe condition as a Ti-bolt with hydrogen embrittlement. This condition could result in failure of the tail rotor ball bearing control Ti-bolt and subsequent loss of tail rotor control.

(f) Compliance

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

(g) Required Actions

(1) Within 50 hours time-in-service or 3 months, whichever occurs first, remove any Ti-bolt identified in paragraph (c) of this AD, located on the aft connection of the tail rotor ball bearing rod end (item 5) and at the input lever (item 2) as shown in Figure 1 to Airbus Helicopters Alert Service Bulletin (ASB) No. ASB MBB–BK117 D–2–00A–001, Revision 1, dated October 16, 2019, from service.

(2) As of the effective date of this AD, do not install a Ti-bolt identified in paragraph (c) of this AD on the aft connection of the tail rotor ball bearing control of any helicopter.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Strategic Policy Rotorcraft Section, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (i)(1) of this AD. Information may be emailed to: 9-ASW-FTW-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(i) Related Information

(1) For more information about this AD, contact Matt Fuller, AD Program Manager, General Aviation & Rotorcraft Unit, Airworthiness Products Section, Operational Safety Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email matthew.fuller@faa.gov.

(2) For service information identified in this AD, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at <https://www.airbus.com/helicopters/services/technical-support.html>. You may view the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(3) The subject of this AD is addressed in European Union Aviation Safety Agency (EASA) AD No. 2019–0258, dated October 18, 2019. You may view the EASA AD on the internet at <https://www.regulations.gov> in the AD Docket.

Issued on February 22, 2021.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives Compliance & Airworthiness Directive, Aircraft Certification Service.

[FR Doc. 2021–03955 Filed 3–2–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–476]

Schedules of Controlled Substances: Placement of 10 Specific Fentanyl-Related Substances in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing *N*-(1-(2-fluorophenethyl)piperidin-4-yl)-*N*-(2-fluorophenyl)propionamide (2'-fluoro *ortho*-fluorofentanyl), *N*-(1-(4-methylphenethyl)piperidin-4-yl)-*N*-phenylacetamide (4'-methyl acetyl fentanyl), *N*-(1-phenethylpiperidin-4-yl)-*N*,3-diphenylpropanamide (β'-phenyl fentanyl; 3-phenylpropanoyl fentanyl), *N*-phenyl-*N*-(1-(2-phenylpropyl)piperidin-4-yl)propionamide (β-methyl fentanyl), *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide (*ortho*-fluorobutyl fentanyl; 2-fluorobutyl fentanyl), *N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl acetylfentanyl; 2-methyl acetylfentanyl), 2-methoxy-*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (*ortho*-methyl methoxyacetylfentanyl), *N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide (*para*-methylfentanyl; 4-methylfentanyl), *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbenzamide (phenyl fentanyl; benzoyl fentanyl), *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide (thiofuran fentanyl), including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, in schedule I of the Controlled Substances Act. These ten specific substances fall within the definition of fentanyl-related substances set forth in the February 6, 2018, temporary scheduling order. Through the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. If finalized, this action would make permanent the existing regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse

distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β '-phenyl fentanyl, β -methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl.

DATES: Comments must be submitted electronically or postmarked on or before April 2, 2021.

Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before April 2, 2021.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-476" on all electronic and written correspondence, including any attachments.

- *Electronic comments:* Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

- *Hearing requests:* Interested persons may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. All

requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT:

Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3249

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively

redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at <http://www.regulations.gov> for easy reference.

Request for Hearing or Waiver of Participation in a Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act, 5 U.S.C. 551-559. 21 CFR 1308.41-1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for hearing or notices of intent to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(a) or (b), and include a statement of interest in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person's position on the matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

All requests for a hearing and waivers of participation must be sent to DEA using the address information provided above.

Legal Authority

The Controlled Substances Act (CSA) provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the Assistant Secretary for Health of U.S. Department of Health and Human Services (HHS) (Assistant Secretary) and an evaluation of all other relevant data by DEA. If finalized, this action would make permanent the existing temporary regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β '-phenyl fentanyl, β -methyl fentanyl, *ortho*-fluorobutyryl

fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl.

Background

On February 6, 2018, pursuant to 21 U.S.C. 811(h)(1), the then-Acting Administrator of DEA published an order in the **Federal Register** (83 FR 5188) temporarily placing fentanyl-related substances, as defined in that order, in schedule I of the CSA upon finding that these substances pose an imminent hazard to the public safety. The 10 substances named in this proposed rule (2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl) meet the existing definition of fentanyl-related substances. On April 19, 2019, DEA specifically identified four of these 10 substances (2'-fluoro *ortho*-fluorofentanyl, β' -phenyl fentanyl, *ortho*-methyl acetylfentanyl, and thiofuranyl fentanyl) as meeting the definition of fentanyl-related substances. 84 FR 16397. Although DEA did not issue a **Federal Register** publication to identify the other six substances, the February 6, 2018, temporary scheduling order emphasized that, even still, a substance is controlled by virtue of the order if it falls within the definition of fentanyl-related substances. 83 FR 5188, 5189. As discussed below in Factor 3, all 10 substances meet the definition as they are not otherwise controlled in any other schedule (*i.e.*, not included under another Administration Controlled Substance Code Number) and are structurally related to fentanyl by one or more of the five modifications listed under the definition.

That temporary order was effective upon the date of publication. Pursuant to 21 U.S.C. 811(h)(2), the temporary control of fentanyl-related substances, a class of substances as defined in the order, as well as the 10 specific substances already covered by that order, was set to expire on February 6, 2020. However, as explained in DEA's April 10, 2020, correcting amendment (85 FR 20155), Congress overrode and extended that expiration date until May 6, 2021, by enacting on February 6, 2020 the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (Pub. L. 116-114, sec. 2, 134 Stat. 103). By operation of law, the temporary control of fentanyl-related substances, which

includes these 10 covered substances, will remain in effect until May 6, 2021, unless DEA permanently places them in schedule I prior to May 6, 2021. As discussed in the above Legal Authority section, proceedings under 21 U.S.C. 811(a) may be initiated by the Administrator of DEA on his own motion.

The Acting Administrator, on his own motion, is initiating proceedings to permanently schedule the following 10 fentanyl-related substances: 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β' -phenyl fentanyl, β -methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. DEA gathered the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for these 10 fentanyl-related substances, as well as for six other fentanyl-related substances (benzodioxole fentanyl, crotonyl fentanyl, fentanyl carbamate, *ortho*-fluoro isobutyryl fentanyl, *ortho*-fluoroacryl fentanyl, and *para*-fluoro furanyl fentanyl). On April 3, and October 2, 2019, the then-Acting Administrator submitted this data to the Assistant Secretary, and requested that HHS provide DEA with a scientific and medical evaluation and a scheduling recommendation for the 16 fentanyl-related substances named above, in accordance with 21 U.S.C. 811(b) and (c).

Upon evaluating the scientific and medical evidence, on July 2, 2020, the Assistant Secretary submitted to the Acting Administrator, HHS's scientific and medical evaluation and scheduling recommendation for 11 of the 16 fentanyl-related substances, including the 10 named substances in this proposed rule as well as crotonyl fentanyl.¹ Upon receipt of the scientific and medical evaluation and scheduling recommendation from HHS, DEA reviewed these documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of the 10 substances in accordance with 21 U.S.C. 811(c). On October 2, 2020, DEA issued a final order (85 FR 62215) for crotonyl fentanyl to remain as a schedule I substance under the CSA in order to meet the United States' obligations

¹ HHS' scientific and medical evaluation for the other five fentanyl-related substances (benzodioxole fentanyl, fentanyl carbamate, *ortho*-fluoro isobutyryl fentanyl, *ortho*-fluoroacryl fentanyl, and *para*-fluoro furanyl fentanyl) is ongoing. DEA will not further discuss these five substances in this proposed rule.

under the 1961 Single Convention on Narcotic Drugs (Single Convention), March 30, 1961, 18 U.S.T. 1407, 570 U.N.T.S. 151, as amended.² As such, crotonyl fentanyl will not be discussed further in this scheduling action.

Proposed Determination To Permanently Schedule 2'-Fluoro *ortho*-Fluorofentanyl, 4'-Methyl Acetyl Fentanyl, β -Methyl Fentanyl, β' -Phenyl Fentanyl, *ortho*-Fluorobutyryl fentanyl, *ortho*-Methyl Acetylfentanyl, *ortho*-Methyl Methoxyacetyl Fentanyl, *para*-Methylfentanyl, Phenyl Fentanyl, and Thiofuranyl Fentanyl

As discussed in the background section, the Acting Administrator is initiating proceedings to permanently add 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl to schedule I. DEA has reviewed the scientific and medical evaluation and scheduling recommendation from HHS, and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of these 10 substances. Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its proposed scheduling action. Please note that both the DEA and HHS 8-Factor analyses and the Assistant Secretary's July 2, 2020, letter are available in their entirety under the tab "Supporting Documents" of the public docket for this action at <http://www.regulations.gov> under Docket Number "DEA-476."

1. *The Drug's Actual or Relative Potential for Abuse:* The term "abuse" is not defined in the CSA. However, the legislative history of the CSA suggests that DEA consider the following criteria when determining whether a particular drug or substance has a potential for abuse:³

(a) *There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a*

² In November 2019, the Director-General of the World Health Organization recommended to the Secretary-General that crotonyl fentanyl be placed in Schedule I of the Single Convention. On May 7, 2020, the Secretary-General advised the Secretary of State of the United States, by letter, that during its 63rd session in March 2020, the Commission on Narcotic Drugs voted to place crotonyl fentanyl in Schedule I of the Single Convention (CND Mar/63/2).

³ Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970); reprinted in 1970 U.S.C.A.N. 4566, 4603.

hazard to their health or to the safety of other individuals or to the community; or

(b) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

(c) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

(d) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

The abuse potential of 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl is associated with their pharmacological similarity to other schedule I and II mu-opioid receptor agonist substances, which have a high potential for abuse. Similar to morphine and fentanyl, these 10 substances have been shown to bind and act as mu-opioid receptor agonists.

These 10 substances have no approved medical use in the United States and have been encountered on the illicit drug market. The use of some fentanyl-related substances has been associated with adverse health outcomes, including death. The appearance of several substances structurally related to fentanyl in the illicit drug market has resulted in a significant increase in drug overdose deaths in the United States. According to the Centers for Disease Control and Prevention (CDC) overdose death data for 2018, there continues to be an increase in the number of deaths related to synthetic opioids. Opioids were involved in about 70 percent of all drug-involved overdose deaths in 2018. Further, CDC reports demonstrate that the increase in synthetic opioid overdose deaths are largely attributed to an increase in the supply of illicitly manufactured fentanyl and substances structurally related to fentanyl. Because 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are not Food

and Drug Administration (FDA)-approved drug products, a practitioner may not legally prescribe them, and these substances cannot be dispensed to an individual. Therefore, the use of 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl is without medical advice, and accordingly leads to the conclusion that these 10 substances are abused for their opioidergic properties.

There are no legitimate drug channels for 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl as marketed FDA-approved drug products, but these substances are available for purchase from legitimate chemical companies for research purposes. However, despite the limited legitimate research use of these 10 substances, reports from public health and law enforcement data indicate that all 10 substances are being abused and taken in amounts sufficient to create a hazard to an individual's health. Data from forensic databases can be used as an indicator of illicit activity with drugs and abuse⁴ within the United States. According to the National Forensic Laboratory Information System (NFLIS),⁵ which collects and analyzes drug exhibits submitted to Federal, State, and local forensic laboratories, there were 235 total reports of seven of the 10 substances (4'-methyl acetyl fentanyl, β -methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl) between 2017 and 2020 (queried on July 16, 2020). In 2017 and 2018, U.S. Customs and Border Protection (CBP) reported that two other of the 10 substances (2'-fluoro *ortho*-fluorofentanyl and β' -phenyl fentanyl) have been positively identified in seized drugs, respectively. In 2018, *ortho*-methyl methoxyacetyl fentanyl was

positively identified in an exhibit submitted to NMS laboratories for analysis by the Department of Homeland Security. Consequently, the positive identification of the 10 substances in law enforcement encounters indicates that these substances are being abused, and thus pose safety hazards to the health of users.

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are pharmacologically similar to other schedule I and schedule II mu-opioid receptor agonist substances. The abuse potential (assessed by drug discriminative studies) of 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl show that these substances share discriminative stimulus effects similar to fentanyl and morphine. Similar to schedule I and II opioid analgesics, these 10 substances bind to and activate the mu-opioid receptor. Additionally, behavioral studies in animals demonstrate these 10 substances produce analgesic effects similar to fentanyl and morphine. Pretreatment with naltrexone, an opioid antagonist, attenuated analgesic effect of these 10 substances, as well as fentanyl and morphine. These data indicate that the 10 substances are mu-opioid receptor agonists with effects on the central nervous system. Data from drug discrimination studies showed that these 10 substances share discriminative stimulus effects similar to those of morphine. Thus, it is concluded from *in vitro* and *in vivo* pharmacological studies that the effects of the 10 substances are similar to that of fentanyl and morphine and are mediated by mu-opioid receptor agonism.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* 2'-Fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are synthetic opioids of the 4-anilidopiperidine structural class, which includes fentanyl. As defined in the February 6,

⁴ While law enforcement data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See 76 FR 77330, 77332, Dec. 12, 2011.

⁵ NFLIS is a DEA program and a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States. The NFLIS database also contains Federal data from U.S. Customs and Border Protection (CBP). NFLIS only includes drug chemistry results from completed analyses.

2018, temporary order, fentanyl-related substances include any substance not otherwise controlled in any schedule (*i.e.*, not included under any other Administration Controlled Substance Code Number) that is structurally related to fentanyl by one or more of the following modifications:

(A) Replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

(B) substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxyl, halo, haloalkyl, amino or nitro groups;

(C) substitution in or on the piperidine ring with alkyl, alkenyl,

alkoxy, ester, ether, hydroxyl, halo, haloalkyl, amino or nitro groups;

(D) replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; and/or

(E) replacement of the *N*-propionyl group by another acyl group.

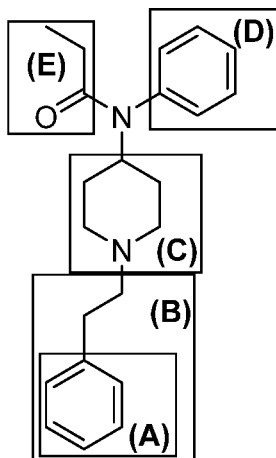


Figure 1: Regions of the chemical structure of fentanyl described in the definition of a fentanyl-related substance

According to the February 6, 2018, temporary scheduling order, the existence of a substance with any one, or any combination, of above-mentioned modifications (see Figure 1) would meet the structural requirements of the definition of fentanyl-related substances. The present 10 substances fall within the definition of fentanyl-related substances by the following modifications:

1. 2'-Fluoro *ortho*-fluorofentanyl: Substitution on the phenethyl group with a halo group and substitution on the aniline ring (meets definition for modifications B and D);

2. 4'-methyl acetyl fentanyl: Substitution on the phenethyl group with an alkyl group and replacement of the *N*-propionyl group by another acyl group (meets definition for modifications B and E);

3. β -methyl fentanyl: Substitution on the phenethyl group with an alkyl group (meets definition for modification B);

4. β' -phenyl fentanyl: Replacement of the *N*-propionyl group by another acyl group (meets definition for modification E);

5. *ortho*-fluorobutyryl fentanyl: Substitution on the aniline ring and replacement of the *N*-propionyl group

with another acyl group (meets definition for modifications D and E);

6. *ortho*-methyl acetylfentanyl: Substitution on the aniline ring and replacement of the *N*-propionyl group with another acyl group (meets definition for modifications D and E);

7. *ortho*-methyl methoxyacetylfentanyl: Substitution on the aniline ring and replacement of the *N*-propionyl group with another acyl group (meets definition for modifications D and E);

8. *para*-methylfentanyl: Substitution on the aniline ring (meets definition for modification D);

9. phenyl fentanyl: Replacement of the *N*-propionyl group by another acyl group (meets definition for modification E); and

10. thiofuranyl fentanyl: Replacement of the *N*-propionyl group by another acyl group (meets definition for modification E).

No study has been undertaken to evaluate the efficacy, toxicology, and safety of the 10 substances in humans. It can be inferred from data obtained from animal studies that these 10 substances have sufficient distribution to the brain to produce depressant effects similar to that of other mu-opioid

receptor agonists such as fentanyl. Data from *in vitro* receptor binding studies show that these 10 substances, similar to fentanyl, display high selectivity for the mu-opioid receptor over other opioid receptor subtypes.

There are no FDA-approved marketing applications for a drug product containing 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl for any therapeutic indication in the United States. Moreover, there are no clinical studies or petitions which have claimed an accepted medical use in the United States for these 10 substances.

4. *Its History and Current Pattern of Abuse*: 2'-Fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, like other substances structurally related to fentanyl, are disguised as a "legal"

alternative to fentanyl. Between 2017 and 2020, law enforcement officials in the United States encountered these 10 substances.

5. *The Scope, Duration, and Significance of Abuse:* 2'-Fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, similar to other substances structurally related to fentanyl, are often used as recreational drugs. The recreational use of these 10 substances and other fentanyl-related substances continues to be of significant concern as the United States currently is in the midst of an opioid epidemic. These substances are distributed to users, often with unpredictable outcomes. Because users of these fentanyl-related substances and their associated drug products are likely to obtain these substances through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to abusers. Evidence that these 10 substances are being abused and trafficked is confirmed by law enforcement encounters. NFLIS contained 235 reports of 4'-methyl acetyl fentanyl, β -methyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl from Federal, State, and local forensic laboratories between 2017 and 2020. In 2017 and 2018, CBP reported that 2'-fluoro *ortho*-fluorofentanyl and β' -phenyl fentanyl have been positively identified in seized drugs, respectively. In 2018, *ortho*-methyl methoxyacetyl fentanyl was positively identified in an exhibit submitted to NMS laboratories for analysis by the Department of Homeland Security.

6. *What, if Any, Risk There Is to the Public Health:* The increase in opioid overdose deaths in the United States has been exacerbated by the availability of potent synthetic opioids such as fentanyl and structurally related substances in the illicit drug market. These substances have a history of being trafficked as replacements for heroin and other synthetic opioids. Increasingly, law enforcement has encountered fentanyl and substances structurally related to fentanyl in counterfeit prescription opioids, heroin, and other street drugs such as cocaine, methamphetamine, and synthetic cannabinoids. Fentanyl is a potent synthetic opioid that is primarily prescribed for acute and chronic pain

and is approximately 100 times more potent than morphine. As such, fentanyl has a high risk of abuse, dependence and overdose that can lead to death. Because fentanyl-related substances, as defined in the February 6, 2018, temporary order, have similar chemical structure to fentanyl, these substances are expected to have similar biological effects. In *in vitro* and *in vivo* studies, 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl produced pharmacological effects similar to fentanyl. Thus, these 10 substances pose the same qualitative public health risks as heroin, fentanyl, and other mu-opioid receptor agonists.

According to a CDC report, from 2013 to 2017, opioid-related overdose deaths in the United States increased 90 percent from 25,052 to 47,600. The increase in the number of opioid-related deaths was primarily driven by illicitly manufactured fentanyl.⁶ According to CDC 2018 provisional data, there were 68,500 drug overdose fatalities; of those, 47,600 (~69 percent) involved an opioid. The use of some fentanyl-related substances has been associated with adverse health outcomes, including death.

7. *Its Psychic or Physiological Dependence Liability:* There are no pre-clinical and clinical studies that have evaluated the dependence potential of 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. These 10 substances are mu-opioid receptor agonists, and discontinuation of the use of mu-opioid receptor agonists such as fentanyl and morphine is known to cause withdrawal indicative of physical dependence. Opioid withdrawal includes nausea and vomiting, depression, agitation, anxiety, craving, sweats, hypertension, diarrhea, and fever.

8. *Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA:* 2'-

⁶ If evidence of prescription or illicit use was not available, fentanyl was categorized as illicitly-manufactured fentanyl ("IMF") because the vast majority of fentanyl overdose deaths involve IMF. Gladden RM, O'Donnell J, Mattson CL, Seth P. Changes in Opioid-Involved Overdose Deaths by Opioid Type and Presence of Benzodiazepines, Cocaine, and Methamphetamine—25 States, July–December 2017 to January–June 2018. *MMWR Morb Mortal Wkly Rep.* 30; 68(34):737–744.

Fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are not considered immediate precursors of any controlled substance of the CSA as defined by 21 U.S.C. 802(23).

Conclusion: After considering the scientific and medical evaluation conducted by HHS, HHS's scheduling recommendation, and DEA's own eight-factor analysis, DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. As such, DEA hereby proposes to permanently schedule 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl in schedule I of the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all other available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

(1) 2'-Fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have a high potential for abuse.

According to HHS, 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, similar to fentanyl, are mu-opioid receptor agonists. These

substances have analgesic effects, and these effects are mediated by mu-opioid receptor agonism. HHS states that substances that produce mu-opioid receptor agonist effects in the central nervous system (e.g., morphine and fentanyl) are considered as having a high potential for abuse. Data obtained from drug discrimination studies indicate that 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl fully substituted for the discriminative stimulus effects of morphine.

(2) 2'-Fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have no currently accepted medical use in treatment in the United States.

According to HHS, there are no FDA-approved new drug applications for 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl in the United States. There are no known therapeutical applications for these fentanyl-related substances and thus they have no currently accepted medical use in the United States.⁷

(3) There is a lack of accepted safety for use of 2'-fluoro *ortho*-fluorofentanyl,

4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl under medical supervision.

Because 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have no FDA-approved medical use and have not been thoroughly investigated as new drugs, their safety for use under medical supervision is undetermined. Thus, there is a lack of accepted safety for use of 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl under medical supervision.

Based on these findings, the Acting Administrator of DEA concludes that 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers warrant continued control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for handling 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl.

If this rule is finalized as proposed, 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl would continue⁸ to be subject to the CSA's

schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importation, exportation, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, or who desires to handle 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl is required to be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Security.* 2'-Fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71–1301.93. Non-practitioners handling 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl also must comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

⁷ Although there is no evidence suggesting that 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by the FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated:

- i. The drug's chemistry must be known and reproducible;
- ii. there must be adequate safety studies;
- iii. there must be adequate and well-controlled studies proving efficacy;
- iv. the drug must be accepted by qualified experts; and
- v. the scientific evidence must be widely available.

57 FR 10499 (1992), *pet. for rev. denied*, *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

⁸ 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, are covered by the February 6, 2018, temporary scheduling order, and are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 83 FR 5188.

4. *Quota.* Only registered manufacturers are permitted to manufacture 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person registered with DEA to handle 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl must have an initial inventory of all stocks of controlled substances (including these substances) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl) on hand every two years pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant is required to maintain records and submit reports with respect to 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl is required to comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures done "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. On February 6, 2018, DEA published an order to temporarily place fentanyl-related substances, as defined in the order, in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl have already established and implemented the systems and processes required to handle these substances which meet the definition of fentanyl-related substances.

There are currently 57 registrations authorized to handle the fentanyl-related substances as a class, which include 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 57 registrations represent 51 entities, of which eight are small entities. Therefore, DEA estimates eight small entities are affected by this proposed rule.

A review of the 57 registrations indicates that all entities that currently handle fentanyl-related substances, including 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl

methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl, also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle 2'-fluoro *ortho*-fluorofentanyl, 4'-methyl acetyl fentanyl, β -methyl fentanyl, β' -phenyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-methyl acetylfentanyl, *ortho*-methyl methoxyacetyl fentanyl, *para*-methylfentanyl, phenyl fentanyl, and thiofuranyl fentanyl. Therefore, DEA anticipates that this proposed rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the eight affected small entities. Therefore, DEA has concluded that this proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any 1 year" Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11:

■ a. Redesignate paragraph (75) as paragraph (b)(84);

■ b. Add paragraph (b)(83);

■ c. Redesignate paragraphs (b)(65) through (71) as paragraphs (b)(76) through (82);

■ d. Add a new paragraph (b)(75);

■ e. Redesignate paragraphs (b)(60) through (64) as paragraphs (b)(70) through (74);

■ f. Add a new paragraph (69);

■ g. Redesignate paragraphs (b)(56) through (59) as paragraphs (b)(65) through (68);

■ h. Add a new paragraph (64);

■ i. Redesignate paragraph (b)(55) as paragraph (b)(63);

■ j. Add new paragraphs (b)(61) and (62);

■ k. Redesignate paragraphs (b)(45) through (54) as paragraphs (b)(51) through (60);

■ l. Add new paragraph (b)(50);

■ m. Redesignate paragraphs (b)(37) through (44) as paragraphs (b)(42) through (49);

■ n. Add a new paragraph (b)(41);

■ o. Redesignate paragraph (b)(36) as paragraph (b)(40);

■ p. Add a reserved paragraph (b)(39);

■ q. Redesignate paragraphs (b)(22) through (35) as paragraphs (b)(25) through (38);

■ r. Add a reserved paragraph (b)(24);

■ s. Redesignate paragraphs (b)(17) through (21) as paragraphs (b)(19) through (23); and

■ t. Add new paragraphs (b)(17) and (18).

The additions to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(17) Beta-methyl fentanyl (<i>N</i> -phenyl- <i>N</i> -(1-(2-phenylpropyl)piperidin-4-yl)propionamide; other name: β -methyl fentanyl)	9856
(18) Beta'-phenyl fentanyl (<i>N</i> -(1-phenethylpiperidin-4-yl)- <i>N</i> ,3-diphenylpropanamide; other names: β' -phenyl fentanyl; 3-phenylpropanoyl fentanyl)	9842
* * * * *	
(41) 2'-Fluoro <i>ortho</i> -fluorofentanyl (<i>N</i> -(1-(2-fluorophenethyl)piperidin-4-yl)- <i>N</i> -(2-fluorophenyl)propionamide; other name: 2'-fluoro 2-fluorofentanyl)	9829
* * * * *	
(50) 4'-Methyl acetyl fentanyl (<i>N</i> -(1-(4-methylphenethyl)piperidin-4-yl)- <i>N</i> -phenylacetamide)	9819
* * * * *	
(61) <i>ortho</i> -Fluorobutyryl fentanyl (<i>N</i> -(2-fluorophenyl)- <i>N</i> -(1-phenethylpiperidin-4-yl)butyramide; other name: 2-fluorobutyryl fentanyl)	9846
(62) <i>ortho</i> -Methyl acetylfentanyl (<i>N</i> -(2-methylphenyl)- <i>N</i> -(1-phenethylpiperidin-4-yl)acetamide; other name: 2-methyl acetylfentanyl)	9848
* * * * *	
(64) <i>ortho</i> -Methyl methoxyacetyl fentanyl (2-methoxy- <i>N</i> -(2-methylphenyl)- <i>N</i> -(1-phenethylpiperidin-4-yl)acetamide; other name: 2-methyl methoxyacetyl fentanyl)	9820
* * * * *	
(69) <i>para</i> -Methylfentanyl (<i>N</i> -(4-methylphenyl)- <i>N</i> -(1-phenethylpiperidin-4-yl)propionamide; other name: 4-methylfentanyl)	9817
* * * * *	
(75) Phenyl fentanyl (<i>N</i> -(1-phenethylpiperidin-4-yl)- <i>N</i> -phenylbenzamide; other name: benzoyl fentanyl)	9841
* * * * *	
(83) Thiofuranyl fentanyl (<i>N</i> -(1-phenethylpiperidin-4-yl)- <i>N</i> -phenylthiophene-2-carboxamide; other names: 2-thiofuranyl fentanyl; thiophene fentanyl)	9839

* * * * *

D. Christopher Evans,
Acting Administrator.

[FR Doc. 2021-04214 Filed 3-2-21; 8:45 am]

BILLING CODE 4410-09-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R04-OAR-2020-0129; FRL-10020-85-Region 4]

Air Plan Approval; AL; NO_x SIP Call and Removal of CAIR

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Alabama through a letter dated February 27, 2020, to add regulations maintaining compliance with the State's Nitrogen Oxide (NO_x) SIP Call obligations for large non-electricity generating units (non-EGUs), to repeal the State's previously sunsetted NO_x Budget Trading Program regulations, and to repeal the State's Clean Air Interstate Rule (CAIR) regulations. EPA is also proposing to conditionally approve into the SIP state regulations that establish monitoring and reporting requirements for units subject to the NO_x SIP Call, including alternative monitoring options for certain sources for NO_x SIP Call purposes. In addition, EPA is proposing to make ministerial changes to reflect the State's renumbering of an existing regulation for "New Combustion Sources."

DATES: Comments must be received on or before April 2, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2020-0129 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:

Steven Scofield, 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) 562-9034. Mr. Scofield can also be reached via electronic mail at scofield.steve@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under Clean Air Act (CAA or Act) section 110(a)(2)(D)(i)(I), also called the good neighbor provision, states are required to address the interstate transport of air pollution. Specifically, the good neighbor provision requires that each state's implementation plan contain adequate provisions to prohibit air pollutant emissions from within the state that will significantly contribute to nonattainment of the national ambient air quality standards (NAAQS), or that will interfere with maintenance of the NAAQS, in any other state.

In October 1998 (63 FR 57356), EPA finalized the "Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone" (NO_x SIP Call). The NO_x SIP Call required eastern states, including Alabama, to submit SIPs that prohibit excessive emissions of ozone season NO_x by implementing statewide emissions budgets.¹ The NO_x SIP Call addressed the good neighbor provision for the 1979 ozone NAAQS and was designed to mitigate the impact of transported NO_x emissions, one of the precursors of ozone.² EPA developed the NO_x Budget Trading Program, an allowance trading program that states could adopt to meet their obligations under the NO_x SIP Call. This trading program allowed the following sources to participate in a regional cap and trade

program: Generally EGUs with capacity greater than 25 megawatts (MW); and large industrial non-EGUs, such as boilers and combustion turbines, with a rated heat input greater than 250 million British thermal units per hour (MMBtu/hr). The NO_x SIP Call also identified potential reductions from cement kilns and stationary internal combustion engines.

To comply with the NO_x SIP Call requirements, in 2001, the Alabama Department of Environmental Management (ADEM) submitted a revision to add new rule sections to the SIP-approved version of Alabama Administrative Code Chapter 335-3-1, General Provisions, and Chapter 335-3-8, Control of Nitrogen Oxides Emissions. EPA approved the revision as compliant with Phase I of the NO_x SIP Call in 2001. *See* 66 FR 36919 (July 16, 2001). The approved revision required EGUs and large non-EGUs in the State to participate in the NO_x Budget Trading Program beginning in 2004. In 2005, Alabama submitted, and EPA approved, a SIP revision to address additional emissions reductions required for the NO_x SIP Call under Phase II. *See* 70 FR 76694 (Dec. 28, 2005).

In 2005, EPA published CAIR, which required several eastern states, including Alabama, to submit SIPs that prohibited emissions consistent with revised ozone season (and annual) NO_x budgets. *See* 70 FR 25162 (May 12, 2005); *see also* 71 FR 25328 (April 28, 2006). CAIR addressed the good neighbor provision for the 1997 ozone NAAQS and 1997 fine particulate matter (PM_{2.5}) NAAQS and was designed to mitigate the impact of transported NO_x emissions with respect to ozone and PM_{2.5}. CAIR established several trading programs that EPA implemented through federal implementation plans (FIPs) for EGUs greater than 25 MW in each affected state, but not large non-EGUs; states could submit SIPs to replace the FIPs that achieved the required emission reductions from EGUs and/or other types of sources.³ When the CAIR trading program for ozone season NO_x was implemented beginning in 2009, EPA discontinued administration of the NO_x Budget Trading Program; however, the requirements of the NO_x SIP Call continued to apply.

On October 1, 2007 (72 FR 55659), EPA approved revisions to Alabama's SIP that incorporated requirements for CAIR. Consistent with CAIR's

¹ *See* 63 FR 57356 (October 27, 1998).

² As originally promulgated, the NO_x SIP Call also addressed good neighbor obligations under the 1997 8-hour ozone NAAQS, but EPA subsequently stayed and later rescinded the rule's provisions with respect to that standard. *See* 65 FR 56245 (September 18, 2000); 84 FR 8422 (March 8, 2019).

³ CAIR had separate trading programs for annual sulfur dioxide emissions, seasonal NO_x emissions, and annual NO_x emissions.

requirements, EPA approved a SIP revision in which Alabama regulations: (1) Sunset its NO_x Budget Trading Program requirements, and (2) incorporated CAIR annual and ozone season NO_x state trading programs. *See* 72 FR 55659. Participation of EGUs in the CAIR ozone season NO_x trading program addressed the State's obligation under the NO_x SIP Call for those units, and Alabama also chose to require non-EGUs subject to the NO_x SIP Call to participate in the same CAIR trading program. In this manner, Alabama's CAIR rules incorporated into the SIP addressed the State's obligations under the NO_x SIP Call with respect to both EGUs and non-EGUs.

The United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) initially vacated CAIR in 2008, but ultimately remanded the rule to EPA without vacatur to preserve the environmental benefits provided by CAIR. *See North Carolina v. EPA*, 531 F.3d 896, *modified on rehearing*, 550 F.3d 1176 (D.C. Cir. 2008). The ruling allowed CAIR to remain in effect temporarily until a replacement rule consistent with the court's opinion was developed. While EPA worked on developing a replacement rule, the CAIR program continued to be implemented with the NO_x annual and ozone season trading programs beginning in 2009 and the SO₂ annual trading program beginning in 2010.

Following the D.C. Circuit's remand of CAIR, EPA promulgated the Cross-State Air Pollution Rule (CSAPR) to replace CAIR and address good neighbor obligations for the 1997 ozone NAAQS, the 1997 PM_{2.5} NAAQS, and the 2006 PM_{2.5} NAAQS. *See* 76 FR 48208 (August 8, 2011). Through FIPs, CSAPR required EGUs in eastern states, including Alabama, to meet annual and ozone season NO_x emission budgets and annual SO₂ emission budgets implemented through new trading programs. Implementation of CSAPR began on January 1, 2015.⁴ CSAPR also contained provisions that would sunset CAIR-related obligations on a schedule coordinated with the implementation of the CSAPR compliance requirements. Participation by a state's EGUs in the CSAPR trading program for ozone season NO_x generally addressed the state's obligation under the NO_x SIP Call for EGUs. CSAPR did not initially contain provisions allowing states to incorporate large non-EGUs into that trading program to meet the requirements of the NO_x SIP Call for non-EGUs. EPA also stopped administering CAIR trading programs

with respect to emissions occurring after December 31, 2014.⁵

To comply with CSAPR, Alabama adopted SO₂ and NO_x CSAPR trading program rules, including budgets, in ADEM Administrative Code Chapters 335–3–5 and 335–3–8. On August 31, 2016, EPA approved Alabama's CSAPR annual SO₂ and annual NO_x trading program rules into the SIP.⁶ *See* 81 FR 59869. Because EPA stopped administering the CAIR trading programs after 2014, the approved CAIR rules in the State's SIP have not been implemented for several years. Furthermore, ADEM repealed all CAIR and CAIR-related regulations from Alabama Administrative Code Chapters 335–3–1, 335–3–5, and 335–3–8 on December 9, 2011.⁷ Even though the CAIR programs were not being implemented in Alabama, ozone season NO_x emissions have remained well below the NO_x SIP Call budget levels.

After litigation that reached the Supreme Court, the D.C. Circuit generally upheld CSAPR but remanded several state budgets to EPA for reconsideration. *EME Homer City Generation, L.P. v. EPA*, 795 F.3d 118, 129–30 (D.C. Cir. 2015). EPA addressed the remanded ozone season NO_x budgets in the Cross-State Air Pollution Rule Update for the 2008 Ozone NAAQS (CSAPR Update), which also partially addressed eastern states' good neighbor obligations for the 2008 ozone NAAQS. *See* 81 FR 74504 (October 26, 2016). The air quality modeling for the CSAPR Update demonstrated that Alabama contributes significantly to nonattainment and/or interferes with maintenance of the 2008 ozone NAAQS in other states. The CSAPR Update reestablished an option for most states to meet their ongoing obligations for non-EGUs under the NO_x SIP Call by including the units in the CSAPR Update trading program.

The CSAPR Update trading program replaced the original CSAPR trading program for ozone season NO_x for most covered states. On October 6, 2017, EPA approved Alabama's CSAPR Update ozone season NO_x trading program rules

for EGUs into the State's SIP.⁸ *See* 82 FR 46674. Alabama's EGUs participate in the CSAPR Update trading program, generally also addressing the state's obligations under the NO_x SIP Call for EGUs. However, Alabama elected not to include its large non-EGUs in the CSAPR Update ozone season trading program. Because Alabama's large non-EGUs no longer participate in any CSAPR or CSAPR Update trading program for ozone season NO_x emissions, the NO_x SIP Call regulations at 40 CFR 51.121(r)(2) as well as anti-backsliding provisions at 40 CFR 51.905(f) and 40 CFR 51.1105(e) require these non-EGUs to maintain compliance with NO_x SIP Call requirements in some other way.

Under 40 CFR 51.121(f)(2) of the NO_x SIP Call regulations, where a State's SIP contains control measures for EGUs and large non-EU boilers and combustion turbines, the SIP must contain enforceable limits on the ozone season NO_x mass emissions from these sources. In addition, under 40 CFR 51.121(i)(4) of the NO_x SIP Call regulations as originally promulgated, the SIP also had to require these sources to monitor emissions according to the provisions of 40 CFR part 75, which generally entails the use of continuous emission monitoring systems (CEMS). Alabama triggered these requirements by including control measures in its SIP for these types of sources, and the requirements have remained in effect despite the discontinuation of the NO_x Budget Trading Program after the 2008 ozone season. On March 8, 2019, EPA revised some of the regulations that were originally promulgated in 1998 to implement the NO_x SIP Call.⁹ The revision gave states covered by the NO_x SIP Call greater flexibility concerning the form of the NO_x emissions monitoring requirements that the states must include in their SIPs for certain emissions sources. The revision amended 40 CFR 51.121(i)(4) to make Part 75 monitoring, recordkeeping, and reporting optional, such that SIPs may establish alternative monitoring requirements for NO_x SIP Call budget units that meet the general requirements of 40 CFR 51.121(f)(1) and (i)(1). Under the updated provision, a state's implementation plan still needs to include some form of emissions monitoring requirements for these types of sources, consistent with the NO_x SIP

⁵ *See* 79 FR 71663 (December 3, 2014) and 81 FR 13275 (March 14, 2016).

⁶ In the 2016 action, EPA did not act on the portion of Alabama's SIP submittal intended to replace Alabama units' obligations to participate in CSAPR's federal trading program for ozone-season NO_x emissions.

⁷ Although CAIR-related regulations were repealed from ADEM Administrative Code on December 11, 2011, the repeal of the regulations was not effective until February 20, 2015. EPA is now proposing to remove the repealed regulations from the SIP.

⁸ This action approved CSAPR and CSAPR Update-related provisions of Alabama SIP submissions dated October 26, 2015, and May 19, 2017.

⁹ *See* "Emissions Monitoring Provisions in State Implementation Plans Required Under the NO_x SIP Call," 84 FR 8422 (March 8, 2019).

⁴ *See* 79 FR 71663 (December 3, 2014).

Call's general enforceability and monitoring requirements at §§ 51.121(f)(1) and (i)(1), respectively, but states are no longer be required to satisfy these general NO_x SIP Call requirements specifically through the adoption of 40 CFR part 75 monitoring requirements.

After evaluating the various options available following EPA's March 8, 2019, revision to the NO_x SIP Call requirements, ADEM revised its regulations to address NO_x SIP Call requirements and adopt alternative monitoring options for certain large non-EGUs. The changes require large non-EGUs in the State to address the NO_x SIP Call's requirements for enforceable limits on ozone season NO_x mass emissions in a manner that does not rely on the administration of an interstate trading program. In addition, Alabama had previously revised its regulations to remove NO_x Budget Trading Program and CAIR trading program provisions after EPA stopped administering those programs. The February 27, 2020 SIP revision submitted by ADEM requests approval into the SIP of all of these rule changes. The contents of the submittal and EPA's analysis is further discussed in Section III.

II. Why is EPA proposing these actions?

ADEM's February 27, 2020, letter¹⁰ requests that EPA approve into the SIP changes to ADEM Administrative Code Chapter 335–3–8 to include Rule 335–3–8–.71, “NO_x Budget Program,” and Rule 335–3–8–.72, “NO_x Budget Program Monitoring and Reporting,” to maintain state compliance with the federal NO_x SIP Call regulations at 40 CFR 51.121 and 51.122, and to provide alternative monitoring options for certain large non-EGUs. Additionally, Alabama requests that EPA approve the removal from the SIP of the State's repealed CAIR trading program and NO_x Budget Trading Program rules, as those state regulations have been replaced by CSAPR for EGUs and by the State's new rules for non-EGUs. ADEM also requests that EPA approve the State's renumbering of the existing regulation titled “New Combustion Sources” from Rule 335–3–8–.14 to Rule 335–3–8–.05. The submission includes a demonstration under CAA section 110(l) intended to show that the revision does not interfere with any applicable CAA requirements. As discussed later, EPA

has reviewed these changes, preliminarily finds them consistent with the CAA and regulations governing the NO_x SIP Call, with one exception, and is proposing to approve the revisions to incorporate the NO_x SIP Call regulations into the State's implementation plan and to remove the NO_x Budget Trading Program and CAIR trading program regulations from the SIP. The exception is that EPA is proposing to conditionally approve the regulations that establish monitoring and reporting requirements for NO_x budget units.

III. Analysis of Alabama's Submission

As discussed above, ADEM has revised its regulations to require non-EGUs to maintain compliance with NO_x SIP Call requirements without participation in an interstate trading program. ADEM updated Chapter 335–3–8, “Control of Nitrogen Oxides Emissions” by revising Chapter 335–3–8 to add Rule 335–3–8–.71, “NO_x Budget Program” and Rule 335–3–8–.72, “NO_x Budget Program Monitoring and Reporting,” to maintain state compliance with the federal NO_x SIP Call regulations at 40 CFR 51.121 and 51.122 for large non-EGUs and to adopt an alternative monitoring option for certain large non-EGUs. EPA previously approved Alabama's sunset of the State's NO_x Budget Trading Program regulations when that program was replaced by the CAIR trading program for ozone season NO_x. The State subsequently repealed its NO_x Budget Trading Program regulations from Alabama Administrative Code Chapters 335–3–1 and 335–3–8 and now requests removal of those regulations from the SIP. Also, because EPA has stopped administering the CAIR trading programs, the State repealed all CAIR and CAIR-related regulations from Alabama Administrative Code Chapters 335–3–1, 335–3–5, and 335–3–8 and now requests removal of these regulations from the SIP as well.¹¹ Lastly, ADEM requests that EPA approve a ministerial change that would update the SIP to reflect the State's renumbering of the existing regulation

titled, “New Combustion Sources” from Rule 335–3–8–.14 to Rule 335–3–8–.05.

1. Revised State Regulations

ADEM added Rule 335–3–8–.71, “NO_x Budget Program,” to establish a state control program for sources that are subject to the NO_x SIP Call, but not covered under the CSAPR Update trading program. ADEM Rule 335–3–8–.71 is designed to ensure that the State's large non-EGUs will continue to satisfy NO_x SIP Call requirements for enforceable limits on ozone season NO_x mass emissions.

ADEM Rule 335–3–8–.71(4) and (5) contain the rule's applicability provisions, generally covering all existing and new non-EGUs (including cogeneration units) that would have been subject to the NO_x Budget Trading Program and that are not subject to the CSAPR Update trading program. ADEM Rule 335–3–8–.71(6)(a) defines the budget for the State at 2,328 tons per ozone season, which is the portion of the State's trading budget under the NO_x Budget Trading Program assigned to non-EGUs, and restricts the collective emissions from the State's affected large non-EGUs from exceeding the budget during each control period. ADEM Rule 335–3–8–.71(6)(a) also states that Alabama will conduct an annual review of the actual NO_x emissions to ensure that the state budget has not been exceeded. Further, in the event of an exceedance, Alabama will submit a revised SIP to EPA which compensates for any potential budget shortfall and ensures the state program budget is met in all future years. ADEM Rule 335–3–8–.71(6)(b) requires monitoring and reporting of NO_x emissions from covered units according to the methods specified in ADEM Rule 335–3–8–.72. Other provisions of ADEM Rule 335–3–8–.71 address definitions, recordkeeping requirements, and liability.

ADEM Rule 335–3–8–.72, “NO_x Budget Program Monitoring and Reporting,” requires all owners and operators of covered NO_x budget units to implement a monitoring and reporting system necessary to attribute ozone season NO_x mass emissions to each individual NO_x budget unit at the source and provide a compliance certification report following each ozone season. ADEM Rule 335–3–8–.72(1) requires units to monitor and report ozone season NO_x mass emissions determined under one of the following alternatives: (1) 40 CFR part 75; (2) NO_x CEMS, with a requirement to convert the NO_x concentration or NO_x emission rate derived from the CEMS to mass emissions; or (3) the use of approved emissions factors, with a requirement to

¹⁰ On February 27, 2020, Alabama also submitted other SIP revisions which will be addressed in separate actions. This submission also includes amended regulations which are not part of the federally-approved SIP and are therefore not addressed in this notice.

¹¹ EPA is proposing to approve removal of the following rules related to the NO_x Budget Trading Program and CAIR from Alabama's SIP: 335–3–1–.14, 335–3–1–.16, 335–3–5–.06 through 335–3–5–.08, 335–3–5–.11 through .14, 335–3–8–.05 through 335–3–8–.13, 335–3–8–.16 through 335–3–8–.18, 335–3–8–.20, 335–3–8–.21, 335–3–8–.23 through 335–3–8–.27, 335–3–8–.29, 335–3–8–.30, 335–3–8–.32, and 335–3–8–.33. Other Alabama rules that share many of the same rule numbers would not be removed from the SIP; these rules relate to the State's CSAPR and CSAPR Update trading programs.

convert the emission factors to mass emissions. ADEM Rule 335–3–8-.72(1)(a) requires units to monitor and report under Part 75 if required by any other regulation or permit, and allows any other unit to choose to report under Part 75. ADEM Rules 335–3–8-.72(1)(b) and 335–3–8-.72(1)(c) together provide the requirements for units that are required to, or choose to, operate a CEMS outside of Part 75 requirements. ADEM Rule 335–3–8-.72(1)(c) requires NO_x budget units operating a CEMS to comply with any applicable monitoring and reporting regulations, and outlines the methods by which a NO_x budget unit shall calculate the NO_x mass emissions (in tons) for compliance under the NO_x Budget Program. ADEM Rule 335–3–8-.72(1)(b) outlines additional quality assurance and compliance requirements for NO_x budget units that choose to operate a CEMS. Last, ADEM Rule 335–3–8-.72(1)(d) provides that any unit not covered under ADEM Rule 335–3–8-.72(1)(a), (b), or (c), must calculate NO_x mass emissions through the use of emissions factors. In addition, ADEM Rule 335–3–8-.72(1)(e) requires units to submit a monitoring protocol to ADEM for review and approval. For all compliance options, ADEM Rule 335–3–8-.72(2) requires units to submit their ozone season NO_x emissions to ADEM as part of an annual compliance report and certification no later than November 30th following each ozone season.

As discussed above, in order to address the requirements of the NO_x SIP Call for sources that are not covered under a CSAPR trading program for ozone season NO_x emissions, SIP revisions must provide for enforceable emissions limitations and require emissions monitoring consistent with the NO_x SIP Call's general enforceability and monitoring requirements.¹² In this notice, EPA is proposing to find that ADEM Rule 335–3–8-.71 meets the requirement under 40 CFR 51.121(f)(2) for enforceable limits on the subject units' collective emissions of ozone season NO_x mass emissions. Thus, EPA is proposing to approve ADEM rule 335–3–8-.71 into the SIP.

Further, EPA is proposing to find that ADEM Rule 335–3–8-.72 meets the State's ongoing obligations under the NO_x SIP Call with respect to monitoring to ensure compliance with required limitations, with the following exception. While ADEM Rule 335–3–8-.72 generally addresses the State's ongoing obligations under the NO_x SIP Call with respect to monitoring, EPA

identified one issue impacting monitoring under ADEM's rule. Accordingly, on September 15, 2020, ADEM sent a letter¹³ requesting that EPA conditionally approve ADEM Rule 335–3–8-.72 under CAA section 110(k)(4), as ADEM inadvertently added stack testing requirements for units choosing to operate a CEMS outside of Part 75 requirements rather than for units using emissions factors, as intended. In that letter, ADEM also commits to EPA that it will make a final submission to EPA within twelve (12) months of the grant of conditional approval of the February 27, 2020 submittal to correct this stack testing issue. Based on the State's commitment to submit a SIP revision addressing the identified deficiency, EPA is proposing to conditionally approve the February 27, 2020 submission, as clarified by the State's September 15, 2020 letter. If Alabama meets its commitment to submit a SIP revision addressing the deficiency by 12 months from the date of final approval of this action, ADEM Rule 335–3–8-.72 will remain a part of the SIP until EPA takes final action approving or disapproving the new SIP revision. However, if the State fails to submit this revision on or before 12 months from the date of final approval of this action, the conditional approval will become a disapproval and EPA will issue a notice to that effect. If the conditional approval becomes a disapproval, the disapproval triggers the requirement for EPA to issue a federal implementation plan (FIP) under CAA section 110(c) to correct the deficiency.

2. Removal of NO_x Budget Trading Program and CAIR Trading Program Regulations From Alabama's SIP

EPA proposes to approve the removal from the SIP of the State's repealed NO_x Budget Trading Program and CAIR trading program regulations. With respect to the State's NO_x Budget Trading Program regulations, removal from the SIP would have no substantive effect because EPA previously approved the sunset of these regulations when Alabama began to meet its ongoing NO_x SIP Call requirements for both EGUs and large non-EGUs through its CAIR regulations instead. With respect to the State's CAIR regulations, EPA proposes to find removal from the SIP is appropriate because the State's ongoing NO_x SIP Call obligations for EGUs are now being met through the State's SIP-approved CSAPR regulations, the State's

ongoing NO_x SIP Call obligations for non-EGUs would be met through the rules proposed for approval into the SIP in this action, as discussed above, and EPA is no longer administering the CAIR trading programs.

CAA section 110(l) provides that EPA cannot approve a SIP revision if the revision would interfere with any applicable requirement concerning attainment or reasonable further progress (RFP), or any other applicable requirement of the CAA. EPA generally considers whether the SIP revision would worsen, preserve, or improve the status quo in air quality.

ADEM's February 27, 2020 submission seeks to remove the SIP-approved portions of the state trading program rules adopted to comply with annual CAIR programs from Alabama's SIP because the CAIR annual programs have been replaced by the CSAPR annual programs. In addition, ADEM's February 27, 2020 submission seeks to remove the SIP-approved portions of the State's trading program rules adopted to comply with ozone season CAIR programs from Alabama's SIP because the CAIR program has been replaced by CSAPR for EGUs, and, if approved, Alabama's state control program would address the outstanding NO_x SIP Call requirements for non-EGUs. With respect to non-EGUs, ADEM's February 27, 2020 submission contains a technical demonstration showing that no increase in NO_x ozone season emissions is expected to result from the removal of CAIR because the combined potential to emit from non-EGU sources remains below CAIR budget levels.

In this notice, EPA is proposing to approve the removal of the CAIR-related provisions from Alabama's SIP because removal of these provisions is appropriate and consistent with all applicable requirements, including 40 CFR 51.121 and CAA section 110(l). As explained above, the D.C. Circuit remanded CAIR to EPA in 2008; however, the court left CAIR in place while EPA worked to develop a new interstate transport rule. CSAPR was promulgated to respond to the Court's concerns and to replace CAIR. The implementation of CSAPR was delayed for several years beyond its originally expected implementation timeframe of 2012, and therefore, the sunset of CAIR was also deferred. CAIR was implemented through the 2014 compliance periods and was replaced by CSAPR on January 1, 2015. EPA promulgated regulations to sunset the CAIR trading programs and is no longer

¹² See 40 CFR 51.121(f)(2)(ii) and 51.121(i)(4).

¹³ See ADEM's September 15, 2020, letter from Lance R. LeFleur, Director, to Mary S. Walker, Regional Administrator, US EPA Region 4, available in the docket for this proposed action.

administering them.¹⁴ EPA preliminarily concludes that approval of the February 27, 2020 Alabama submittal would not result in increased NO_x emissions, and therefore, would have no impact on any requirements related to attainment, reasonable further progress (RFP), or any other NAAQS requirements under the CAA. EPA therefore proposes to approve the removal of Alabama's SIP provisions related to CAIR.

ADEM further provided an analysis to demonstrate that the monitoring flexibilities comply with CAA section 110(l). Given that several of the original large non-EGU sources are no longer subject to the NO_x SIP Call due to shut-downs and that the remaining facilities, through compliance with federal permit restrictions, have potentials-to-emit that are well below the NO_x SIP Call budget levels, accompanied by replacement monitoring requirements sufficient to ensure compliance with the unchanged emissions requirements, this SIP revision is not expected to result in increases in emissions. EPA also preliminarily concludes that Alabama's monitoring regulations related to the NO_x SIP Call will not interfere with continued attainment of the NAAQS, RFP, or any other applicable requirement of the Clean Air Act.

3. Ministerial Change

EPA also proposes to approve into the SIP ADEM's non-substantive renumbering of the existing regulation titled, "New Combustion Sources" from Rule 335-3-8-.14 to Rule 335-3-8-.05.

IV. 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 requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference Alabama Administrative Code Rule 335-3-8-.71, "NO_x Budget Program," which reestablishes enforceable limits on ozone season NO_x mass emission for certain units as required by EPA's NO_x SIP Call regulations, and Rule 335-3-8-.72, "NO_x Budget Program Monitoring and Reporting," which establishes alternative emission monitoring requirements for the units, effective April 13, 2020. Also in this document, EPA is proposing to remove from the SIP the State's NO_x Budget Trading Program and CAIR trading program regulations at 335-3-1-.14, 335-3-1-.16, 335-3-5-.06 through 335-3-5-.08,

335-3-5-.11 through 335-3-5-.14, 335-3-8-.05 through 335-3-8-.13, 335-3-8-.16 through 335-3-8-.18, 335-3-8-.20, 335-3-8-.21, 335-3-8-.23 through 335-3-8-.27, 335-3-8-.29, 335-3-8-.30, 335-3-8-.32, and 335-3-8-.33. EPA has made, and will continue to make, the SIP 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).

V. Proposed Actions

EPA is proposing to approve Alabama's February 27, 2020 SIP revision to Rule 335-3-8-.71, "NO_x Budget Program," into the SIP, and conditionally approve Alabama's February 27, 2020 SIP revision to Rule 335-3-8-.72, "NO_x Budget Program Monitoring and Reporting," into the SIP. In addition, EPA is proposing to remove from the SIP the State's NO_x Budget Trading Program and CAIR trading program regulations within Chapters 335-3-1, titled "General Provisions," 335-3-5, titled "Control of Sulfur Compound Emissions," and 335-3-8, titled "Control of Nitrogen Oxides Emissions," as identified earlier. EPA is also proposing to update the SIP to reflect the State's renumbering of the existing regulation titled "New Combustion Sources" from Rule 335-3-8-.14 to Rule 335-3-8-.05.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA 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. Accordingly, these proposed actions merely propose to approve, or conditionally approve, state law as meeting Federal requirements and do not impose additional requirements beyond those imposed by state law. For that reason, these proposed 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 information collection burdens under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are certified as not having significant economic impacts on a substantial number of small entities

under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- Do not contain any unfunded mandates 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, 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, these proposed actions do not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

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

Dated: February 25, 2021.

John Blevins,

Acting Regional Administrator, Region 4.

[FR Doc. 2021-04324 Filed 3-2-21; 8:45 am]

BILLING CODE 6560-50-P

¹⁴ 40 CFR 51.123(ff) and 52.35(f) (SIP and FIP requirements related to NO_x); 40 CFR 51.124(s) and 52.36(e) (SIP and FIP requirements related to SO₂).

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2020–0735; FRL–10020–57–Region 9]

Air Plan Approval; Arizona; Miami Copper Smelter Sulfur Dioxide Control Measures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Arizona State Implementation Plan (SIP). These revisions concern emissions of sulfur dioxide (SO₂) from the copper smelter in Miami, Arizona. We are proposing to approve the rescission of two Arizona Department of Environmental Quality (ADEQ) Arizona Administrative Code (A.A.C.) provisions from the Arizona SIP that are no longer needed to regulate this emission source under the Clean Air Act (CAA or the “Act”). We are taking comments on this proposal and plan to follow with a final action.

DATES: Comments must be received on or before April 2, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2020–0735 at <https://www.regulations.gov>. For comments

submitted at [Regulations.gov](https://www.regulations.gov), follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [Regulations.gov](https://www.regulations.gov). The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT:

Kevin Gong, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3073 or by email at gong.kevin@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us” and “our” refer to the EPA.

Table of Contents

- I. The State’s Submittal
 - A. Of what rule provisions did the State request rescission?
 - B. What was the purpose of the SIP-approved rule provisions, and what is the purpose of the State’s rescission request?
- II. The EPA’s Evaluation and Action
 - A. How is the EPA evaluating the request for rescission?
 - B. Does the rule rescission meet the evaluation criteria?
 - C. Public Comment and Proposed Action
- III. Incorporation by Reference
- IV. Statutory and Executive Order Reviews

I. The State’s Submittal

A. Of what rule provisions did the State request rescission?

Table 1 lists the rule provisions addressed by this proposal with the dates that they were adopted, submitted, and approved. On March 10, 2020, ADEQ submitted a formal request to the EPA requesting that the EPA rescind these provisions from the SIP.¹

TABLE 1—RULE FOR WHICH RESCISSION FROM THE SIP IS REQUESTED

Local agency	Citation	Rule title	Adopted	SIP approval date
ADEQ	A.A.C. R18–2–715(F)(2) and (H).	Standards of Performance for Existing Primary Copper Smelters; Site-specific Requirements.	March 7, 2009	September 23, 2014.

On September 10, 2020 the submittal for the rescission of A.A.C. R18–2–715(F)(2) and (H) was deemed by operation of law to meet the completeness criteria in 40 CFR part 51 appendix V, which must be met before formal EPA review.

B. What was the purpose of the SIP-approved rule provisions, and what is the purpose of the State’s rescission request?

ADEQ adopted A.A.C. R18–2–715(F)(2) and (H) in order to establish source-specific SO₂ emissions limits for the copper smelter located in Miami, Arizona (“Miami Smelter”). ADEQ also adopted compliance and monitoring

provisions for these limits in A.A.C. R18–2–715.01. These provisions were necessary to provide for attainment of the 1971 National Ambient Air Quality Standard (NAAQS), for which the Miami area was designated nonattainment in 1978.² The State of Arizona submitted regulations to the EPA in 1979 and 1980 to reduce emissions from criteria pollutant sources in Miami and across the state. The EPA approved these measures on January 14, 1983, but found that further analysis and control of smelter fugitive emissions was needed.³ The Miami smelter operators submitted fugitive emissions studies in the 1990s to better estimate fugitive emissions during

typical operation to eventually determine maximum emissions. This analysis resulted in the implementation of further control measures and emission limits at the Miami Smelter to provide for attainment of the 1971 SO₂ NAAQS. On November 1, 2004, the EPA approved rules R18–2–715 (sections F, G, and H), R18–2–715.01 and R18–2–715.02, which codified these new requirements.⁴ In 2007, the EPA

¹ Letter from Daniel Czecholinski, Director, Air Quality Division, ADEQ, to John Busterud, Regional Administrator, EPA Region IX, RE: Miami SO₂ Nonattainment Area State Implementation Plan

Revision (undated; received by EPA on March 10, 2020).

² The Miami SO₂ NAA (nonattainment area) initially included all of Gila County (43 FR 8968, March 3, 1978), but its boundaries were later

revised to include only the nine townships in and around Miami (44 FR 21261, April 10, 1979).

³ 48 FR 1717. These provisions were codified within A.A.C. R9–3–515, which was the predecessor to A.A.C. R18–2–715.

redesignated the Miami area to attainment for the 1971 NAAQS.⁵

In 2010, the EPA promulgated a new 1-hour SO₂ NAAQS, and simultaneously established provisions for revoking the 1971 SO₂ NAAQS.⁶ The EPA designated the Miami area as nonattainment for the 2010 SO₂ NAAQS in 2013.⁷ ADEQ submitted a new SO₂ attainment plan and rule for Miami (R18–2–C1302) in 2017 to comply with CAA requirements for 2010 SO₂ nonattainment areas. ADEQ also submitted new transitional provisions in A.A.C. R18–2–715(I) and R18–2–715.01(V) in order to sunset the existing rule provisions upon the effective date of R18–2–B1302, which regulates SO₂ emissions from the copper smelter in Hayden, Arizona along with the provisions for Miami, Arizona in R18–2–C1302.

The EPA approved A.A.C. R18–2–C1302 into the Arizona SIP on November 14, 2018,⁸ and approved the Miami SO₂ attainment plan on March 12, 2019.⁹ However, we have not yet proposed to act on the transitional provisions in A.A.C. R18–2–715(I) and R18–2–715.01(V). As explained in our recent final limited approval and limited disapproval of R18–2–B1302 (“Limits on SO₂ Emissions from the Hayden Smelter”) “because the transitional provisions that apply to Hayden and Miami are inseparable from one another (*i.e.*, both are contained within a single paragraph within R18–2–715(I) and R18–2–715.01(V)), we cannot separately approve the transitional provisions for Miami without also approving the provisions for Hayden, which is prohibited by CAA section 110(l).”¹⁰ Therefore, the Miami smelter remains subject to the emission limits in R18–2–715(F)(2) and (H) and associated requirements in R18–2–715.01.

ADEQ is requesting that EPA rescind R18–2–715(F)(2) and (H) from the Arizona SIP in order to remove the emissions limits and associated requirements that were established to meet the now-revoked 1971 SO₂ NAAQS. In support of this request, ADEQ submitted a demonstration of how rescission of these provisions from

the SIP would comply with applicable CAA requirements.¹¹

II. The EPA’s Evaluation and Action

A. How is the EPA evaluating the request for rescission?

Once a rule has been approved as part of a SIP, the rescission of that rule from the SIP constitutes a SIP revision. To approve such a revision, the EPA must determine whether the revision meets relevant CAA criteria for stringency, and complies with restrictions on relaxation of SIP measures under CAA section 110(l), and the General Savings Clause in CAA section 193 for SIP-approved control requirements in effect before November 15, 1990.

Stringency: CAA section 172(c)(1) requires that SIPs for nonattainment areas provide for the implementation of all reasonably available control measures (RACM), including any reasonably available control technology (RACT), in order to provide for attainment of the NAAQS.

Plan Revisions: States must demonstrate that SIP revisions would not interfere with attainment, reasonable further progress (RFP) or any other applicable requirement of the CAA under the provisions of CAA section 110(l). Therefore, consistent with CAA section 110(l) requirements, ADEQ must demonstrate that the rescission of R18–2–715(F)(2) and (H) from the SIP would not interfere with attainment and RFP of the NAAQS or any other applicable CAA requirement.

General Savings Clause: CAA section 193 prohibits the modification of any control requirement in effect, or required to be adopted by an order, settlement agreement or plan in effect before November 15, 1990, in areas designated as nonattainment for an air pollutant unless the modification ensures equivalent or greater emission reductions of the relevant pollutant.

B. Does the rule rescission meet the evaluation criteria?

The EPA previously determined that R18–2–C1302 and the Miami SO₂ attainment plan meet the requirements for RACM/RACT for the Miami 2010 SO₂ nonattainment area.¹² We have also found that the emissions limits in R18–

2–C1302 are more stringent than those in R18–2–715.¹³ In particular, the 30-day rolling average emission limit of 142.45 pounds per hour (lb/hr) in R18–2–C1302(C), which covers both stack and fugitive emissions, is far more stringent than the annual average limit of 2,420 lb/hr for combined stack and fugitive emissions in R18–2–715(H). The 142.45 lb/hr limit in R18–2–C1302 is also clearly more stringent than annual average emission limit of 604 lb/hr and 3-hour limits of 712–8,678 lb/hr for stack emissions in R18–2–715(F)(2).

We also note that while ADEQ is not requesting rescission of the compliance and monitoring requirements in R18–2–715.01, the removal of R18–2–715(F)(2) and (H) from the SIP would effectively render the provisions of R18–2–715.01 inapplicable to the Miami smelter.¹⁴ We find that the nullification of these provisions with respect to the Miami smelter would not interfere with any CAA requirements because the Miami smelter is already required to comply with the more prescriptive requirements for compliance and monitoring in R18–2–C1302(E).

For the foregoing reasons, we propose to find that the rescission of R18–2–715(F)(2) and (H) from the Arizona SIP would not interfere with any CAA requirements and would therefore comply with CAA section 110(l). We also propose to find that our prior approval of R18–2–C1302 ensures equivalent or greater emission reductions of SO₂ than the rescission of R18–2–715(F)(2) and (H) and therefore satisfies the requirements of CAA section 193.

C. Public Comment and Proposed Action

As authorized in section 110(k)(3) of the Act, the EPA proposes to approve the rescission of R18–2–715(F)(2) and (H) from the Arizona SIP because these provisions are no longer needed to meet any CAA requirement and rescission would comply with CAA sections 110(l) and 193. We will accept comments from the public on this proposal until April 2, 2021. If we take final action to approve the rule rescission, our final action will rescind these provisions from the federally enforceable SIP.

2020 (“Rule B1302 TSD”), 10 –12; 84 FR 8813, March 12, 2019.

¹³ Rule B1302 TSD, 12–13.

¹⁴ The Hayden Smelter will remain subject to the applicable requirements of both R18–2–715 and R18–2–715.01 until we take action to remove those requirements from the SIP or approve the transitional provisions in A.A.C. R18–2–715(I) and R18–2–715.01(V) into the SIP.

⁴ 69 FR 63324. The EPA later approved minor revisions to A.A.C. R18–2–715. 79 FR 56655 (September 23, 2014).

⁵ 72 FR 3061 (January 24, 2007).

⁶ 75 FR 35520 (June 22, 2010).

⁷ 78 FR 47191 (August 5, 2013; effective October 4, 2013). This action also established an effective date for revocation of the 1971 SO₂ NAAQS in the Miami area of October 4, 2014. See 40 CFR 50.4(e).

⁸ 83 FR 56736.

⁹ 84 FR 8813.

¹⁰ 85 FR 70483, 70485 (November 5, 2020).

¹¹ “State Implementation Plan Revision; Miami SO₂ Nonattainment Area Demonstration of Compliance with Clean Air Act Sections 110(l) and 193 for the 2010 SO₂ National Ambient Air Quality Standards,” dated February 27, 2020.

¹² EPA, “Technical Support Document for the EPA’s Rulemaking for the Arizona State Implementation Plan; Arizona Administrative Code, Title 18, Chapter 2, Article 13, Part B—Hayden, Arizona, Planning Area, R18–2–B1302—Limits on SO₂ Emissions from the Hayden Smelter,” April

III. Incorporation by Reference

In this document, the EPA is proposing to amend regulatory text that includes incorporation by reference. The EPA is proposing to remove R18–2–715(F)(2) and (H) as described in Table 1 of this preamble from the Arizona State Implementation Plan, which is incorporated by reference in accordance with the requirements of 1 CFR part 51.

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. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

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

disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur dioxide.

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

Dated: February 18, 2021.

Deborah Jordan,

Acting Regional Administrator, Region IX.

[FR Doc. 2021–03753 Filed 3–2–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 63

[IB Docket No. 16–155; DA 20–1545; FRS 17408]

International Bureau Seeks Comment on Standard Questions for Applicants Whose Applications Will Be Referred to the Executive Branch for Review Due to Foreign Ownership

AGENCY: Federal Communications Commission.

ACTION: Proposed rules.

SUMMARY: In this document, the International Bureau seeks comment on a set of standardized national security and law enforcement questions (Standard Questions) that proponents of certain applications and petitions involving reportable foreign ownership will be required to answer as part of the application review process and whose application and petition will be referred to the Executive Branch.

DATES: Comments are due April 2, 2021. Reply comments are due April 19, 2021.

ADDRESSES: You may submit comments, identified by IB Docket No. 16–155, by any of the following methods:

- **Electronic Filers:** Comments may be filed electronically using the internet by accessing the ECFs: <http://www.fcc.gov/ecfs/>.

- **Paper Filers:** Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.

- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 45 L Street NE, Washington, DC 20554.

- Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19.

See FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Policy, Public Notice, 35 FCC Rcd 2788 (2020), <https://www.fcc.gov/document/fcc-closes-headquarters-open-window-and-changes-hand-delivery-policy>.

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

In addition, filers should provide one copy of each filing to each of the following:

- (1) Arthur Lechtman, Attorney, Telecommunications and Analysis Division, International Bureau, at Arthur.Lechtman@fcc.gov, and
- (2) David Krech, Associate Division Chief, Telecommunications and Analysis Division, International Bureau, at David.Krech@fcc.gov.

FOR FURTHER INFORMATION CONTACT:

Arthur Lechtman, International Bureau, Telecommunications and Analysis Division, at (202) 418–1465. For information regarding the Paperwork Reduction Act (PRA) information collection requirements contained in the PRA, contact Cathy Williams, Office of Managing Director, at (202) 418–2918 or Cathy.Williams@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Public Notice, DA 20–

1545, released on December 30, 2020. The full text of this document is available on the Federal Communications Commission's website at <https://www.fcc.gov/document/standard-questions-applications-referred-executive-branch>.

Supplemental Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the International Bureau has prepared a Supplemental Initial Regulatory Flexibility Analysis (Supplemental IRFA) of the possible significant economic impact on small entities of the proposals addressed in this Public Notice to supplement the Federal Communications Commission's (Commission) Final Regulatory Flexibility Analyses completed in the *Executive Branch Review Order*, 85 FR 76360 (Nov. 27, 2020).

Synopsis

By this Public Notice, the International Bureau (Bureau) seeks comment on a set of standardized national security and law enforcement questions (Standard Questions) that proponents of certain applications and petitions involving reportable foreign ownership will be required to answer as part of the review process. In the *Executive Branch Review Order*,¹ the Commission adopted rules and procedures to facilitate a more streamlined and transparent review process for coordinating these applications and petitions with the Executive Branch agencies (the Departments of Justice, Homeland Security, Defense, State, and Commerce, as well as the U.S. Trade Representative) for any national security, law enforcement, foreign policy, or trade policy issues. The Commission refers applications for international section 214 authorizations and submarine cable 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.

To expedite the Executive Branch agencies' review of such applications and petitions, applicants and petitioners will provide responses to the Standard Questions directly to the Committee for

the Assessment of Foreign Participation in the United States Telecommunications Services Sector (Committee) prior to or at the same time that they file applications or petitions with the Commission. The Commission adopted five categories of information to be provided by an applicant or petitioner: (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 available on a publicly available website the Standard Questions that will elicit the information needed by the Committee within those categories of information. The Bureau will also maintain and update the Standard Questions, as needed.

We seek comment on the Standard Questions set out in each of the following Appendices, which are identified by the type of application or petition. The Standard Questions are based upon current questionnaires used by the Committee to obtain information from applicants and petitioners.

- *Appendix A—Standard Questions for an International Section 214 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;

- *Appendix B—Standard Questions for an Application for an 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;

- *Appendix C—Standard Questions for 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;

- *Appendix 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;

- *Appendix E—Standard Questions for 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 benchmark in section 310(b)(4) of the Communications Act (the Act) filed pursuant to 47 CFR 1.5000–1.5004;

- *Appendix F—Standard Questions for 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)(3) or 310(b)(4) of the Act filed pursuant to 47 CFR 1.5000–1.5004; and

- *Appendix G—Personally Identifiable Information (PII) Supplement.* All of the Standard Questions reference this supplement to assist the Committee in identifying PII.

We seek comment on the questions in each of the Appendices. If needed, to help clarify the questions for applicants and petitioners, we ask that commenting parties provide specific suggested changes to the language of the questions. We seek comment on whether there are questions that are not necessary or if there are any questions that we should include to help expedite the review process. We ask parties for comment on the definitions of key terms that are used in the Appendices, such as “corporate officers” and “senior-level” officers as well as “remote access” and “managed services.” We seek comment on how often, and under what circumstances, the Bureau should reevaluate the Standard Questions. Finally, we seek comment on how long it would take applicants to fill out each questionnaire.

After we review and consider the comments received on the Standard Questions, we will issue an Order addressing the comments and will seek approval for the Standard Questions under the Paperwork Reduction Act. We will issue a Public Notice informing the public of the effective date of the Standard Questions. Following Public Notice of the effective date, the Standard Questions will be made available on the Commission's website and all parties filing applications or petitions 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 the application or petition with the Commission. Until that time, the Committee will continue to send its own questions to the applicant or petitioner upon the Commission's referral of the application or petition.

¹ *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 (2020) (*Executive Branch Review Order*); *Erratum* (Appendix B—Final Rules), 35 FCC Rcd 13164 (OMD/IB 2020).

Supplemental Initial Regulatory Flexibility Analysis

Pursuant to the Regulatory Flexibility Act of 1980, as amended (RFA),² we have prepared this Supplemental Initial Regulatory Flexibility Analysis (Supplemental IRFA) of the possible significant economic impact on small entities of the proposals addressed in this Public Notice to supplement the Commission's Final Regulatory Flexibility Analyses completed in the *Executive Branch Review Order*.³ Written public comments are requested on this Supplemental IRFA. Comments must be identified as responses to the Supplemental IRFA and must be filed by the same deadline for comments specified on the first page of this Public Notice. We will send a copy of this Public Notice, including this Supplemental IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).⁴

This Public Notice sets forth the specific proposed "Standard Questions" for applications and petitions prescribed by the *Executive Branch Review Order*. As noted in the Initial and Final Regulatory Flexibility Analyses associated with that proceeding, 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. That 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 proposed Standard Questions constitute the more specific implementation of the requirements set forth in the *Executive Branch Review Order* and are fully consistent therewith, and as directed by the Commission in that order take due account of the sample questions previously made available in this docket and the comments provided to the Commission thereon. 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 Public Notice, we hereby incorporate by reference the descriptions and estimates of the number of small entities, as well as the associated analyses, set forth therein.

A copy of this Public Notice, including the Supplemental Initial Regulatory Flexibility Analysis, shall be sent to the Chief Counsel for Advocacy of the Small Business Administration.

Ex Parte Information

This proceeding shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the

presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda, or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with section 1.1206(b) of the Commission's rules. In proceedings governed by section 1.49(f) of the Commission's rules or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (e.g., .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Federal Communications Commission

Troy Tanner,

Deputy Chief, International Bureau.

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

BILLING CODE 6712-01-P

² 5 U.S.C. 603. The RFA, 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, 110 Stat. 857 (1996).

³ *Executive Branch Review Order*, 35 FCC Rcd at 10990–11000, App. C.

⁴ See 5 U.S.C. 603(a).

Appendix A

Standard Questions for an International Section 214 Authorization Application

Applicant:**FCC File Number(s):**

Purpose: This list of standard questions solicits the initial information that the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (Committee) will review in connection with any referral of the above-referenced application by the Federal Communications Commission (FCC) in order to assess any national security and law enforcement concerns raised by the application. After review, the Committee may request additional information, including through tailored questions. The 120-day initial review period will typically start on the date the Chair of the Committee determines that your responses to these standard questions and any tailored questions, when required, are complete. If the Committee determines no tailored questions are necessary, the 120-day initial review period will start no more than 30 days after the FCC's referral, on the date the Committee informs the FCC that the responses to the standard questions are complete and that no tailored questions are required. If you fail to provide timely responses to any Committee requests for information, the Committee may recommend that the FCC dismiss the application without prejudice.

Dissemination of Information: The information received by the Committee pursuant to 47 CFR 1.40003 and any subsequent requests for information by the Committee may be shared and used in accordance with Section 8 of Executive Order 13913 of April 4, 2020, Establishing the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector, 85 FR 19643 (Apr. 8, 2020).

Instructions

- 1) **Complete all Sections:** When a “Yes” answer is indicated, provide further information as appropriate. The questions seek further details regarding the Applicant and its security-related practices, and some questions are particularly directed at identifying and assessing the complete scope of the equipment that the Applicant will be operating and the services the Applicant will be offering should the FCC grant those authorities. Accordingly, in answering the “Section V: Applicant’s Services” questions and “Section VI: Applicant Services Portfolio Checklist and Reference Questions,” the Applicants must file complete and accurate responses and identify all switches, routing equipment, and all services offered in retail markets.
- 2) **Identify Sensitive Information:** Specifically 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. If 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. Personally Identifiable Information (PII) may be submitted in a separate attachment. The PII Supplement is Appendix G.

- 3) **Response Format:** Uniquely and sequentially Bates-number your responses to the standard questions, including any attachments, with an endorsement on each page. The Bates number must be a unique, consistently formatted identifier; the number of digits in the numeric portion of the format should not change in subsequent productions, if any, nor should spaces, hyphens, or other separators be added or deleted. Produce any Excel documents in native format (if desired, you may also produce a PDF version for record keeping purposes).
- 4) **Individuals' Names:** For names that follow different naming conventions, such as the use of surnames as first names (e.g., Korean names), or the use of mother's last name as one of two last names that are often hyphenated (e.g., Spanish names), follow standard English convention for purposes of completing this information. For example, if the name is Kim Chul-su, write "Chul-su Kim" in the form. If the name in Spanish is Juan Garcia-Reyes, write "Juan Garcia Reyes."
- 5) **Residential Addresses:** Contract mail receipt locations, post office boxes, co-working, or shared virtual locations may not be used in lieu of residence addresses.
- 6) **Business Addresses:** For each business address, clearly indicate whether the address is a shared business venue, co-working location, virtual office, or traditional physical office.
- 7) **Obligation to Update:** The Applicant must inform the Committee if there is any material change to any of the information provided in the Applicant's responses while the Committee's review is ongoing, including, but not limited to, changes in ownership, equipment, and Communications Assistance for Law Enforcement Act (CALEA) compliance.
- 8) **Definitions** – These terms, as used in this questionnaire, have the following definitions:
 - A "Controlling Interest" is generally a 50% or greater Ownership Interest (either equity or voting). Also, a Controlling Interest shall be determined on a case-by-case basis considering the distribution of ownership, and the relationships of the owners, including family relationships. The term Controlling Interest includes Individuals or Entities with positive or negative *de jure* or *de facto* control of the Applicant/Licensee. *De jure* control includes holding 50% or more of the voting stock of a corporation or holding a general partnership interest in a partnership. Ownership Interests that are held indirectly by any party through one or more intervening corporations may be determined by successive multiplication of the ownership percentages for each link in the vertical ownership chain except that if the ownership percentage for an interest in any link in the chain is equal to or exceeds 50% or represents actual control, it may be treated as if it were a 100% interest. *De facto* control is determined on a case-by-case basis. Examples of *de facto*, or actual, control include constituting or appointing 50% or greater of the board of directors or management committee; having authority to appoint, promote, demote, and fire senior executives that control the day-to-day activities of the Licensee; or playing an integral role in management decisions. In the case of a consortium, each member of the consortium shall be considered to have a Controlling Interest in the consortium.
 - "Ultimate Owner" and "Ultimate Parent" refer to the Entity or Individual that ultimately owns and controls the Applicant/Licensee.

- “Immediate Owner” refers to the Entity or Individual in the vertical ownership chain that immediately owns and controls the Applicant/Licensee. In other words, the Immediate Owner is the Entity or Individual in the ownership chain that is closest to the Applicant/Licensee.
- An Entity or Individual with an “Ownership Interest” is any Entity in the ownership chain with more than a 5% attributable interest in the Applicant/Licensee, including the “Ultimate Owner/Parent” and the “Immediate Owner,” and all Controlling Interest holders. Note that Controlling Interests include *de facto* controlling interests, for which equity and/or voting ownership may be below 5%.
- “Corporate Officer” refers to any Individual hired or appointed by the Entity’s board of directors that has actual or apparent authority to exercise day-to-day management responsibilities over an Entity.
- “Director” refers to any Individual serving on an Applicant’s board of directors or similar governing body organized to set policies for corporate management of or oversight for an Applicant/Licensee.
- “Entity” includes a partnership, association, estate, trust, corporation, limited liability company, consortium, joint venture, governmental authority, or other organization.
- An “Equity Interest Holder” is any Individual or Entity that has the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, a share or other ownership stake in the Applicant.
- The term “Foreign Government” includes any person or group of persons exercising sovereign *de facto* or *de jure* political jurisdiction over any country, other than the United States, or over any part of such country, and includes any subdivision of any such group and any group or agency to which such sovereign *de facto* or *de jure* authority or functions are directly or indirectly delegated. Such term shall include any faction or body of insurgents within a country assuming to exercise governmental authority whether such faction or body of insurgents has or has not been recognized by the United States.
- “Individual” refers to a natural person, as distinguished from an Entity.
- “Managed Services” or “Enterprise Services” refers to the provision of a complete, end-to-end communications solution to customers.
- A “Non-U.S. Individual” is an Individual who is not a U.S. citizen.
- An “Owner” is an Individual or Entity that holds an Ownership Interest in the Applicant/Licensee.
- An “Ownership Interest” is 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 (i.e., all entities that exist in the ownership structure between the Applicant itself and its Ultimate Parent).
- “Remote Access” is 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.
- “Senior Officer” refers to the Chief Executive Officer, President, Chief Financial Officer, Chief Information Officer, Chief Technical Officer, Chief Operating Officer, or any other similarly situated Individual that has actual or apparent authority to act on behalf of the Entity.

Section I: Identification of Applicant

- 1) Provide the Applicant's name, address, principal place of business, and place of incorporation.

Section II: Applicant's Ownership

- 2) Identify each Individual or Entity that holds an Ownership Interest in the 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.
- a) For each such Individual or Entity with Ownership Interest in Applicant, include a clear explanation of its involvement in the Applicant, including whether it will have a management role.
- b) For each such Individual or Entity with an Ownership Interest in Applicant, provide all identifying information, as follows:
- i) For Individuals, provide the name (including all names and aliases used by that person), country of citizenship (indicate whether the individual is a dual citizen and all countries where citizenship is held), date and place of birth, U.S. alien number (indicate if individual is a U.S. Lawful Permanent Resident) and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses and all phone numbers. Personally Identifiable Information (PII) may be provided in Appendix G, a PII Supplement.
- ii) For Entities, provide country of incorporation (if the United States, include state of incorporation), principal place of business, general business type (e.g., holding company, investment firm, etc.), all business addresses, email addresses, and related phone numbers.

Section III: Applicant Details

- 3) Does the Applicant have existing (or planned) relationships/partnerships (formal or informal), funding or service contracts, directly or indirectly, with any foreign Individuals, foreign companies, Foreign Governments, and/or any Foreign Government-controlled companies?

Yes ☐ No ☐

If yes, indicate whether the relationship/partnership includes a management role by any foreign Individuals, foreign companies or Foreign Governments. Provide the name(s) of the foreign Individuals, foreign companies and Foreign Governments and explain the nature of the relationship/partnership, including whether the relationship/partnership currently exists and/or is intended to continue in the future.

- 4) Identify the total number of current employees, and planned number of employees for the Applicant for the next 12 months.

- 5) Does the Applicant currently operate or plan to operate a website?

Yes ☐ No ☐

If yes, provide all URL addresses for any current or known future company websites and describe whether the information in the website is up to date.

- 6) Has the Applicant, any Entity with an Ownership Interest in the Applicant, or any of the Applicant's Corporate Officers, Senior Officers or Directors been involved in bankruptcy proceedings, or any other legal proceeding undertaken for the purpose of liquidating, reorganizing, refinancing, or otherwise seeking relief from all or some of the Applicant's or its parent's debts, in any jurisdiction over the past 5 years?

Yes ☐ No ☐

If yes, provide details.

- 7) Has the Applicant, any Corporate Officers, Senior Officers, Directors, or any Individual/Entity with an Ownership Interest in the Applicant ever been involved or associated with a previous application to the FCC?

Yes ☐ No ☐

If yes, provide application identifying information.

- 8) Has the Applicant, any Corporate Officers, Senior Officers, Directors, or any Individual/Entity with an Ownership Interest in the Applicant ever been involved or associated with a previous filing with the Committee on Foreign Investment in the United States (CFIUS)?

Yes ☐ No ☐

If yes, provide filing identifying information.

- 9) Has the Applicant, any Corporate Officers, Senior Officers, Directors, or any Individual/Entity with an Ownership Interest in the Applicant ever been blocked, sanctioned, penalized, or had an authorization or other permission revoked/terminated by the FCC?

Yes ☐ No ☐

If yes, provide details.

- 10) Has the Applicant, any Corporate Officers, Senior Officers, Directors, or any Individual/Entity with an Ownership Interest in the Applicant ever been blocked, sanctioned, penalized, or had an authorization or other permission prohibited, suspended, or revoked by CFIUS?

Yes ☐ No ☐

If yes, provide details.

- 11) Has the Applicant, any Corporate Officers, Senior Officers, Directors, or any Individual/Entity with an Ownership Interest in the Applicant, ever been convicted of any felony (an offense carrying a maximum potential sentence of a term of imprisonment of more than a year) in the United States or any other country? This includes any settlements or negotiated resolutions, non-prosecution agreements, or deferred prosecution agreements.

Yes ☐ No ☐

If yes, provide details, including name(s) of the Individual and/or Entity involved, dates, offenses, jurisdiction/court, and sentence.

- 12) Has the Applicant, any Corporate Officers, Senior Officers, Directors, or any Individual/Entity with an Ownership Interest in the Applicant, ever been subject to any criminal, administrative, or civil penalties imposed for violating the regulations of the FCC, the U.S. Department of State, U.S. Department of the Treasury (including, but not be limited to, the Internal Revenue Service, Office of Foreign Assets Control, Financial Crimes Enforcement Network (FinCEN), or the Office of the Comptroller of the Currency), U.S. Department of Energy, U.S. Department of Commerce, U.S. Federal Trade Commission, U.S. Securities and Exchange Commission, U.S. Environmental Protection Agency, the World Bank Group, or the U.S. Commodity Futures Trading Commission, or for violating the regulations of any comparable state or foreign agency? This includes any settlements or negotiated resolutions, non-prosecution agreements, or deferred prosecution agreements.

Yes ☐ No ☐

If yes, provide details, including name(s) of the Individual and/or Entity involved, dates, violations, agency, penalty, and if a fine was imposed, status of payment.

- 13) Has the Applicant, any investor with an Ownership Interest in the Applicant, any of its Corporate Officers, or any associated foreign entities, ever been on the Specially Designated Nationals And Blocked Persons List (SDN List), the BIS Unverified List or Entity List in 15 CFR part 744, or equivalent list of the United Nations Security Council or European Union?

Yes ☐ No ☐

If yes, describe in detail, including providing the specific category of list, the name of the Individual or Entity placed on the list, the date the Individual or Entity was placed on the list, and the factual circumstances underlying the reason for the Individual or Entity being placed on the list.

- 14) Has the Applicant, any Corporate Officers, Senior Officers, Directors, or any Individual/Entity with an Ownership Interest in the Applicant, ever been investigated, arraigned, arrested, indicted or convicted of any of the following:

a) Criminal violations of U.S. law, including espionage-related acts or criminal violations of the International Trade in Arms Regulations (ITAR) or the Export Administration Regulations (EAR)?

Yes ☐ No ☐

b) Deceptive sales practices, violations of the Consumer Fraud Act and regulations, and/or other fraud or abuse practices whether pursuant to Federal, state, or local law?

Yes ☐ No ☐

c) Violations of Federal, state, or local law in connection with the provision of telecommunications services, equipment and/or products and/or any other practices regulated by the Telecommunications Act of 1996 and/or by state public utility commissions?

Yes ☐ No ☐

If yes to any of the above, describe in detail, including name(s) of Corporate Officers and Senior Officers involved, date(s), and current status or final disposition of matter, including any terms of settlement. Provide any available supporting documentation.

Section IV: Applicant Operations

15) Has the Applicant been operational over the course of the current or previous year?

Yes ☐ No ☐

If yes, answer the following:

- a) Provide separately for each year its gross revenue.
- b) Provide separately for each year the Cost of Goods Sold (COGS).
- c) What was the total amount of COGS allocated for telecommunications equipment and service types?
- d) Describe the customer base of the Applicant (business, residential, carrier, enterprise).
- e) Describe, for all services provided to each category of customer (e.g., enterprise, residential, carrier, etc.):
 - i. Total number of subscribers;
 - ii. Total annual gross revenue for preceding fiscal year; and
 - iii. Percentage of total gross revenue per category of customer for preceding fiscal year.

16) List all expected and actual Federal, state, and local government customers including pursuant to any classified contracts and include a description of all services to be provided, or services that are currently being provided, to such customers.

17) Name each of the Applicant's Senior Officers and Directors and for each provide the following:

- a) Explain the nature and extent of each Senior Officer's or Director's involvement in the Applicant; and
- b) Provide the countries of citizenship, date and place of birth, U.S. alien number (indicate whether the individual is a U.S. Lawful Permanent Resident) and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses and all phone numbers. PII may be provided in Appendix G.

18) Identify the Senior Officer or employee (who is a U.S. citizen residing in the United States with an active security clearance or who is eligible to obtain one) who will be the Applicant's authorized law enforcement point of contact responsible for accepting and responding to requests or compulsory processes from U.S. law enforcement or other U.S. government agencies.

- a) Explain the Individual's relationship to the Applicant and provide name, all countries of citizenship, date and place of birth, U.S. social security number, all passport identifying information (including number and country), all residence addresses, all business addresses and all phone numbers. Also identify whether the Individual has an active U.S. Government security clearance. PII may be provided in Appendix G.

19) Identify whether, if required by law, regulation or license condition, the Applicant will report to the appropriate law enforcement agencies, immediately upon discovery:

- a) Any act of compromise of a lawful interception of communications?
Yes ☐ No ☐
- b) Any unauthorized access to customer information and/or call-identifying information?
Yes ☐ No ☐
- c) Any artificially inflated or fraudulent call traffic detected on your network?
Yes ☐ No ☐
- d) Any felony (an offense carrying a maximum potential sentence of a term of imprisonment of more than a year) conviction, U.S. or foreign, of the Applicant or its officers/directors, or any Individual/Entity Ownership Interest in the Applicant?
Yes ☐ No ☐
- e) Any act of unlawful electronic surveillance that occurred on its premises or via electronic systems under its control?
Yes ☐ No ☐

20) Will the Applicant store and/or maintain any U.S. communications content, transactional data, call-associated data, billing records or other subscriber information?

Yes ☐ No ☐

If yes, answer the following:

- a) Describe the types of records that will be stored.
- b) Provide all addresses of locations where such records will be stored and/or remotely accessed/managed via electronic systems.
- c) If any storage location differs from the Applicant's address, explain the general purpose of the location and its function within the Applicant's business.
- d) If any of the records will be accessible from outside the United States, explain where, how, and who will have access to them.
- e) Describe all physical/electronic security measures utilized for all locations/systems to protect the confidentiality of records.

21) Will any Non-U.S. Individual have access to one or more of the following:

- a) Physical facilities and/or equipment under the Applicant's control?

Yes ☐ No ☐

If yes, provide the identity of the Individual(s) and explain the type(s) of access that will be provided.

- b) Customer records, including Customer Proprietary Network Information (CPNI), billing records, and Call Detail Records (CDRs)?

Yes ☐ No ☐

If yes, provide identity of the Individual(s) and explain the type(s) of access and records that will be provided.

- c) Network control, monitoring, and/or auditing features?

Yes ☐ No ☐

If yes, explain the type(s) of access that will be provided, and how access will be logged and archived.

- d) Electronic interfaces that allow control and/or monitoring of the infrastructure under the Applicant's control including, but not limited to, access to actual communications content and data?

Yes ☐ No ☐

If yes, provide the identity of the Individual(s) and explain the type(s) of access and control that will be provided.

For each Individual identified in response to these questions, provide the following information: name, countries of citizenship, date and place of birth, U.S. alien number and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. PII may be provided in Appendix G.

- 22) What access control/security policies (physical and cyber) are in place, or will be in place prior to commencing operations, for your network? If the policies exist and are available in writing, provide copies of these policies.

- 23) What encryption products/technologies have been installed on this network, or will be installed prior to commencing operations?

- 24) Does/will the Applicant have any screening and/or vetting procedures which will be applied to U.S. or non-U.S. Individuals who have access, remote or otherwise, to the Applicant's communications network facilities, equipment, or data?

Yes ☐ No ☐

If yes, explain all such procedures.

- 25) Identify whether, if required by law, regulation, or a license condition, the Applicant will inform the National Security Division (NSD) of the U.S. Department of Justice if, in the future, any record storage/access location is transferred and/or newly established outside of the United States.

Yes ☐ No ☐

- 26) Explain how the Applicant would make any and all records not stored in the United States electronically available in the United States within 5 business days pursuant to a lawful request to the authorized law enforcement point of contact identified above.
- 27) Describe all lawful intercept capabilities of the Applicant and its Ownership Interest holders.
- 28) What, if any, outside capabilities via Remote Access will exist within the Applicant to control or monitor operations over the network (e.g., audit mechanisms, record access monitoring)?
- 29) Do/will any third-party Individual or Entity have Remote Access to the Applicant's network, systems, or records to provide Managed Services?
Yes ☐ No ☐

If yes, provide a detailed explanation.

Section V: Applicant's Services

- 30) Provide a general summary of the nature of the Applicant's current and planned services and operations, including an explanation of the Applicant's intended overall business model and its relationship with any sister and/or partner companies.
- 31) Why is the Applicant seeking an FCC Authorization?
- 32) Provide all addresses of the present and anticipated physical locations for all of the Applicant's network equipment, data centers, and infrastructure, advise whether they are owned or leased--if leased, provide details of the owner(s) and a list of goods/services the owner(s) provides--and the make and model of the primary equipment used, including, but not be limited to, the portions of the network covered below:
- a) Describe the carrier transport facilities (e.g., T1, DS3, Optical Carrier) that will enable customer data flow into and out of owned and/or leased equipment.
- b) Will the Applicant be operating any physical and/or virtual telecommunications switching platforms (e.g., TDM and/or VoIP switches)?
Yes ☐ No ☐
- If yes, provide a network architecture diagram that shows all switches and connection points.
- c) Provide a description of any other intended network equipment and/or proposed infrastructure (e.g., routers, media gateways, multiplexing/cross-connect facilities, signaling devices, data centers, other equipment).
- d) Does the Applicant have a network topology map that shows its Points of Presence (POPs), Network Operation Centers (NOC), and other network elements?
Yes ☐ No ☐

If yes, attach to your response.

- e) Is the Applicant or its affiliates or anyone else able to control operations at any POP and/or NOC from any overseas locations?

Yes ☐ No ☐

If yes, describe the nature of the foreign-based control, where it is, who has the control, and how?

- 33) Will the Applicant use interconnecting carriers and/or peering relationships?

Yes ☐ No ☐

If yes, provide details and list the carriers.

- 34) Will the Applicant rely on underlying carrier(s) to furnish services to its customers and/or resell any services?

Yes ☐ No ☐

If yes, provide details and list whose services and what services will be resold.

- 35) In what manner will services be delivered to customers?

- 36) Does/will the Applicant serve any sectors of U.S. critical infrastructure?

Yes ☐ No ☐

If yes, check all that apply:

- | | |
|--|---|
| a. <input type="checkbox"/> Defense Industrial Base | i. <input type="checkbox"/> Information Technology |
| b. <input type="checkbox"/> U.S. Intelligence Community | j. <input type="checkbox"/> Chemical |
| c. <input type="checkbox"/> Emergency Services
(i.e., Federal, state, local law enforcement,
fire, police) | k. <input type="checkbox"/> Commercial Facilities |
| d. <input type="checkbox"/> Government Facilities
(i.e., Federal, state, local entities) | l. <input type="checkbox"/> Agriculture and Food Supply |
| e. <input type="checkbox"/> Banking and Finance | m. <input type="checkbox"/> Health Care |
| f. <input type="checkbox"/> Nuclear Reactors, Materials, or Waste | n. <input type="checkbox"/> National Monuments |
| g. <input type="checkbox"/> Drinking Water and Water Supply | o. <input type="checkbox"/> Transportation |
| h. <input type="checkbox"/> Energy | p. <input type="checkbox"/> Postal Shipping |
| | q. <input type="checkbox"/> Dams |
| | r. <input type="checkbox"/> Other (explain in detail) |

Section VI: Applicant Services Portfolio Checklist and Reference Questions

Instructions: Check all applicable boxes that reflect the types of telecommunication services the Applicant intends to provide in the United States only. Do not select any services that will be provided outside the United States.

For each checked box: (1) provide a **separate and full explanation** at the end of this questionnaire and (2) answer the Reference Questions below the table regarding the services you have indicated in the checklist.

PROPOSED SERVICES	
VoIP (Voice over Internet Protocol)	<input type="checkbox"/>
POTS (Plain Old Telephone Service)	<input type="checkbox"/>
TDM (Time Division Multiplexing)	<input type="checkbox"/>
Voicemail	<input type="checkbox"/>
PBX (Private Branch Exchange)	<input type="checkbox"/>
Centrex (Hosted/Managed PBX)	<input type="checkbox"/>
Callback Service	<input type="checkbox"/>
Calling Card	<input type="checkbox"/>
Dial Tone Service	<input type="checkbox"/>
Issue DID (Direct Inward Dial) Local Telephone Numbers	<input type="checkbox"/>
Local Exchange Service	<input type="checkbox"/>
Local Toll Service	<input type="checkbox"/>
Domestic/International Long Distance (Interexchange Service)	<input type="checkbox"/>
Tollfree Service	<input type="checkbox"/>
IVR (Interactive Voice Response)	<input type="checkbox"/>
Conference Calling	<input type="checkbox"/>
Operator Service	<input type="checkbox"/>
Directory Assistance	<input type="checkbox"/>
Dial Around Service (1010XXX Casual Calling)	<input type="checkbox"/>
Switched Access	<input type="checkbox"/>
Special Access (Dedicated Line)	<input type="checkbox"/>
Mobile Top Up/Reload Services	<input type="checkbox"/>
Mobile Network Operator Services (MNO)	<input type="checkbox"/>
Mobile Virtual Network Operator Services (MVNO)	<input type="checkbox"/>
Automatic Call Distribution (ACD)	<input type="checkbox"/>
Other	<input type="checkbox"/>
	<input type="checkbox"/>
Data/Private Line	<input type="checkbox"/>
ISP (Internet Service Provider)	<input type="checkbox"/>
VPN (Virtual Private Network)	<input type="checkbox"/>
Web Hosting	<input type="checkbox"/>
LAN (Local Area Network)	<input type="checkbox"/>
WAN (Wide Area Network)	<input type="checkbox"/>
ISDN (Integrated Services Digital Network) BRI (Basic Rate Interface)	<input type="checkbox"/>
ISDN PRI (Primary Rate Interface)	<input type="checkbox"/>
DSL (Digital Subscriber Line)	<input type="checkbox"/>
Frame Relay	<input type="checkbox"/>
Email	<input type="checkbox"/>
International Voice/Data Service	<input type="checkbox"/>
Wireless/Mobile Voice/Data Services	<input type="checkbox"/>
Satellite Services	<input type="checkbox"/>
RF (Radio Frequency), Microwave	<input type="checkbox"/>
Video	<input type="checkbox"/>
Cloud Services	<input type="checkbox"/>
Other	<input type="checkbox"/>
	<input type="checkbox"/>
Routing, Signaling Services	<input type="checkbox"/>

Transport Facilities	<input type="checkbox"/>
Leased Lines	<input type="checkbox"/>
Collocation Services	<input type="checkbox"/>
Other	<input type="checkbox"/>

Reference Questions:

Instructions: Answer each question below as it relates to each of the services selected in the above table.

- 1) In what manner will the service(s) be delivered to your customers?
- 2) What kind of network infrastructure will be utilized to deliver the service(s)?
- 3) What equipment (manufacturer, make and model) and software version will be utilized to provide the service(s)? Will the software be regularly updated?
- 4) Will the service(s) be facilities-based, resold, or both? Describe in detail.
- 5) Are you planning to implement and deploy 5G? If so, describe the plans, approach, anticipated services, and the intended vendors.

WARNING

If an Applicant knowingly and willfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, the Applicant may be subject to prosecution under Title 18, United States Code, Section 1001. The FCC may also terminate, revoke, or render null and void any license or authorization granted in this matter if any responses provided are false or intentionally misleading.

Applicant Certification

Pursuant to Title 28, United States Code, Section 1746, I, an authorized representative of the Applicant, declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this _____ day of _____, year of _____.

Representative Name: _____

Representative Title: _____

Representative Signature: _____

Appendix B

Standard Questions for an Application for an Assignment or Transfer of Control of an International Section 214 Authorization

Applicants:

FCC File Number(s):

Purpose: This list of standard questions solicits the initial information that the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (Committee) will review in connection with any referral of the above-referenced application by the Federal Communications Commission (FCC) in order to assess any national security and law enforcement concerns raised by the application. After review, the Committee may request additional information, including through tailored questions. The 120-day initial review period will typically start on the date the Chair of the Committee determines that your responses to these standard questions and any tailored questions, when required, are complete. If the Committee determines no tailored questions are necessary, the 120-day initial review period will start no more than 30 days after the FCC's referral, on the date the Committee informs the FCC that the responses to the standard questions are complete and that no tailored questions are required. If you fail to provide timely responses to any Committee requests for information, the Committee may recommend that the FCC dismiss the application without prejudice.

Dissemination of Information: The information received by the Committee pursuant to 47 CFR 1.40003 and any subsequent requests for information by the Committee may be shared and used in accordance with Section 8 of Executive Order 13913 of April 4, 2020, Establishing the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector, 85 FR 19643 (Apr. 8, 2020).

Instructions

- 1) **Complete all Sections:** When a “Yes” answer is indicated, provide further information as appropriate. The questions seek further details regarding the Applicant and its security-related practices, and some questions are particularly directed at identifying and assessing the complete scope of the equipment that the Applicant will be operating and the services the Applicant will be offering should the FCC grant those authorities. Accordingly, in answering the “Section V: Applicants’ Services” questions and “Section VI: Applicant Services Portfolio Checklist and Reference Questions,” the Applicants must file complete and accurate responses and identify all switches, routing equipment, and all services offered in retail markets.
- 2) **Response Format:** Uniquely and sequentially Bates-number your responses to the standard questions, including any attachments, with an endorsement on each page. The Bates number must be a unique, consistently formatted identifier; the number of digits in the numeric portion of the format should not change in subsequent productions, if any, nor should spaces, hyphens, or other separators be added or deleted. Produce any Excel documents in native format (if desired, you may also produce a PDF version for record keeping purposes).
- 3) **Identify Sensitive Information:** Specifically 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. If 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. Personally Identifiable Information (PII) may be submitted in a separate attachment. The PII Supplement is Appendix G.

- 4) **Individuals' Names:** For names that follow different naming conventions, such as the use of surnames as first names (e.g., Korean names), or the use of mother's last name as one of two last names that are often hyphenated (e.g., Spanish names), follow standard English convention for purposes of completing this information. For example, if the name is Kim Chul-su, write "Chul-su Kim" in the form. If the name in Spanish is Juan Garcia-Reyes, write "Juan Garcia Reyes."
- 5) **Residential Addresses:** Contract mail receipt locations, post office boxes, co-working, or shared virtual locations may not be used in lieu of residence addresses.
- 6) **Business Addresses:** For each business address, clearly indicate whether the address is a shared business venue, co-working location, virtual office, or traditional physical office.
- 7) **Obligation to Update:** The Applicant must inform the Committee if there is any material change to any of the information provided in the Applicant's responses while the Committee's review is ongoing, including, but not limited to, changes in ownership, equipment, and Communications Assistance for Law Enforcement Act (CALEA) compliance.
- 8) **Definitions** – These terms, as used in this questionnaire, have the following definitions:
 - A "Controlling Interest" is generally a 50% or greater Ownership Interest (either equity or voting). Also, a Controlling Interest shall be determined on a case-by-case basis considering the distribution of ownership, and the relationships of the owners, including family relationships. The term Controlling Interest includes Individuals or Entities with positive or negative *de jure* or *de facto* control of the Applicant/Licensee. *De jure* control includes holding 50% or more of the voting stock of a corporation or holding a general partnership interest in a partnership. Ownership Interests that are held indirectly by any party through one or more intervening corporations may be determined by successive multiplication of the ownership percentages for each link in the vertical ownership chain except that if the ownership percentage for an interest in any link in the chain is equal to or exceeds 50% or represents actual control, it may be treated as if it were a 100% interest. *De facto* control is determined on a case-by-case basis. Examples of *de facto*, or actual, control include constituting or appointing 50% or greater of the board of directors or management committee; having authority to appoint, promote, demote, and fire senior executives that control the day-to-day activities of the Licensee; or playing an integral role in management decisions. In the case of a consortium, each member of the consortium shall be considered to have a Controlling Interest in the consortium.
 - "Ultimate Owner" and "Ultimate Parent" refer to the Entity or Individual that ultimately owns and controls the Applicant/Licensee.
 - "Immediate Owner" refers to the Entity or Individual in the vertical ownership chain that immediately owns and controls the Applicant/Licensee. In other words, the Immediate Owner is the Entity or Individual in the ownership chain that is closest to the Applicant/Licensee.

- An Entity or Individual with an “Ownership Interest” is any Entity in the ownership chain with more than a 5% attributable interest in the Applicant/Licensee, including the “Ultimate Owner/Parent” and the “Immediate Owner,” and all Controlling Interest holders. Note that Controlling Interests include *de facto* controlling interests, for which equity and/or voting ownership may be below 5%.
- “Corporate Officer” refers to any Individual hired or appointed by the Entity’s board of directors that has actual or apparent authority to exercise day-to-day management responsibilities over an Entity.
- “Director” refers to any Individual serving on an Applicant’s board of directors or similar governing body organized to set policies for corporate management of or oversight for an Applicant/Licensee.
- “Entity” includes a partnership, association, estate, trust, corporation, limited liability company, consortium, joint venture, governmental authority, or other organization.
- An “Equity Interest Holder” is any Individual or Entity that has the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, a share or other ownership stake in the Applicant.
- The term “Foreign Government” includes any person or group of persons exercising sovereign *de facto* or *de jure* political jurisdiction over any country, other than the United States, or over any part of such country, and includes any subdivision of any such group and any group or agency to which such sovereign *de facto* or *de jure* authority or functions are directly or indirectly delegated. Such term shall include any faction or body of insurgents within a country assuming to exercise governmental authority whether such faction or body of insurgents has or has not been recognized by the United States.
- “Individual” refers to a natural person, as distinguished from an Entity.
- “Managed Services” or “Enterprise Services” refers to the provision of a complete, end-to-end communications solution to customers.
- A “Non-U.S. Individual” is an Individual who is not a U.S. citizen.
- An “Owner” is an Individual or Entity that holds an Ownership Interest in the Applicant/Licensee.
- An “Ownership Interest” is 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 (i.e., all entities that exist in the ownership structure between the Applicant itself and its Ultimate Parent).
- “Remote Access” is 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.
- “Senior Officer” refers to the Chief Executive Officer, President, Chief Financial Officer, Chief Information Officer, Chief Technical Officer, Chief Operating Officer, or any other similarly situated Individual that has actual or apparent authority to act on behalf of the Entity.

Section I: Identification of Relevant Parties

- 1) Provide the name, address, principal place of business, and place of incorporation of Relevant Parties. For the purposes of the following questions “Relevant Parties” means the following:
 - a) Current International Section 214 Authorization Holder(s) (“**Authorization Holder(s)**”);

- b) Proposed International Section 214 Authorization Holder(s) (“**Proposed Authorization Holder(s)**”);
- c) Any Individual and Entity with an Ownership Interest in the Authorization Holder(s) (“**Owner(s)/Controller(s)**”);
- d) Any Individual or Entity with an Ownership Interest in the Proposed Authorization Holder(s) (“**Proposed Owner(s)/Controller(s)**”):

Section II: Applicants’ Ownership

- 2) Identify each Individual or Entity that holds/will hold an Ownership Interest in the Relevant Parties, specifically identifying any foreign Entities or Foreign Government-controlled entities, including the ultimate parent owner of the Relevant Parties and any other Individuals/Entities holding an Ownership Interest in the chain of ownership.
 - a) For each such Individual or Entity with an Ownership Interest in the Relevant Parties, include a clear explanation of its involvement in the Proposed Authorization Holder(s), including whether it will have a management role; and
 - b) Provide all necessary identifying information, as follows:
 - i) For Individuals, provide the name (including all names and aliases used by that Individual), country of citizenship (indicate whether the Individual is a dual citizen and all countries where citizenship is held), date and place of birth, U.S. alien number (indicate whether the individual is a U.S. Lawful Permanent Resident) and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. Personally Identifiable Information (PII) may be provided in Appendix G, a PII Supplement.
 - ii) For Entities, provide country of incorporation (if the United States, include state of incorporation), principal place of business, general business type (e.g., holding company, investment firm), all business addresses, email addresses, and related phone numbers.

Section III: Applicant Details

- 3) Do any of the Relevant Parties have existing (or planned) relationships/partnerships (formal or informal), funding or service contracts, directly or indirectly, with any foreign Individuals, foreign companies, Foreign Governments, and/or any Foreign Government-controlled companies?

Yes ☐ No ☐

If yes, indicate whether the relationship/partnership includes a management role by any foreign Individuals, foreign companies, or Foreign Governments. Provide the name(s) of the foreign Individuals, foreign companies, and Foreign Governments, and explain the nature of the relationship/partnership, including whether the relationship/partnership currently exists and/or is intended to continue in the future.

- 4) Identify the total number of current employees, and planned number of employees for each of the Proposed Authorization Holder(s) and Proposed Owner(s)/Controller(s) for the next 12 months.

- 5) Does the Proposed Authorization Holder(s) and/or the Proposed Owner(s)/Controller(s) currently operate or plan to operate a website?

Yes ☐ No ☐

If yes, provide all URL addresses for any current or known future websites and describe whether the information in the website is up to date.

- 6) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors been involved in bankruptcy proceedings, or any other legal proceeding undertaken for the purpose of liquidating, reorganizing, refinancing, or otherwise seeking relief from all or some of the Applicant's or its parent's debts, in any jurisdiction over the past 5 years?

Yes ☐ No ☐

If yes, describe in detail.

- 7) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been involved or associated with a previous application to the FCC?

Yes ☐ No ☐

If yes, provide the application identifying information.

- 8) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been blocked, sanctioned, penalized, or had an authorization or other permission revoked/terminated by the FCC?

Yes ☐ No ☐

If yes, describe in detail.

- 9) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been involved or associated with a previous filing to the Committee on Foreign Investment in the United States (CFIUS)?

Yes ☐ No ☐

If yes, provide the filing identifying information.

- 10) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been blocked, sanctioned, penalized, or had an authorization or other permission prohibited, suspended, or revoked by CFIUS?

Yes ☐ No ☐

If yes, describe in detail.

- 11) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been convicted of any felony (an offense carrying a maximum potential sentence of a term of imprisonment of more than a year) in the United States or any other country? This includes any settlements or negotiated resolutions, non-prosecution agreements, or deferred prosecution agreements.

Yes ☐ No ☐

If yes, provide the details including name(s) of the Individual or Entity involved, dates, offenses, jurisdiction/court, and sentence.

- 12) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors been subject to any criminal, administrative, or civil penalties imposed for violating the regulations of the FCC, the U.S. Department of State, U.S. Department of the Treasury (including, but not be limited to, the Internal Revenue Service, Office of Foreign Assets Control, Financial Crimes Enforcement Network (FinCEN), or the Office of the Comptroller of the Currency), U.S. Department of Energy, U.S. Department of Commerce, U.S. Federal Trade Commission, U.S. Securities and Exchange Commission, U.S. Environmental Protection Agency, the World Bank Group, or the U.S. Commodity Futures Trading Commission, or for violating the regulations of any comparable state or foreign agency? This includes any settlements or negotiated resolutions, non-prosecution agreements, or deferred prosecution agreements.

Yes ☐ No ☐

If yes, provide the details including name(s) of the Individual or Entity involved, dates, violations, agency, penalty, and if a fine was imposed, status of payment.

- 13) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, Directors, or any associated foreign entities, ever been on the Specially Designated Nationals And Blocked Persons List (SDN List), the BIS Unverified List or Entity List in 15 CFR part 744, or equivalent list of the United Nations Security Council or European Union?

Yes ☐ No ☐

If yes, describe in detail, including providing the specific category of list, the name of the Individual or Entity placed on the list, the date the Individual or Entity was placed on the list, and the factual circumstances underlying the reason for the Individual or Entity being placed on the list.

- 14) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been investigated, arraigned, arrested, indicted or convicted of any of the following:

- a) Criminal violations of U.S. law, including espionage-related acts or criminal violations of the International Trade in Arms Regulations (ITAR) or the Export Administration Regulations (EAR)?

Yes ☐ No ☐

- b) Deceptive sales practices, violations of the Consumer Fraud Act and regulations, and/or other fraud or abuse practices whether pursuant to Federal, state, or local law?

Yes ☐ No ☐

- c) Violations of Federal, state, or local law in connection with the provision of telecommunications services, equipment and/or products and/or any other practices regulated by the Telecommunications Act of 1996 and/or by state public utility commissions?

Yes ☐ No ☐

If yes to any of the above, describe in detail, including name(s) of the Individual or Entity involved, date(s), and current status or final disposition of matter, including any terms of settlement. Provide any available supporting documentation.

Section IV: Applicant Operations

- 15)** Have any of the Relevant Parties been operational over the course of the current or previous year?

Yes ☐ No ☐

If yes, answer the following:

- a) Provide separately for each Entity for each year the gross revenue.
 - b) Provide separately for each Entity for each year the Cost of Goods Sold (COGS).
 - c) What was the total amount of COGS allocated for telecommunications equipment and service types?
 - d) Describe the customer base of the Authorization Holder(s) and Proposed Authorization Holder(s) (business, residential, carrier, enterprise).
 - e) Describe, for all services provided to each category of customer (e.g., enterprise, residential, carrier, etc.):
 - i. Total number of subscribers;
 - ii. Total annual gross revenue for preceding fiscal year; and
 - iii. Percentage of total gross revenue per category of customer for preceding fiscal year.
- 16)** List all expected and actual Federal, state, and local government customers of the Authorization Holder(s) and the Proposed Authorization Holder(s), including pursuant to any classified contracts, and include a description of all services to be provided, or services that are currently being provided, to such customers.
- 17)** Name the Senior Officers and Directors of the Proposed Authorization Holder(s) and the Proposed Owner(s)/Controller(s) and for each provide the following:
- a) Explain the nature and extent of each Senior Officer's or Director's involvement in the Applicant; and
 - b) Provide the countries of citizenship, date and place of birth, U.S. alien number (indicate whether the individual is a U.S. Lawful Permanent Resident) and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. PII may be provided in Appendix G.
- 18)** Identify the Individual (who is a U.S. citizen residing in the United States with an active security clearance or who is eligible to obtain one) who will be the Proposed Authorization

Holder(s)'s point of contact for law enforcement concerns, including responding to requests or compulsory processes from U.S. law enforcement or other U.S. government agencies.

- a) Explain the relationship to the Proposed Authorization Holder(s) and provide name, all countries of citizenship, date and place of birth, U.S. social security number (if applicable), all passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. Also identify whether the Individual has an active U.S. Government security clearance. PII may be provided in Appendix G.

19) Identify whether, if required by law, regulation, or a license condition, the Proposed Authorization Holder(s) will report to the appropriate law enforcement agencies, immediately upon discovery:

- a) Any act of compromise of a lawful interception of communications?
Yes ☐ No ☐
- b) Any unauthorized access to customer information and/or call-identifying information?
Yes ☐ No ☐
- c) Any artificially inflated or fraudulent call traffic detected on your network?
Yes ☐ No ☐
- d) Any felony (an offense carrying a maximum potential sentence of a term of imprisonment of more than a year) conviction, U.S. or foreign, of the Applicant or its officers/directors, or any Individual or Entity Ownership Interest in the Applicant? Yes ☐ No ☐
- e) Any act of unlawful electronic surveillance that occurred on its premises or via electronic systems under its control?
Yes ☐ No ☐

20) Will the Proposed Authorization Holder(s) store and/or maintain any U.S. communications content, transactional data, call-associated data, billing records or other subscriber information?
Yes ☐ No ☐

If yes, answer the following:

- a) Describe the types of records that will be stored.
- b) Provide all addresses of locations where such records will be stored and/or remotely accessed/managed via electronic systems.
- c) If any storage location differs from the Applicant's address, explain the general purpose of the location and its function within the Applicant's business.
- d) If any of the records will be accessible from outside the United States, explain where, how, and who will have access to them.

- e) Describe all physical/electronic security measures utilized for all locations/systems to protect the confidentiality of records.

21) Will any Non-U.S. Individual have access to one or more of the following:

- a) Physical facilities and/or equipment under the Proposed Authorization Holder(s) or Proposed Owner(s)/Controller(s) control?

Yes ☐ No ☐

If yes, provide the identity of the Individual (s) and explain the type of access that will be provided.

- b) Customer records, including Customer Proprietary Network Information (CPNI), billing records, and Call Detail Records (CDRs)?

Yes ☐ No ☐

If yes, provide the identity of the Individual(s) and explain the type of access and records that will be provided.

- c) Network control, monitoring, and/or auditing features?

Yes ☐ No ☐

If yes, explain the type of access that will be provided, and how access will be logged and archived.

- d) Electronic interfaces that allow control and/or monitoring of the infrastructure under the Proposed Authorization Holder(s) or the Proposed Owner(s)/Controller(s)'s control including, but not limited to, access to actual communications content and data?

Yes ☐ No ☐

If yes, provide the identity of the Individual(s) and explain the type of access and control that will be provided.

For each Individual identified in response to these questions, provide the following information: name, countries of citizenship, date and place of birth, U.S. alien number and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. PII may be provided in Appendix G.

22) What access control/security policies (physical and cyber) are in place, or will be in place prior to commencing operations, for the Proposed Authorization Holder(s) or the Proposed Owner(s)/Controller(s)'s network? If the policies exist and are available in writing, provide copies of these policies.

23) What encryption products/technologies have been installed on these networks or will be installed prior to commencing operations?

24) Does/will the Proposed Authorization Holder(s) or the Proposed Owner(s)/Controller(s) have any screening and/or vetting procedures which will be applied to U.S. or non-U.S. Individuals who have access, remote or otherwise, to communications network facilities, equipment, or data?

Yes ☐ No ☐

If yes, explain all such procedures.

- 25) Identify whether, if required by law, regulation, or a license condition, the Proposed Authorization Holder(s) will inform the National Security Division (NSD) of the U.S. Department of Justice if, in the future, any record storage/access location is transferred and/or newly established outside of the United States.

Yes ☐ No ☐

- 26) Explain how the Proposed Authorization Holder(s) would make any and all records not stored in the United States electronically available in the United States within 5 business days pursuant to a lawful request to the authorized law enforcement point of contact identified above.

- 27) Describe all lawful intercept capabilities of the Authorization Holder, the Proposed Authorization Holder and/or the Proposed Ownership Interest holders.

- 28) What, if any, outside capabilities via Remote Access will exist within the Proposed Authorization Holder(s) to control or monitor operations over the network (e.g., audit mechanisms, record access monitoring)?

- 29) Do/will any third-party Individual or Entity have Remote Access to the Proposed Authorization Holder(s) network, systems, or records to provide Managed Services?

Yes ☐ No ☐

If yes, provide a detailed explanation.

- 30) Do/will any third parties have access to the Applicant's network, systems, or records for any other reason (e.g., sharing subscriber data for marketing purposes)?

Yes ☐ No ☐

If yes, provide a detailed explanation.

Section V: Applicants' Services

- 31) Provide a general summary of the nature of the Authorization Holder(s) and Proposed Authorization Holder(s)'s current and planned services and operations, including an explanation of the intended overall business model and its relationship with any sister and/or partner companies.

- 32) Provide all addresses of the present and anticipated physical locations for all of the Proposed Authorization Holder(s) and the Proposed Owner(s)/Controller(s) network equipment, data centers, and infrastructure, whether owned or leased – if leased, provide details of the owners and a list of goods/services the owner provides – and the make and model of the primary equipment used, including, but not be limited to, the portions of the network covered below:

- a) Describe the carrier transport facilities (e.g., T1, DS3, Optical Carrier) that will enable customer data flow into and out of owned and/or leased equipment.

- b) Will the Proposed Authorization Holder(s) be operating any physical and/or virtual telecommunications switching platforms (e.g., TDM and/or VoIP switches)?

Yes ☐ No ☐

If yes, provide a network architecture diagram that shows all switches and connection points.

- c) Provide a description of any other intended network equipment and/or proposed infrastructure (e.g., routers, media gateways, multiplexing/cross-connect facilities, signaling devices, other equipment).
- d) Does the Authorization Holder(s) and/or Proposed Authorization Holder(s) have a network topology map that shows its Points of Presence (POPs), Network Operation Centers (NOC), and other network elements?

Yes ☐ No ☐

If yes, attach to Response.

- e) Will the Proposed Authorization Holder(s) and the Proposed Owner(s)/Controller(s) or its affiliates be able to control operations at any POP and/or NOC from any overseas locations?

Yes ☐ No ☐

If yes, describe the nature of the foreign-based control, where it is, who has the control, and how?

- 33) Will the Proposed Authorization Holder(s) use interconnecting carriers and/or peering relationships?

Yes ☐ No ☐

If yes, provide details and list the carriers.

- 34) Will the Proposed Authorization Holder(s) rely on underlying carrier(s) to furnish services to its customers and/or resell any services?

Yes ☐ No ☐

If yes, provide details and list whose services and what services will be resold.

- 35) In what manner will services be delivered to customers?

- 36) Does/will the Proposed Authorization Holder(s) serve any sectors of U.S. critical infrastructure?

Yes ☐ No ☐

If yes, check all that apply:

- | | |
|---|---|
| a. <input type="checkbox"/> Defense Industrial Base | i. <input type="checkbox"/> Information Technology |
| b. <input type="checkbox"/> U.S. Intelligence Community | j. <input type="checkbox"/> Chemical |
| c. <input type="checkbox"/> Emergency Services | k. <input type="checkbox"/> Commercial Facilities |
| (i.e., Federal, state, local law enforcement, | l. <input type="checkbox"/> Agriculture and Food Supply |
| fire, | m. <input type="checkbox"/> Health Care |

- police)
- d. ☐ Government Facilities
(i.e., Federal, state, local entities)
- e. ☐ Banking and Finance
- f. ☐ Nuclear Reactors, Materials, or Waste
- g. ☐ Drinking Water and Water Supply
- h. ☐ Energy
- n. ☐ National Monuments
- o. ☐ Transportation
- p. ☐ Postal Shipping
- q. ☐ Dams
- r. ☐ Other (explain in detail)

Section VI: Applicant Services Portfolio Checklist and Reference Questions

Instructions: Check all applicable boxes that reflect the types of telecommunication services the Proposed Authorization Holder(s) intends to provide in the United States only. Do not select any services that will be provided outside the United States.

For each checked box: (1) provide a **separate and full explanation** at the end of this questionnaire and (2) answer the Reference Questions below the table regarding the services you have indicated in the checklist.

PROPOSED SERVICES	
VoIP (Voice over Internet Protocol)	<input type="checkbox"/>
POTS (Plain Old Telephone Service)	<input type="checkbox"/>
TDM (Time Division Multiplexing)	<input type="checkbox"/>
Voicemail	<input type="checkbox"/>
PBX (Private Branch Exchange)	<input type="checkbox"/>
Centrex (Hosted/Managed PBX)	<input type="checkbox"/>
Callback Service	<input type="checkbox"/>
Calling Card	<input type="checkbox"/>
Dial Tone Service	<input type="checkbox"/>
Issue DID (Direct Inward Dial) Local Telephone Numbers	<input type="checkbox"/>
Local Exchange Service	<input type="checkbox"/>
Local Toll Service	<input type="checkbox"/>
Domestic/International Long Distance (Interexchange Service)	<input type="checkbox"/>
Tollfree Service	<input type="checkbox"/>
IVR (Interactive Voice Response)	<input type="checkbox"/>
Conference Calling	<input type="checkbox"/>
Operator Service	<input type="checkbox"/>
Directory Assistance	<input type="checkbox"/>
Dial Around Service (1010XXX Casual Calling)	<input type="checkbox"/>
Switched Access	<input type="checkbox"/>
Special Access (Dedicated Line)	<input type="checkbox"/>
Other	<input type="checkbox"/>
Mobile Top Up/Reload Services	<input type="checkbox"/>
Mobile Network Operator Services (MNO)	<input type="checkbox"/>
Mobile Virtual Network Operator Services (MVNO)	<input type="checkbox"/>
Automatic Call Distribution (ACD)	<input type="checkbox"/>
ISP (Internet Service Provider)	<input type="checkbox"/>
Data/Private Line	<input type="checkbox"/>

VPN (Virtual Private Network)	<input type="checkbox"/>	<input type="checkbox"/>
Web Hosting	<input type="checkbox"/>	<input type="checkbox"/>
LAN (Local Area Network)	<input type="checkbox"/>	<input type="checkbox"/>
WAN (Wide Area Network)	<input type="checkbox"/>	<input type="checkbox"/>
ISDN (Integrated Services Digital Network) BRI (Basic Rate Interface)	<input type="checkbox"/>	<input type="checkbox"/>
ISDN PRI (Primary Rate Interface)	<input type="checkbox"/>	<input type="checkbox"/>
DSL (Digital Subscriber Line)	<input type="checkbox"/>	<input type="checkbox"/>
Frame Relay	<input type="checkbox"/>	<input type="checkbox"/>
Email	<input type="checkbox"/>	<input type="checkbox"/>
International Voice/Data Service	<input type="checkbox"/>	<input type="checkbox"/>
Wireless/Mobile Voice/Data Services	<input type="checkbox"/>	<input type="checkbox"/>
Satellite Services	<input type="checkbox"/>	<input type="checkbox"/>
RF (Radio Frequency), Microwave	<input type="checkbox"/>	<input type="checkbox"/>
Video	<input type="checkbox"/>	<input type="checkbox"/>
Cloud Services	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>
Routing, Signaling Services	<input type="checkbox"/>	<input type="checkbox"/>
Transport Facilities	<input type="checkbox"/>	<input type="checkbox"/>
Leased Lines	<input type="checkbox"/>	<input type="checkbox"/>
Collocation Services	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>

Reference Questions

Instructions: Answer each question below as it relates to each of the services selected in the above table.

- 1) In what manner will the service(s) be delivered to customers?
- 2) What kind of network infrastructure will be utilized to deliver the service(s)?
- 3) What equipment (manufacturer, make, and model) and software version will be utilized to provide the service(s)? Will the software be regularly updated?
- 4) Will the service(s) be facilities-based, resold, or both? Describe in detail.
- 5) Are you planning to implement and deploy 5G? If so, describe the plans, approach, anticipated services, and the intended vendors.

WARNING

If an Applicant knowingly and willfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, the Applicant may be subject to prosecution under Title 18, United States Code, Section 1001. The FCC may also terminate, revoke, or render null and void any license or authorization granted in this matter if any responses provided are false or intentionally misleading.

Authorization Holder Certification

Pursuant to Title 28, United States Code, Section 1746, I, an authorized representative of the Authorization Holder, declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this _____ day of _____, year of _____.

Representative Name: _____

Representative Title: _____

Representative Signature: _____

Proposed Authorization Holder Certification

Pursuant to Title 28, United States Code, Section 1746, I, an authorized representative of the Assignee/Transferee, declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this _____ day of _____, year of _____.

Representative Name: _____

Representative Title: _____

Representative Signature: _____

Appendix C

Standard Questions for Submarine Cable Landing License Application

Submarine Cable Name:

Applicant(s):

FCC File Number:

Purpose: This list of standard questions solicits the initial information that the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (Committee) will review in connection with any referral of the above-referenced application by the Federal Communications Commission (FCC) in order to assess any national security and law enforcement concerns raised by the application. After review, the Committee may request additional information from you, including through tailored questions. The 120-day initial review period will typically start on the date the Chair of the Committee determines that your responses to these standard questions and any tailored questions, where required, are complete. If the Committee determines no tailored questions are necessary, the 120-day initial review period will start no more than 30 days after the FCC's referral, on the date the Committee informs the FCC that the responses to the standard questions are complete and that no tailored questions are required. If you fail to provide timely responses to any Committee requests for information, the Committee may recommend that the FCC dismiss the application without prejudice.

Dissemination of Information: The information received by the Committee pursuant to 47 CFR 1.40003 and any subsequent requests for information by the Committee may be shared and used in accordance with Section 8 of Executive Order 13913 of April 4, 2020, Establishing the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector, 85 FR 19643 (Apr. 8, 2020).

Instructions

- 1) **Complete all Sections:** When a "Yes" answer is indicated, provide further information as appropriate. The questions seek further details regarding the Applicant and its security-related practices, and some questions are particularly directed at identifying and assessing the complete scope of the equipment that the Applicant will be operating and the services the Applicant will be offering should the FCC grant those authorities.
- 2) **Response Format:** Uniquely and sequentially, Bates-number your responses to the standard questions, including any attachments, with an endorsement on each page. The Bates number must be a unique, consistently formatted identifier; the number of digits in the numeric portion of the format should not change in subsequent productions, if any, nor should spaces, hyphens, or other separators be added or deleted. Produce any Excel documents in native format (if desired, you may also produce a PDF version for record keeping purposes).
- 3) **Identify Sensitive Information:** Specifically 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. If 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. Personally Identifiable Information (PII) may be submitted in a separate attachment. The PII Supplement is Appendix G.

- 4) **Individuals' Names:** For names that follow different naming conventions, such as the use of surnames as first names (e.g., Korean names), or the use of mother's last name as one of two last names that are often hyphenated (e.g., Spanish names), follow standard English convention for purposes of completing this information. For example, if the name is Kim Chul-su, write "Chul-su Kim" in the form. If the name in Spanish is Juan Garcia-Reyes, write "Juan Garcia Reyes."
- 5) **Residential Addresses:** Contract mail receipt locations, post office boxes, co-working, or shared virtual locations may not be used in lieu of residence addresses.
- 6) **Business Addresses:** For each business address, clearly indicate whether the address is a shared business venue, co-working location, virtual office, or traditional physical office.
- 7) **Obligation to Update:** The Applicant must inform the Committee if there is any material change to any of the information provided in the Applicant's responses while the Committee's review is ongoing, including, but not limited to, changes in ownership, equipment, and Communications Assistance for Law Enforcement Act (CALEA) compliance.
- 8) **Definitions** – These terms, as used in this questionnaire, have the following definitions:
 - "Applicant" shall have the same meaning as the term is defined in 47 CFR 1.767(h).
 - A "Controlling Interest" is generally a 50% or greater Ownership Interest (either equity or voting). Also, a Controlling Interest shall be determined on a case-by-case basis considering the distribution of ownership, and the relationships of the Owners, including family relationships. The term Controlling Interest includes Individuals or Entities with positive or negative *de jure* or *de facto* control of the applicant/licensee. *De jure* control includes holding 50% or more of the voting stock of a corporation or holding a general partnership interest in a partnership. Ownership Interests that are held indirectly by any party through one or more intervening corporations may be determined by successive multiplication of the ownership percentages for each link in the vertical ownership chain except that if the ownership percentage for an interest in any link in the chain is equal to or exceeds 50% or represents actual control, it may be treated as if it were a 100% interest. *De facto* control is determined on a case-by-case basis. Examples of *de facto*, or actual, control include constituting or appointing 50% or greater of the board of directors or management committee; having authority to appoint, promote, demote, and fire senior executives that control the day-to-day activities of the licensee; or playing an integral role in management decisions. In the case of a consortium, each member of the consortium shall be considered to have a Controlling Interest in the consortium.
 - "Ultimate Owner" and "Ultimate Parent" refer to the Entity or Individual that ultimately owns and controls the Applicant/Licensee.
 - "Immediate Owner" refers to the Entity or Individual in the vertical ownership chain that immediately owns and controls the Applicant/Licensee. In other words, the Immediate Owner is the Entity or Individual in the ownership chain that is closest to the Applicant/Licensee.

- An Entity or Individual with an “Ownership Interest” is any Entity in the ownership chain with more than a 5% attributable interest in the Applicant/Licensee, including the “Ultimate Owner/Parent” and the “Immediate Owner,” and all Controlling Interest holders. Note that Controlling Interests include *de facto* controlling interests, for which equity and/or voting ownership may be below 5%.
- “Corporate Officer” refers to any Individual hired or appointed by the Entity’s board of directors that has actual or apparent authority to exercise day-to-day management responsibilities over an Entity.
- “Director” refers to any Individual serving on an Applicant’s board of directors or similar governing body organized to set policies for corporate management of or oversight for an Applicant/Licensee.
- “Entity” includes a partnership, association, estate, trust, corporation, limited liability company, consortium, joint venture, governmental authority, or other organization.
- An “Equity Interest Holder” is any Individual or Entity that has the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, a share or other ownership stake in the Applicant.
- The term “Foreign Government” includes any person or group of persons exercising sovereign *de facto* or *de jure* political jurisdiction over any country, other than the United States, or over any part of such country, and includes any subdivision of any such group and any group or agency to which such sovereign *de facto* or *de jure* authority or functions are directly or indirectly delegated. Such term shall include any faction or body of insurgents within a country assuming to exercise governmental authority whether such faction or body of insurgents has or has not been recognized by the United States.
- “Individual” refers to a natural person, as distinguished from an Entity.
- “Managed Services” or “Enterprise Services” refers to the provision of a complete, end-to-end communications solution to customers.
- A “Non-U.S. Individual” is an Individual who is not a U.S. citizen.
- An “Owner” is an Individual or Entity that holds an Ownership Interest in the Applicant/Licensee.
- An “Ownership Interest” is 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 (i.e., all Entities that exist in the ownership structure between the Applicant itself and its ultimate parent).
- “Principal Equipment” means the primary components of the Domestic Communications Infrastructure (DCI) and the Wet Plant. Principal Equipment includes: network element servers; routers; switches; repeaters; submarine line terminal equipment (SLTE); system supervisory equipment (SSE); signal modulators and amplifiers; power feed equipment (PFE); tilt and shape equalizer units (TEQ/SEQ); optical distribution frames (ODF); branching units (BU); synchronous optical network (SONET), synchronous digital hierarchy (SDH), wave division multiplexing (WDM), dense wave division multiplexing (DWDM), coarse wave division multiplexing (CWDM), or optical carrier network (OCx) equipment, as applicable; and any non-embedded software necessary for the proper monitoring, administration, and provisioning of the submarine cable system (with the exception of commercial-off-the-shelf (COTS) software used for common business functions, e.g., MS Office).
 - “Domestic Communications Infrastructure” or “DCI” means:
 - (a) any portion of the cable system that physically is located in the United States, up to the submarine line terminating equipment, including (if any)

transmission, switching, bridging, and routing equipment, and any associated software (with the exception of COTS software used for common business functions, e.g., MS Office) used by or on behalf of the Applicant to provide, process, direct, control, supervise, or manage domestic communications; and

- (b) Network Operations Center (NOC) facilities.
- “Wet Plant” means hardware components installed and residing on the undersea portion of the submarine cable system, including fiber optic cables, repeaters, branching units, and routers (if any). Wet Plant includes all the components used in order to define the topology of the undersea portion of the submarine cable system.
- “Remote Access” is 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.
- “Senior Officer” refers to the Chief Executive Officer, President, Chief Financial Officer, Chief Information Officer, Chief Technical Officer, Chief Operating Officer, or any other similarly situated Individual that has actual or apparent authority to act on behalf of the Entity.

Section I: Identification of Applicant(s)

- 1) Provide the name, address, principal place of business, and place of incorporation for each Applicant.

Section II: Applicant(s)' Ownership

- 2) Identify all the Owners of the proposed submarine cable system. If more than one, indicate the ownership percentage.
- 3) 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.
 - a) For each such Individual or Entity, include a clear explanation of its involvement in the submarine cable system Applicant, including whether it will have a management role.
 - b) For each such Individual or Entity, provide all identifying information, as follows:
 - i) For Individuals, provide the name (including all names and aliases used by that Individual), country of citizenship (indicate whether the Individual is a dual citizen and all countries where citizenship is held), date and place of birth, U.S. alien number (indicate whether the individual is a U.S. Lawful Permanent Resident) and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. PII may be provided in Appendix G, a PII supplement.
 - ii) For Entities, provide country of incorporation (if United States, include state of incorporation), principal place of business, general business type (e.g., holding company, investment firm, etc.), all business addresses, email addresses, and related phone numbers.
- 4) Provide a detailed ownership structure diagram for each cable Owner.
- 5) Provide the dollar amount that each cable Applicant has invested/will invest in the submarine cable system.
- 6) What is the source of funding for each cable Applicant's investment?
- 7) List all other submarine cable systems in which each cable Applicant or its parents have equity and detail the amount of equity each Applicant holds in each cable system.

Section III: Overview of Submarine Cable System Applicants

- 8) Do any of the submarine cable system Applicants have existing (or planned) relationships/partnerships (formal or informal), funding or service contracts, directly or

indirectly, with any foreign Individuals, foreign Entities, Foreign Governments, and/or any Foreign Government-controlled Entities?

Yes ☐ No ☐

If yes, indicate whether the relationship/partnership includes a management role by any foreign Individuals, foreign Entities or Foreign Governments. Provide the name(s) of the foreign Individuals, foreign entities and Foreign Governments and explain the nature of the relationship/partnership, including whether the relationship/partnership currently exists and/or is intended to continue in the future.

- 9) Do the submarine cable system Applicants currently operate or plan to operate a website?

Yes ☐ No ☐

If yes, provide all URL addresses for any current or known future websites and describe whether the information in the website is up to date.

- 10) Name each of the Applicant's Senior Officers and Directors and for each provide the following:

(a) Explain the nature and extent of each Senior Officer's or Director's involvement in the Applicant; and

(b) Provide the countries of citizenship, date and place of birth, U.S. alien number (indicate whether the individual is a U.S. Lawful Permanent Resident) and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. PII may be provided in Appendix G, a PII supplement.

- 11) Has the Applicant or any Individual or Entity included as part of the Applicant been involved in bankruptcy proceedings, or any other legal proceeding undertaken for the purpose of liquidating, reorganizing, refinancing, or otherwise seeking relief from all or some of the Applicant's and the Individual or Entity's debts, in any jurisdiction over the past 5 years?

Yes ☐ No ☐

If yes, describe in detail.

- 12) Has the Applicant, any of its Corporate Officers, Senior Officers or Directors, or any other Individual or Entity with an Ownership Interest in the Applicant ever been involved or associated with a previous application to the FCC?

Yes ☐ No ☐

If yes, provide the application identifying information.

- 13) Has the Applicant, any of its Corporate Officers, Senior Officers or Directors, or any other Individual or Entity with an Ownership Interest in the Applicant ever been blocked, sanctioned, penalized, or had an authorization or other permission revoked/terminated by the FCC?

Yes ☐ No ☐

If yes, describe in detail.

- 14) Has the Applicant, any of its Corporate Officers, Senior Officers or Directors, or any other Individual or Entity with an Ownership Interest in the Applicant ever been involved or associated with a previous filing to the Committee on Foreign Investment in the United States (CFIUS)?

Yes ☐ No ☐

If yes, provide filing identifying information.

- 15) Has the Applicant, any of its Corporate Officers, Senior Officers or Directors, or any other Individual or Entity with an Ownership Interest in the Applicant ever been blocked, sanctioned, penalized, or had an authorization or other permission prohibited, suspended, or revoked by CFIUS?

Yes ☐ No ☐

If yes, describe in detail.

- 16) Has the Applicant, any of its Corporate Officers, Senior Officers or Directors, or any other Individual or Entity with an Ownership Interest in the Applicant, ever been convicted of any felony (an offense carrying a maximum potential sentence of a term of imprisonment of more than a year) in the United States or any other country? This includes any settlements or negotiated resolutions, non-prosecution agreements, or deferred prosecution agreements.

Yes ☐ No ☐

If yes, provide the details, including name(s) of the Individual and/or Entity involved, dates, offenses, jurisdiction/court, and sentence.

- 17) Has the Applicant, any of its Corporate Officers, Senior Officers or Directors, or any other Individual or Entity with an Ownership Interest in the Applicant, ever been subject to any criminal, administrative, or civil penalties imposed for violating the regulations of the FCC, the U.S. Department of State, the U.S. Department of the Treasury (including, but not be limited to, the Internal Revenue Service, the Office of Foreign Assets Control, the Financial Crimes Enforcement Network (FinCEN), and the Office of the Comptroller of the Currency), the U.S. Department of Energy, the U.S. Department of Commerce, the U.S. Federal Trade Commission, the U.S. Securities and Exchange Commission, the U.S. Environmental Protection Agency, the World Bank Group or the U.S. Commodity Futures Trading Commission, or for violating the regulations of any comparable state or foreign agency? Include any settlements or negotiated resolutions, non-prosecution agreements, or deferred prosecution agreements.

Yes ☐ No ☐

If yes, provide details, including name(s) of the Individual and/or Entity involved, dates, violations, agency, penalty, and if a fine was imposed, status of payment.

- 18) Has the Applicant, any of its Corporate Officers, Senior Officers or Directors, or any associated foreign Entities, ever been on the Specially Designated Nationals And Blocked Persons List (SDN List), the BIS Unverified List or Entity List in 15 CFR part 744, or equivalent list of the United Nations Security Council or European Union?

Yes ☐ No ☐

If yes, describe in detail, including providing the specific category of list, the name of the Individual or Entity placed on the list, the date the Individual or Entity was placed on the list,

and the factual circumstances underlying the reason for the Individual or Entity being placed on the list.

- 19) Have any of the submarine cable system Applicants, any of its Corporate Officers, Senior Officers or Directors, or any other Individual or Entity with an Ownership Interest in the Applicants, ever been investigated, arraigned, arrested, indicted, or convicted of any of the following:
- a) Criminal violations of U.S. law, including espionage-related acts or criminal violations of the International Trade in Arms Regulations (ITAR) or the Export Administration Regulations (EAR)?
Yes ☐ No ☐
 - b) Deceptive sales practices, violations of the Consumer Fraud Act and regulations, and/or other fraud or abuse practices whether pursuant to Federal, state, or local law?
Yes ☐ No ☐
 - c) Violations of any laws (Federal, state, or local) in connection with the provision of telecommunications services, equipment and/or products and/or any other practices regulated by the Telecommunications Act of 1996 and/or by state public utility commissions?
Yes ☐ No ☐

If yes to any of the above, describe in detail, including name(s) of the Individual or Entity involved, date(s), and current status or final disposition of matter, including any terms of settlement. Provide any available supporting documentation.

Section IV: Submarine Cable System Overview

- 20) When is the submarine cable system expected to go into service?
- 21) How many fiber pairs comprise the submarine cable system and what is its design capacity?
- 22) Identify which Entity owns and/or controls each segment of the cable and which Entity owns or controls which fiber pairs and/or what capacity.
- 23) Provide a brief description of the operational purpose of the submarine cable system, and the anticipated market segmentation. Provide copies of any Joint Build Agreement, maintenance agreement, or similar document for the submarine cable system, if available.
- 24) Provide a list of the anticipated addresses or physical locations for all of the submarine equipment, transmission/transport equipment, network equipment and infrastructure, who owns/leases it -- if leased provide details for the Applicant(s) -- information on any party sharing the facility or equipment, and if it is an existing or new facility, including, but not be limited to:
- a) The NOC (and back-up NOC, if any);
 - b) All Submarine Cable Landing Stations;
 - c) All associated data centers and distribution facilities; and
 - d) All associated Points of Presence.

- 25) List current and anticipated vendors, contractors, or subcontractors involved in providing, installing, operating, managing or maintaining the Principal Equipment. For each Entity, provide country of incorporation, principal place of business, general business type (e.g., holding company, investment firm), all business addresses, and related phone numbers.
- 26) Provide a description of all Principal Equipment, including a list of functions supported and information related to the manufacturer, model, and/or version number of any such equipment.
- 27) List current and anticipated vendors, contractors, or subcontractors involved in providing maintenance and security of the submarine cable system. For each Entity, provide country of incorporation, principal place of business, general business type (e.g., holding company, investment firm), all business addresses, and related phone numbers.
- 28) List all expected and actual Federal, state, and local government customers, including pursuant to any classified contracts, and include a description of all services to be provided, or services that are currently being provided, to such customers.

Section V: Security Overview

- 29) What, if any, outside capabilities via remote access will exist for the submarine cable system Applicants to control or monitor operations over the network (e.g., audit mechanisms, record access monitoring)? If remote access is available, provide a copy of the remote access security policy, if available.
- 30) Will any third-party vendors, associated companies, or Owners have remote access/monitoring to the network, systems, or records to provide managed services? If so, provide additional details, i.e., third party identifying information, role, and reason for their access.
- 31) What access control provisions, physical and logical security policies are in place for your submarine cable system for day-to-day operations and maintenance? If the policies exist and are available in writing, provide copies of these policies.
- 32) Do the submarine cable system Applicants have any screening and/or vetting procedures which will be applied to U.S. or non-U.S. persons (employees, contractors or others) who have access, remote or otherwise, to the submarine cable system Applicants' facilities, equipment, or data?
Yes ☐ No ☐
- If yes, provide copies of the written procedures. If these procedures are not available in writing, explain all such procedures in detail.
- 33) What provision will be made to monitor suspicious activity occurring over the paths of the cables?
- 34) Will any Non-U.S. Individual have access to one or more of the following:
- a) Physical facilities and/or Principal Equipment?
Yes ☐ No ☐

If yes, provide the identity of person(s) and explain the type of access and records that will be provided.

- b) Network control, monitoring, and/or auditing features, including any NOC facilities?
Yes ☐ No ☐

If yes, provide the identity of person(s) and explain the type of access and records that will be provided.

- c) Communications content and data?
Yes ☐ No ☐

If yes, provide the identity of person(s) and explain the type of access and records that will be provided.

- d) Customer records and billing records?
Yes ☐ No ☐

If yes, provide the identity of the Individual(s) and explain the type of access and records that will be provided.

For each Individual identified in response to these questions, provide the following information: name, all countries of citizenship, date and place of birth, U.S. alien number (indicate whether the individual is a U.S. Lawful Permanent Resident) and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. PII may be provided in Appendix G.

- 35) Will the submarine cable system Applicants store and/or maintain any domestic communications content, customer records, or billing records?
Yes ☐ No ☐

- a) Describe the types of records that will be stored.
- b) Provide all addresses of locations where such records will be stored and/or remotely accessed/managed via electronic systems.
- c) If any storage location differs from the submarine cable system Applicants' primary business address, explain the general purpose of the location and its function within the cable Applicants' business.
- d) If any of the records will be accessible from outside the United States, explain where, how, and who will have access to them.
- e) Describe all physical/electronic security measures utilized for all locations/systems to protect the confidentiality of records.

- 36) Identify whether, if required by law, regulation, or a license condition, the Applicant(s) will inform the Committee if, in the future, any record storage/access location is transferred and/or newly established outside of the United States.

- 37) Identify an Individual (who is a U.S. citizen residing in the United States with an active security clearance or who is eligible to obtain one) who will be the Licensee's authorized law enforcement point of contact responsible for accepting and responding to requests or compulsory processes from U.S. law enforcement or other U.S. government agencies.
- a) Explain the Individual's relationship to the Licensee and provide name, all countries of citizenship, date and place of birth, U.S. social security number, all passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. Also identify whether the Individual has an active U.S. Government security clearance. PII may be provided in Appendix G.
- 38) Explain how the Applicant(s) would make any and all records not stored in the United States electronically available in the United States within five (5) business days pursuant to a lawful request to the authorized law enforcement point of contact identified above.
- 39) Describe all lawful intercept capabilities of the submarine cable system Applicants including switching platforms, mediation devices, and use of 3rd party service providers for provisioning and delivery.

Section VI: Submarine Cable System Network Overview

40) Provide:

- a) A network topology map or diagram that includes end-to-end physical and logical topology;
- b) Network and telecommunications architecture descriptions and associated descriptions of interconnection points and controlled gateways to the DCI and Wet Plant;
- c) Network operational plans, processes, and procedures; and
- d) Descriptions of interfaces and connections to the cable system for service offload, disaster recovery or administrative functions.

41) Will the Applicant(s) use interconnecting carriers and/or peering relationships?

Yes ☐ No ☐

If yes, provide details and list the carriers.

42) Will the submarine cable system Applicants rely on underlying carrier(s) to furnish services to its customers and/or resell any services?

Yes ☐ No ☐

If yes, provide details and list whose services will be utilized or resold.

43) Are the submarine cable system Applicants or their affiliates able to control operations at any Point of Presence, data center, and/or NOC from any overseas locations?

Yes ☐ No ☐

If yes, what is the nature of the foreign-based control?

- 44) Explain how disaster recovery will be managed, including interconnection mechanisms with other submarine cable landings for restoration in the case of outages due to cable disruptions. Identify any third parties who will be contracted for the restoration/repair of damaged cables. Provide a copy of a restoration plan for the submarine cable system, if available.

Section VII: Submarine Cable System Critical Infrastructure Services

- 45) Will the submarine cable system provide services to any sectors of U.S. critical infrastructure?

Yes ☐ No ☐

If yes, check all that apply:

- | | |
|---|---|
| a. <input type="checkbox"/> Defense Industrial Base | i. <input type="checkbox"/> Information Technology |
| b. <input type="checkbox"/> U.S. Intelligence Community | j. <input type="checkbox"/> Chemical |
| c. <input type="checkbox"/> Emergency Services
(i.e., Federal, state, local law enforcement, fire, police) | k. <input type="checkbox"/> Commercial Facilities |
| d. <input type="checkbox"/> Government Facilities
(i.e., Federal, state, local Entities) | l. <input type="checkbox"/> Agriculture and Food Supply |
| e. <input type="checkbox"/> Banking and Finance | m. <input type="checkbox"/> Health Care |
| f. <input type="checkbox"/> Nuclear Reactors, Materials, or Waste | n. <input type="checkbox"/> National Monuments |
| g. <input type="checkbox"/> Drinking Water and Water Supply | o. <input type="checkbox"/> Transportation |
| h. <input type="checkbox"/> Energy | p. <input type="checkbox"/> Postal Shipping |
| | q. <input type="checkbox"/> Dams |
| | r. <input type="checkbox"/> Other (explain in detail) |

- 46) If the submarine cable system provides or will provide services to any sectors of U.S. critical infrastructure, answer the below as it relates to each type of service provided:

- a) Does/will the submarine cable system have any service contracts with Entities in these sectors?
- b) In what manner are/will the service(s) to be delivered to its customers?
- c) What kind of network infrastructure is/will be utilized to deliver the service(s)?
- d) What equipment (manufacturer, make and model) and software version is/will be utilized to provide the service(s)?

WARNING

If an Applicant knowingly and willfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, the Applicant may be subject to prosecution under Title 18, United States Code, Section 1001. The FCC may also terminate, revoke, or render null and void any license or authorization granted in this matter if any responses provided are false or intentionally misleading.

Applicant Certification

Pursuant to Title 28, United States Code, Section 1746, I, an authorized representative of the Applicant _____, declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this _____ day of _____, year of _____.

Representative Name: _____

Representative Title: _____

Representative Signature: _____

Appendix D

Standard Questions for an Application for Assignment or Transfer of Control of a Submarine Cable Landing License

Submarine Cable Name:

Applicant(s):

FCC File Number(s):

Purpose: This list of standard questions solicits the initial information that the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (Committee) will review in connection with any referral of the above-referenced application by the Federal Communications Commission (FCC) in order to assess any national security and law enforcement concerns raised by the application. After review, the Committee may request additional information from you, including through tailored questions. The 120-day initial review period will typically start on the date the Chair of the Committee determines that your responses to these standard questions and any tailored questions, when required, are complete. If the Committee determines no tailored questions are necessary, the 120-day initial review period will start no more than 30 days after the FCC's referral, on the date the Committee informs the FCC that the responses to the standard questions are complete and that no tailored questions are required. If you fail to provide timely responses to any Committee requests for information, the Committee may recommend that the FCC dismiss the application without prejudice.

Dissemination of Information: The information received by the Committee pursuant to 47 CFR 1.40003 and any subsequent requests for information by the Committee may be shared and used in accordance with Section 8 of Executive Order 13913 of April 4, 2020, Establishing the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector, 85 FR 19643 (Apr. 8, 2020).

Instructions

- 1) Complete all Sections:** When a "Yes" answer is indicated, provide further information as appropriate. The questions seek further details regarding the Applicant and its security-related practices, and some questions are particularly directed at identifying and assessing the complete scope of the equipment that the Applicant will be operating and the services that the Applicant will be offering should the FCC grant those authorities.
- 2) Response Format:** Uniquely and sequentially Bates-number your responses to the standard questions, including any attachments, with an endorsement on each page. The Bates number must be a unique, consistently formatted identifier; the number of digits in the numeric portion of the format should not change in subsequent productions, if any, nor should spaces, hyphens, or other separators be added or deleted. Produce any Excel documents in native format (if desired, you may also produce a PDF version for record keeping purposes).

- 3) **Identify Sensitive Information:** Specifically identify answers or documents that you deem to be privileged or confidential as the information contains trade secrets or commercial or financial information. If 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. Personally Identifiable Information (PII) may be submitted in a separate attachment. The PII Supplement is Appendix G.
- 4) **Individuals' names:** For names that follow different naming conventions, such as the use of surnames as first names (e.g., Korean names), or the use of mother's last name as one of two last names that are often hyphenated (e.g., Spanish names), follow standard English convention for purposes of completing this information. For example, if the name is Kim Chul-su, write "Chul-su Kim" in the form. If the name in Spanish is Juan Garcia-Reyes, write "Juan Garcia Reyes."
- 5) **Residential Addresses:** Contract mail receipt locations, post office boxes, co-working, or shared virtual locations may not be used in lieu of residence addresses.
- 6) **Business Addresses:** For each business address, clearly indicate whether the address is a shared business venue, co-working location, virtual office, or traditional physical office.
- 7) **Obligation to Update:** The Applicant must inform the Committee if there is any material change to any of the information provided in the Applicant's responses while the Committee's review is ongoing, including, but not limited to, changes in ownership, equipment, and Communications Assistance for Law Enforcement Act (CALEA) compliance.
- 8) **Definitions** – These terms, as used in this questionnaire, have the following definitions:
 - "Applicant" shall have the same meaning as the term is defined in 47 CFR 1.767(h).
 - A "Controlling Interest" is generally a 50% or greater Ownership Interest (either equity or voting). Also, a Controlling Interest shall be determined on a case-by-case basis considering the distribution of ownership, and the relationships of the Owners, including family relationships. The term Controlling Interest includes Individuals or Entities with positive or negative *de jure* or *de facto* control of the Applicant/Licensee. *De jure* control includes holding 50% or more of the voting stock of a corporation or holding a general partnership interest in a partnership. Ownership Interests that are held indirectly by any party through one or more intervening corporations may be determined by successive multiplication of the ownership percentages for each link in the vertical ownership chain except that if the ownership percentage for an interest in any link in the chain is equal to or exceeds 50% or represents actual control, it may be treated as if it were a 100% interest. *De facto* control is determined on a case-by-case basis. Examples of *de facto*, or actual, control include constituting or appointing 50% or greater of the board of directors or management committee; having authority to appoint, promote, demote, and fire senior executives that control the day-to-day activities of the Licensee; or playing an integral role in management decisions. In the case of a consortium, each member of the consortium shall be considered to have a Controlling Interest in the consortium.
 - "Ultimate Owner" and "Ultimate Parent" refer to the Entity or Individual that ultimately owns and controls the Applicant/Licensee.
 - "Immediate Owner" refers to the Entity or Individual in the vertical ownership chain that immediately owns and controls the Applicant/Licensee. In other

words, the Immediate Owner is the Entity or Individual in the ownership chain that is closest to the Applicant/Licensee.

- An Entity or Individual with an “Ownership Interest” is any entity in the ownership chain with more than a 5% attributable interest in the Applicant/Licensee, including the “Ultimate Owner/Parent” and the “Immediate Owner,” and all Controlling Interest holders. Note that Controlling Interests include *de facto* controlling interests, for which equity and/or voting ownership may be below 5%.
- “Corporate Officer” refers to any Individual hired or appointed by the Entity’s board of directors that has actual or apparent authority to exercise day-to-day management responsibilities over an Entity.
- “Director” refers to any Individual serving on an Applicant’s board of directors or similar governing body organized to set policies for corporate management of or oversight for an Applicant/Licensee.
- “Entity” includes a partnership, association, estate, trust, corporation, limited liability company, consortium, joint venture, governmental authority, or other organization.
- An “Equity Interest Holder” is any Individual or Entity that has the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, a share or other ownership stake in the Applicant.
- The term “Foreign Government” includes any person or group of persons exercising sovereign *de facto* or *de jure* political jurisdiction over any country, other than the United States, or over any part of such country, and includes any subdivision of any such group and any group or agency to which such sovereign *de facto* or *de jure* authority or functions are directly or indirectly delegated. Such term shall include any faction or body of insurgents within a country assuming to exercise governmental authority whether such faction or body of insurgents has or has not been recognized by the United States.
- “Individual” refers to a natural person, as distinguished from an Entity.
- “Managed Services” or “Enterprise Services” refers to the provision of a complete, end-to-end communications solution to customers.
- A “Non-U.S. Individual” is an Individual who is not a U.S. citizen.
- An “Owner” is an Individual or Entity that holds an Ownership Interest in the Applicant/Licensee.
- An “Ownership Interest” is 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 (i.e., all entities that exist in the ownership structure between the Applicant itself and its Ultimate Parent).
- “Principal Equipment” means the primary components of the Domestic Communications Infrastructure (DCI) and the Wet Plant. Principal Equipment includes: network element servers; routers; switches; repeaters; submarine line terminal equipment (SLTE); system supervisory equipment (SSE); signal modulators and amplifiers; power feed equipment (PFE); tilt and shape equalizer units (TEQ/SEQ); optical distribution frames (ODF); branching units (BU); synchronous optical network (SONET), synchronous digital hierarchy (SDH), wave division multiplexing (WDM), dense wave division multiplexing (DWDM), coarse wave division multiplexing (CWDM), or optical carrier network (OCx) equipment, as applicable; and any non-embedded software necessary for the proper monitoring, administration, and provisioning of the submarine cable system (with the exception of commercial-off-the-shelf (COTS) software used for common business functions, e.g., MS Office).

- “Domestic Communications Infrastructure” or “DCI” means: (a) any portion of the cable system that physically is located in the United States, up to the submarine line terminating equipment, including (if any) transmission, switching, bridging, and routing equipment, and any associated software (with the exception of COTS software used for common business functions, *e.g.*, MS Office) used by or on behalf of the Applicant to provide, process, direct, control, supervise, or manage domestic communications; and (b) Network Operations Center (NOC) facilities.
- “Wet Plant” means hardware components installed and residing on the undersea portion of the submarine cable system, including fiber optic cables, repeaters, branching units, and routers (if any). Wet Plant includes all the components used in order to define the topology of the undersea portion of the submarine cable system.
- “Remote Access” is 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.
- “Senior Officer” refers to the Chief Executive Officer, President, Chief Financial Officer, Chief Information Officer, Chief Technical Officer, Chief Operating Officer, or any other similarly situated Individual that has actual or apparent authority to act on behalf of the Entity.

Section I: Identification of Relevant Parties

- 1) Provide the name, address, principal place of business, and place of incorporation of Relevant Parties. For the purposes of the following questions “Relevant Parties” means the following:
 - a) Current Cable Landing Licensee(s) (“**Licensee(s)**”):
 - b) Any Individual or Entity with an Ownership Interest in the Licensee(s) (“**Owner(s)/Controller(s)**”):
 - c) Assignee(s)/Transferee(s) of the Cable Landing License(s) (“**Proposed Licensee(s)**”):
 - d) Any Individual or Entity with an Ownership Interest in the Proposed Licensee(s) (“**Proposed Owner(s)/Controller(s)**”):

Section II: Applicants’ Ownership

- 2) Identify the current and proposed ownership percentage in the submarine cable system of each of the Relevant Parties.
- 3) Identify each Individual or Entity that holds an Ownership Interest in the Proposed Licensee(s) and the Proposed Owner(s)/Controller(s), highlighting any foreign Entities or Foreign Government-controlled Entities, including the Ultimate Parent/Owner of the Proposed Licensee(s) and any other companies/individuals holding an Ownership Interest in the chain of ownership.
 - a) For each such Individual or Entity with Ownership Interest in Relevant Parties, include a clear explanation of its involvement in the submarine cable system Proposed Licensee(s), including whether it has or will have a management role:
 - b) For each such Individual or Entity with Ownership Interest in Relevant Parties, provide all identifying information, as follows:
 - i) For Individuals, provide name (to include all names and aliases used by that person), country of citizenship (indicate whether the individual is a dual citizen and all countries where citizenship is held), date and place of birth, U.S. alien number (indicate whether the individual is a U.S. Lawful Permanent Resident) and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses and all phone numbers. Personally Identifiable Information (PII) may be provided in Appendix G.
 - ii) For Entities, provide country of incorporation (if United States, include state of incorporation), principal place of business, general business type (e.g., holding company, investment firm, etc.), all business addresses, email addresses and related phone numbers.
- 4) Provide the dollar amount that each Proposed Owner(s)/Controller(s) or Proposed Licensee(s) has/will invest in the submarine cable system.

- 5) What is the source of funding for each Proposed Owner(s)/Controller(s) or Proposed Licensee(s)'s investment?
- 6) Provide a detailed ownership structure diagram for the all Proposed Owner(s)/Controller(s) or Proposed Licensee(s).
- 7) List all other submarine cable systems in which each Proposed Owner(s)/Controller(s) or Proposed Licensee(s) have equity and provide the amount of the equity for each Proposed Owner(s)/Controller(s) or Licensee(s) in each cable system.

Section III: Overview of Submarine Cable Owners

- 8) How many fiber pairs comprise the submarine cable system and what is its design capacity?
- 9) What Entity owns or controls each segment of the cable and what Entities own or control which fiber pairs or what capacity? How will that change after the proposed transaction?
- 10) Do the Relevant Parties currently operate or plan to operate a website?
Yes ☐ No ☐

If yes, provide all URL addresses for any current or known future sites and describe whether the information in the website is up to date.

- 11) For each of the Proposed Owner(s)/Controller(s) and Proposed Licensee(s), name the Senior Officers and Directors and provide the following:
 - a) Explain the nature and extent of each Senior Officer's or Director's involvement in the Entity's business; and,
 - b) Provide citizenship (indicate whether the Individual is a dual citizen, list all countries of citizenship), date and place of birth, U.S. alien number (indicate whether the individual is a U.S. Lawful Permanent Resident) and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses and all phone numbers.

- 12) Has the Proposed Licensee been involved in bankruptcy proceedings, or any other legal proceeding undertaken for the purpose of liquidating, reorganizing, refinancing, or otherwise seeking relief from all or some of the debts of the Proposed Licensee or any Proposed Owner(s)/Controller(s), in any jurisdiction over the past 5 years?
Yes ☐ No ☐

If yes, provide details.

- 13) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been involved or associated with a previous application to the FCC?
Yes ☐ No ☐
If yes, provide application identifying information.

- 14) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors, ever been blocked, sanctioned, penalized, or had an authorization or other permission revoked/terminated by the FCC?

Yes ☐ No ☐

If yes, provide details.

- 15) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been involved or associated with a previous filing to the Committee on Foreign Investment in the United States (CFIUS)?

Yes ☐ No ☐

If yes, provide filing identifying information.

- 16) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been blocked, sanctioned, penalized, or had an authorization or other permission prohibited, suspended, or revoked by CFIUS?

Yes ☐ No ☐

If yes, provide details.

- 17) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors, ever been convicted of any felony (an offense carrying a maximum potential sentence of a term of imprisonment of more than a year) in the United States or any other country? This includes any settlements or negotiated resolutions, non-prosecution agreements, or deferred prosecution agreements.

Yes ☐ No ☐

If yes, provide details, including name(s) of the Individual and/or Entity with an Ownership Interest involved, dates, offenses, jurisdiction/court, sentence.

- 18) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been subject to any criminal, administrative, or civil penalties imposed for violating the regulations of the FCC, the U.S. Department of State, the U.S. Department of the Treasury (to include, but not be limited to, the Internal Revenue Service, the Office of Foreign Assets Control, the Financial Crimes Enforcement Network (FinCEN), and the Office of the Comptroller of the Currency), the U.S. Department of Energy, the U.S. Department of Commerce, the U.S. Federal Trade Commission, the U.S. Securities and Exchange Commission, the World Bank Group, the U.S. Environmental Protection Agency, or the U.S. Commodity Futures Trading Commission, or for violating the regulations of any comparable state or foreign agency? This includes any settlements or negotiated resolutions, non-prosecution agreements, or deferred prosecution agreements.

Yes ☐ No ☐

If yes, provide details, including name(s) of the Individual and/or Entity with an Ownership Interest, dates, violations, agency, penalty, and if a fine was imposed, status of payment.

- 19) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, Directors, or any associated foreign Entities ever been on the Specially Designated Nationals And Blocked Persons List (SDN List), the BIS Unverified List or Entity List in 15 CFR part 744, or equivalent list of the United Nations Security Council or European Union?

Yes ☐ No ☐

If yes, provide details.

- 20) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been investigated, arraigned, arrested, indicted, or convicted of any of the following:
- a) Criminal violations of U.S. law, including espionage-related acts or criminal violations of the International Trade in Arms Regulations (ITAR) or the Export Administration Regulations (EAR)?
Yes ☐ No ☐
 - b) Deceptive sales practices, violations of the Consumer Fraud Act and regulations, and/or other fraud or abuse practices whether pursuant to Federal, state, or local law?
Yes ☐ No ☐
 - c) Violations of any laws (Federal, state, or local) in connection with the provision of telecommunications services, equipment and/or products and/or any other practices regulated by the Telecommunications Act of 1996 and/or by state public utility commissions?
Yes ☐ No ☐

If yes to any of the above, describe in detail, including name(s) of the Individual and/or Entity with an Ownership Interest involved, date(s), and current status or final disposition of matter, including any terms of settlement. Provide any available supporting documentation.

- 21) Do any of the present or Proposed Owner(s)/Controller(s) or Proposed Licensee(s) have existing (or planned) relationships/partnerships (formal or informal), funding or service contracts, directly or indirectly, with any foreign individuals, foreign companies, Foreign Governments, and/or any Foreign Government-controlled companies?
Yes ☐ No ☐

If yes, indicate whether the relationship/partnership includes a management role by any foreign Individuals, foreign Entities or Foreign Governments. Provide the name(s) of the foreign individuals, foreign Entities and/or Foreign Government and explain the nature of the relationship/partnership, including whether the relationship/partnership currently exists and/or is intended to continue in the future.

Section IV: Submarine Cable System(s) Overview

- 22) When did the submarine cable system(s) first go into service?
- 23) What is the design capacity of the submarine cable system(s)? What is the current lit capacity? Is this expected to change post-transfer? If yes, describe in detail the changes.
- 24) Provide a brief description of the operational purpose of the submarine cable system(s), and the current market segmentation:
- Is this expected to change post-transfer? If yes, describe in detail the changes.
- 25) Describe the nature of services delivered by the submarine cable system and the customer base:
- Is this expected to change post-transfer? If yes, describe in detail the changes.

- 26)** Provide addresses or physical locations for all of the submarine equipment, transmission/transport equipment, network equipment and infrastructure, who owns/leases it (if leased provide details for the Applicant):

- a) The NOC (and back-up NOC, if any);
- b) All submarine Cable Landing Stations;
- c) All associated data centers and distribution facilities; and
- d) All associated Points of Presence.

Is this expected to change post-transfer? If yes, describe in detail the changes.

- 27)** List current vendors, contractors, or subcontractors involved in operating, managing or maintaining the Principal Equipment. For each Entity, provide country of incorporation, principal place of business, general business type (e.g., holding company, investment firm), all business addresses, and related phone numbers:

Is this expected to change post-transfer? If yes, describe in detail the changes.

- 28)** Provide a description of all Principal Equipment, including a list of functions supported and information related to the manufacturer, model, and/or version number of any such equipment:

Is this expected to change post-transfer? If yes, describe in detail the changes.

- 29)** List current vendors, contractors, or subcontractors involved in maintaining or securing the submarine cable system. For each entity, provide country of incorporation, principal place of business, general business type (e.g., holding company, investment firm), all business addresses, and related phone numbers:

Is this expected to change post-transfer? If yes, describe in detail the changes.

- 30)** List any Federal, state, and local government customers, including pursuant to any classified contracts, and include a description of all services that are currently being provided to such customers:

Is this expected to change post-transfer? If yes, describe in detail the changes.

Section V: Cable System Security Overview

- 31)** What, if any, capability do Owner(s)/Controller(s) and Licensee(s) have to control or monitor operations over the network (e.g., audit mechanisms, record access monitoring) via Remote Access?

If Remote Access is available, provide a copy of the Remote Access security policy, if available.

Is this expected to change post-transfer? If yes, describe in detail the changes.

- 32)** Do/will any third-party vendors, associated companies, or investors have remote access/monitoring to the network, systems, or records to provide managed services? If so,

provide additional details, i.e., who are they, what are their role(s), and why do they need this capability.

Is this expected to change post-transfer? If yes, describe in detail the changes.

- 33)** What access control provisions, physical and logical security policies are in place for your submarine cable system for day-to-day operations and maintenance? If the policies exist and are available in writing, provide copies of these policies.

Is this expected to change post-transfer? If yes, describe in detail the changes.

- 34)** What provision is in place to monitor suspicious activity occurring over the paths of the cables?

Do the Relevant Parties have any screening and/or vetting procedures which are applied to U.S. or non-U.S. Individuals (employees, contractors or others) who have access, remote or otherwise, to the submarine cable system Owners' facilities, equipment, or data?

Yes ☐ No ☐

If yes, provide copies of the written procedures. If these procedures are not available in writing, explain all such procedures in detail.

Is this expected to change post-transfer? If yes, describe in detail the changes.

- 35)** Does/will any Non-U.S. Individual have access to one or more of the following:

- a)** Physical facilities and/or Principal Equipment?

Yes ☐ No ☐

If yes, provide identity of Individual(s) and explain the type of access provided.

- b)** Network control, monitoring, and/or auditing features, including any NOC facilities?

Yes ☐ No ☐

If yes, provide identity of Individual(s) and explain the type of access provided.

- c)** Communications content and data?

Yes ☐ No ☐

If yes, provide identity of Individual(s) and explain the type of access provided.

- d)** Customer records and billing records?

Yes ☐ No ☐

If yes, provide identity of Individual(s) and explain the type of access and records that will be provided.

Is this expected to change post-transfer? If yes, describe in detail the changes.

For each Individual identified in response to these questions, provide the following information: name, all countries of citizenship, date and place of birth, U.S. alien number

(indicate whether the individual is a U.S. Lawful Permanent Resident) and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses and all phone numbers. PII may be provided in Appendix G.

- 36) Does/will the submarine cable system Proposed Owner(s)/Controller(s) store and/or maintain any domestic communications content, customer records, or billing records?

Yes ☐ No ☐

- a) Describe the types of records that will be stored.
- b) Provide all addresses of locations where such records will be stored and/or remotely accessed/managed via electronic systems.
- c) If any storage location differs from the submarine cable system Owners' primary business address, explain the general purpose of the location and its function within the cable owners' business.
- d) If any of the records will be accessible from outside the United States, explain where, how, and who will have access to them.

Describe all physical/electronic security measures utilized for all locations/systems to protect the confidentiality of records.

- 37) Identify whether, if required by law, regulation, or a license condition, the Applicant(s) will inform the Committee if, in the future, any record storage/access location is transferred and/or newly established outside of the United States.
- 38) Identify an Individual (who is a U.S. citizen residing in the United States with an active security clearance or who is eligible to obtain one) who will be the Licensee's authorized law enforcement point of contact responsible for accepting and responding to requests or compulsory processes from U.S. law enforcement or other U.S. government agencies.
- a) Explain the Individual's relationship to the Licensee and provide name, all countries of citizenship, date and place of birth, U.S. social security number, all passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. Also identify whether the Individual has an active U.S. Government security clearance. PII may be provided in Appendix G.
- 39) Explain how the Applicant(s) would make any and all records not stored in the United States electronically available in the United States within five (5) business days pursuant to a lawful request to the authorized law enforcement point of contact identified above. PII may be provided in Appendix G.
- 40) Describe all lawful intercept capabilities of the submarine cable system Owners to include switching platforms, mediation devices, and use of third-party service providers for provisioning and delivery.

Section VI: Submarine Cable System Network Overview

- 41) Provide:

- a) The most current submarine cable system network diagram/topology map showing all Cable Landing Stations, fiber termination points, Principal Equipment, Point of Presence, segments and branching units;
- b) Network and telecommunications architecture descriptions and associated descriptions of interconnection points and controlled gateways to the DCI and Wet Plant;
- c) Submarine cable system network operational plans, processes, and procedures; and
- d) Descriptions of interfaces and connections to the submarine cable system for service offload, disaster recovery or administrative functions.

Is this expected to change post-transfer? If yes, describe in detail the changes.

- 42) Do the submarine cable system Owner(s)/Controller(s) or Licensee(s) use interconnecting carriers and/or peering relationships?
Yes ☐ No ☐

If yes, provide details and list the carriers.

Is this expected to change post-transfer? If yes, describe in detail the changes.

- 43) Do the submarine cable system Owner(s)/Controller(s) or Licensee(s) rely on underlying carrier(s) to furnish services to its customers and/or resell any services?
Yes ☐ No ☐

If yes, provide details and list whose services are utilized or resold.

Is this expected to change post-transfer? If yes, describe in detail the changes.

- 44) Are the submarine cable system Owner(s)/Controller(s) or Licensee(s) or their affiliates able to control operations at any Point of Presence, data center, and/or NOC from any overseas locations?
Yes ☐ No ☐

If yes, what is the nature of the foreign-based control?

Is this expected to change post-transfer? If yes, describe in detail the changes.

- 45) Explain how disaster recovery is managed, including interconnection mechanisms with other submarine cable systems for restoration in the case of outages due to cable disruptions. Identify any third parties who will be contracted for restoration/repair of damaged cables. Provide a copy of a restoration plan for the submarine cable system, if available.

Is this expected to change post-transfer? If yes, describe in detail the changes.

- 46) Has the cable experienced any outages during its operational history? If so, provide the date, cause and duration of the outage(s).

Section VII: Submarine Cable System Critical Infrastructure Services

47) Does the submarine cable system provide services to any sectors of U.S. critical infrastructure?

Yes ☐ No ☐

If yes, check all that apply:

- | | |
|---|--|
| a. <input type="checkbox"/> Defense Industrial Base | i. <input type="checkbox"/> Information Technology |
| b. <input type="checkbox"/> U.S. Intelligence Community | j. <input type="checkbox"/> Chemical |
| c. <input type="checkbox"/> Emergency Services
(i.e., Federal, state, local law enforcement,
fire,
police) | k. <input type="checkbox"/> Commercial Facilities |
| d. <input type="checkbox"/> Government Facilities
(i.e., Federal, state, local entities) | l. <input type="checkbox"/> Agriculture and Food
Supply |
| e. <input type="checkbox"/> Banking and Finance | m. <input type="checkbox"/> Health Care |
| f. <input type="checkbox"/> Nuclear Reactors, Materials, or Waste | n. <input type="checkbox"/> National Monuments |
| g. <input type="checkbox"/> Drinking Water and Water Supply | o. <input type="checkbox"/> Transportation |
| h. <input type="checkbox"/> Energy | p. <input type="checkbox"/> Postal Shipping |
| | q. <input type="checkbox"/> Dams |
| | r. <input type="checkbox"/> Other (explain in detail) |

Is this expected to change post-transfer? If yes, describe in detail the changes.

48) If the submarine cable system provides or will provide services to any sectors of U.S. critical infrastructure, answer each question below as it relates to each type of service provided:

- a) Does/will the submarine cable system have a service contract with any entity in the sector? If so, provide details.
- b) In what manner are/will the service(s) be delivered to its customers?
- c) What kind of network infrastructure is/will be utilized to deliver the service(s)?
- d) What equipment (make & model) and software version is/will be utilized to provide the service(s)?

WARNING

If an Applicant knowingly and willfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, the Applicant may be subject to prosecution under Title 18, United States Code, Section 1001. The FCC may also terminate, revoke, or render null and void any license or authorization granted in this matter if any responses provided are false or intentionally misleading.

Licensee Certification

Pursuant to Title 28, United States Code, Section 1746, I, an authorized representative of _____, the License Holder, declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this _____ day of _____, year of _____.

Representative Name: _____

Representative Title: _____

Representative Signature: _____

Proposed Licensee(s) Certification

Pursuant to Title 28, United States Code, Section 1746, I, an authorized representative of _____, the Proposed Licensee, declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this _____ day of _____, year of _____.

Representative Name: _____

Representative Title: _____

Representative Signature: _____

Appendix E

Standard Questions for Section 310(b) Petition for Declaratory Ruling Involving a Broadcast Licensee

Petitioner(s):**FCC File Number(s):**

Purpose: This list of standard questions solicits the initial information that the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (Committee) will review in connection with any referral of the above-referenced Petition by the Federal Communications Commission (FCC) in order to assess any national security and law enforcement concerns raised by the Petition. After review, the Committee may request additional information, including through tailored questions. The 120-day initial review period will typically start on the date the Chair of the Committee determines that your responses to these standard questions and any tailored questions, when required, are complete. If the Committee determines no tailored questions are necessary, the 120-day initial review period will start no more than 30 days after the FCC's referral, on the date the Committee informs the FCC that the responses to the standard questions are complete and that no tailored questions are required. If you fail to provide timely responses to any Committee requests for information, the Committee may recommend that the FCC dismiss the Petition without prejudice.

Dissemination of Information: The information received by the Committee pursuant to 47 CFR 1.40003 and any subsequent requests for information by the Committee may be shared and used in accordance with Section 8 of Executive Order 13913 of April 4, 2020, Establishing the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector, 85 FR 19643 (Apr. 8, 2020).

Instructions

- 1) Who Must Respond to this Questionnaire:** A Petitioner that seeks to obtain (a) a section 310(b)(4) foreign ownership ruling in connection with an application for a new broadcast license or (b) a new or modified 310(b)(4) foreign ownership ruling in connection with an application for assignment, transfer of control, or other change in ownership or control of the Licensee must respond to this questionnaire. In the case of (b), a Petitioner must provide information pertaining to the post-transaction ownership, structure, and operations of the Licensee and Relevant Parties. As used in this questionnaire, the term "Licensee" refers to both an Applicant for a broadcast license and an existing licensee.
- 2) Complete all Sections:** When a "Yes" answer is indicated, provide further information as appropriate. The questions seek further details regarding the Applicant and security-related practices and some questions are particularly directed at identifying and assessing the complete scope of the equipment that the Applicant will be operating and the services the Applicant will be offering should the FCC grant those authorities. Accordingly, in answering the "Section V: Licensee Services" questions, the Applicant(s) must file complete and accurate responses.

- 3) **Response Format:** Uniquely and sequentially Bates-number your responses to the standard questions, including any attachments, with an endorsement on each page. The Bates number must be a unique, consistently formatted identifier; the number of digits in the numeric portion of the format should not change in subsequent productions, if any, nor should spaces, hyphens, or other separators be added or deleted. Produce any Excel documents in native format (if desired, you may also produce a PDF version for record keeping purposes).
- 4) **Identify Sensitive Information:** Specifically identify answers or documents that you deem to be privileged or confidential as the information contains trade secrets or commercial or financial information. If there are multiple petitioners, each petitioner should also clearly mark any answers or documents that contain sensitive information that should not be disclosed to the other petitioners. Personally Identifiable Information (PII) may be submitted in a separate attachment. The PII Supplement is Appendix G.
- 5) **Individuals' names:** For names that follow different naming conventions, such as the use of surnames as first names (e.g., Korean names), or the use of mother's last name as one of two last names that are often hyphenated (e.g., Spanish names), follow standard English convention for purposes of completing this information. For example, if the name is Kim Chul-su, write "Chul-su Kim" in the form. If the name in Spanish is Juan Garcia-Reyes, write "Juan Garcia Reyes."
- 6) **Residential Addresses:** Contract mail receipt locations, post office boxes, co-working or shared virtual locations may not be used in lieu of residence addresses.
- 7) **Business Addresses:** For each business address, clearly indicate whether the address is a shared business venue, co-working location, virtual office, or traditional physical office.
- 8) **Obligation to Update:** The Applicant must inform the Committee if there is any material change to any of the information provided in the Applicant's responses while the Committee's review is ongoing, including, but not limited to, changes in ownership and equipment.
- 9) **Definitions** – These terms, as used in this questionnaire, have the following definitions:
 - A "Controlling Interest" is generally a 50% or greater Ownership Interest (either equity or voting). Also, a Controlling Interest shall be determined on a case-by-case basis considering the distribution of ownership, and the relationships of the owners, including family relationships. The term Controlling Interest includes Individuals or Entities with positive or negative *de jure* or *de facto* control of the Applicant/Licensee. *De jure* control includes holding 50% or more of the voting stock of a corporation or holding a general partnership interest in a partnership. Ownership Interests that are held indirectly by any party through one or more intervening corporations may be determined by successive multiplication of the ownership percentages for each link in the vertical ownership chain except that if the ownership percentage for an interest in any link in the chain is equal to or exceeds 50% or represents actual control, it may be treated as if it were a 100% interest. *De facto* control is determined on a case-by-case basis. Examples of *de facto*, or actual, control include constituting or appointing 50% or greater of the board of directors or management committee; having authority to appoint, promote, demote, and fire senior executives that control the day-to-day activities of the Applicant/Licensee; or playing an integral role in management decisions. In the case of a consortium, each member of the consortium shall be considered to have a Controlling Interest in the consortium.

- “Ultimate Owner” and “Ultimate Parent” refer to the Entity or Individual that ultimately owns and controls the Applicant/Licensee.
 - “Immediate Owner” refers to the Entity or Individual in the vertical ownership chain that immediately owns and controls the Applicant/Licensee. In other words, the Immediate Owner is the Entity or Individual in the ownership chain that is closest to the Applicant/Licensee.
 - An Entity or Individual with an “Ownership Interest” is any entity in the ownership chain with more than a 5% attributable interest in the Applicant/Licensee, including the “Ultimate Owner/Parent” to the “Immediate Owner,” and all Controlling Interest holders. Note that Controlling Interests include *de facto* control, for which equity and/or voting ownership may be below 5%.
- “Corporate Officer” refers to any Individual hired or appointed by the Entity’s board of directors that has actual or apparent authority to exercise day-to-day management responsibilities over an Entity .
- “Director” refers to any Individual serving on an Applicant’s board of directors or similar governing body organized to set policies for corporate management of or oversight for an Applicant.
- “Entity” includes a partnership, association, estate, trust, corporation, limited liability company, consortium, joint venture, governmental authority, or other organization.
- An “Equity Interest Holder” is any Individual or Entity that has the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, a share or other ownership stake in the Applicant.
- The term “Foreign Government” includes any person or group of persons exercising sovereign *de facto* or *de jure* political jurisdiction over any country, other than the United States, or over any part of such country, and includes any subdivision of any such group and any group or agency to which such sovereign *de facto* or *de jure* authority or functions are directly or indirectly delegated. Such term shall include any faction or body of insurgents within a country assuming to exercise governmental authority whether such faction or body of insurgents has or has not been recognized by the United States.
- The term “Foreign Political Party” includes any organization, or any other combination of individuals in a country other than the United States, or any unit or branch thereof, having for an aim or purpose, or which is engaged in any activity devoted in whole or in part, to the establishment, administration, control, or acquisition of, administration, or control, of a government of a foreign country, or a subdivision thereof, or the furtherance, or influencing, of the political, or public, interests, policies, or relations of a government of a foreign country, or a subdivision thereof.
- The term “Foreign Principal” includes:
 - (1) a government of a foreign country and a foreign political party;
 - (2) a person outside of the United States, unless it is established that such person is an individual and a citizen of and domiciled within the United States, or that such person is not an individual and is organized under or created by the laws of the United States or of any State or other place subject to the jurisdiction of the United States and has its principal place of business within the United States; and
 - (3) a partnership, association, corporation, organization, or other combination of persons organized under the laws of or having its principal place of business in a foreign country.
- “Individual” refers to a natural person, as distinguished from an Entity.
- The term “Information-service Employee” includes any person who is engaged in furnishing, disseminating, or publishing accounts, descriptions, information, or data with respect to the political, industrial, employment, economic, social, cultural, or other

benefits, advantages, facts, or conditions of any country other than the United States or of any government of a foreign country or of a foreign political party or of a partnership, association, corporation, organization, or other combination of individuals organized under the laws of, or having its principal place of business in, a foreign country.

- A “Non-U.S. Individual” is an Individual who is not a U.S. citizen.
- An “Owner” is an Individual or Entity that holds an Ownership Interest in the Applicant/Licensee.
- An “Ownership Interest” is 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 (i.e., all entities that exist in the ownership structure between the Applicant itself and its ultimate parent).
- The term “Political Consultant” means any person who engages in informing or advising any other person with reference to the domestic or foreign policies of the United States the political or public interest, policies, or relations of a foreign country or of a Foreign Political Party.
- The term “Publicity Agent” includes any person who engages directly or indirectly in the publication or dissemination of oral, visual, graphic, written, or pictorial information or matter of any kind, including publication by means of advertising, books, periodicals, newspapers, lectures, broadcasts, motion pictures, or otherwise.
- The term “Public-Relations Counsel” includes any person who engages directly or indirectly in informing, advising, or in any way representing a principal in any public relations matter pertaining to political or public interests, policies, or relations of such principal. “Remote Access” is 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.
- “Senior Officer” refers to the Chief Executive Officer, President, Chief Financial Officer, Chief Information Officer, Chief Technical Officer, Chief Operating Officer, Senior Vice President, or any other similarly situated Individual that has actual or apparent authority to act on behalf of the Entity.

Section I: Identification of Relevant Parties

- 1) Provide the name, address, principal place of business, and place of incorporation of Relevant Parties. For the purposes of the following questions, “Relevant Parties” means the following:
 - a) Proposed Broadcast Licensee (“**Licensee**”);
 - b) Proposed Controlling U.S. Parent of the Licensee (“**Petitioner**”); and
 - c) Any Individual or Entity with an Ownership Interest in either the Licensee or the Petitioner (“**Owner(s)/Controller(s)**”).

Section II: Petitioner/Licensee Ownership

- 2) To the extent not otherwise identified in response to Question 1, identify each Individual or Entity that holds an Ownership Interest in the Relevant Parties specifically identifying any foreign Entities, Foreign Government-controlled Entities, including the Ultimate Parent Entity of the Licensee and Petitioner and any other Individuals or Entities holding an Ownership Interest in the chain of ownership.
 - a) For each Individual or Entity with Ownership Interest in any of the Relevant Parties (identified in response to either Question 1 or Question 2), include a clear explanation of its involvement in the Relevant Party, including whether the Individual or Entity will have a management role in the Petitioner or Licensee.
 - b) For each Individual or Entity with Ownership Interest in any of the Relevant Parties (identified in response to either Question 1 or Question 2), provide all identifying information, as follows:
 - i) For Individuals, provide name (including all names and aliases used by that person), country of citizenship (indicate whether the individual is a dual citizen and all countries where citizenship is held), date and place of birth, U.S. alien number (indicate whether the individual is a U.S. Lawful Permanent Resident) and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. PII may be provided in Appendix G, a PII Supplement to the Standard Questions.
 - ii) For Entities, provide country of incorporation (if United States, include state of incorporation), principal place of business, general business type (e.g., holding company, investment firm, etc.), all business addresses, email addresses, and related phone numbers.

Section III: Petitioner/Licensee Details

- 3) Do any of the Relevant Parties have existing, planned, or prior relationships, partnerships, funding arrangements, or service contracts, directly or indirectly, with any of the following:
 - a) Foreign companies or foreign Entities;
 - b) Any Foreign Government or any Entity owned or controlled by a Foreign Government;

- c) Any foreign political entities or Foreign Political Parties;
- d) An Individual or Entity outside the United States, not a citizen of, or domiciled within, the United States, or not subject to the jurisdiction of the United States, and not having as a principal place of business or presence in the United States; or
Yes ☐ No ☐

If yes to any question above, explain each answer in detail.

If yes, all such parties identified by the Relevant Parties will be referred to as a “Foreign Party.”

- 4) Have any of the Relevant Parties been involved in bankruptcy proceedings, or any other legal proceeding undertaken for the purpose of liquidating, reorganizing, refinancing, or otherwise seeking relief from all or some of the Relevant Party’s debts in any jurisdiction over the past 5 years?
Yes ☐ No ☐

If yes, provide details.

- 5) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been involved or associated with a previous application to the FCC?
Yes ☐ No ☐

If yes, provide application identifying information.

- 6) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been involved or associated with a previous filing with the Committee on Foreign Investment in the United States (CFIUS)?
Yes ☐ No ☐

If yes, provide filing identifying information.

- 7) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been blocked, sanctioned, penalized, or had an authorization or other permission revoked/terminated by the FCC?
Yes ☐ No ☐

If yes, provide details.

- 8) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been blocked, sanctioned, penalized, or had an authorization or other permission prohibited, suspended, or revoked by CFIUS?
Yes ☐ No ☐

If yes, provide details.

- 9) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been convicted of any felony (an offense carrying a maximum potential sentence of a term of imprisonment of more than a year) in the United States or any other

country? This includes any settlements or negotiated resolutions, non-prosecution agreements, or deferred prosecution agreements.

Yes ☐ No ☐

If yes, provide details, including name(s) of the Individual or Entity involved, dates, offenses, jurisdiction/court, and sentence.

- 10) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors ever been subject to any criminal, administrative, or civil penalties imposed for violating the regulations of the FCC, U.S. Department of State, U.S. Department of the Treasury (including, but not be limited to, the Internal Revenue Service, Office of Foreign Assets Control, Financial Crimes Enforcement Network (FinCEN), or the Office of the Comptroller of the Currency), U.S. Department of Energy, U.S. Department of Commerce, U.S. Federal Trade Commission, U.S. Securities and Exchange Commission, U.S. Environmental Protection Agency, the World Bank Group, or the U.S. Commodity Futures Trading Commission, or for violating the regulations of any comparable state or foreign agency? This includes any settlements or negotiated resolutions, non-prosecution agreements, or deferred prosecution agreements.

Yes ☐ No ☐

If yes, provide details, including name(s) of the Individual or Entity involved, dates, violations, agency, penalty, and if a fine was imposed, status of payment.

- 11) Have any of the Relevant Parties, any of their Corporate Officers, Senior Officers, or Directors, or any associated foreign Entities ever been on the Specially Designated Nationals And Blocked Persons List (SDN List), the BIS Unverified List, or Entity List in 15 CFR part 744, or equivalent list of the United Nations Security Council or European Union?

Yes ☐ No ☐

If yes, provide details.

- 12) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers, or Directors, or any Foreign Party ever been investigated, arraigned, arrested, indicted or convicted of any of the following (to include any settlements or negotiated resolutions, non-prosecution agreements, or deferred prosecution agreements):

- a) Criminal violations of U.S. law, including espionage-related acts or violations of the Foreign Agents Registration Act (FARA)?

Yes ☐ No ☐

- b) Deceptive sales practices, violations of the Telemarketing and Consumer Fraud Act and regulations, 15 U.S.C. 6101 *et seq.*, 16 CFR 310.1-310.8, and/or Fraud or Prohibited Practices in Contests in violation of 47 U.S.C. 509, 18 U.S.C. 1304, and/or other fraud or abuse practices whether pursuant to local, state, or federal law?

Yes ☐ No ☐

- c) Bribery or kickbacks paid in any foreign country, to a foreign official or foreign candidate for any office, in order to establish or enhance business, influence any government decision whether or not related to telecommunications, or to gain access to or advantage over broadcast frequencies or markets, natural resources, telecommunications

markets, or infrastructure, or any other advantage, whether or not such investigation resulted in a conviction, fine, or loss of any license or privilege?

Yes ☐ No ☐

If yes to any of the above questions, describe in detail, including name(s) of Individuals and Entities involved, date(s), and current status or final disposition of matter, including any terms of settlement. Provide any available supporting documentation.

- 13) Is any Relevant Party or Foreign Party registered as an agent under the Foreign Agents Registration Act, 22 U.S.C. 611(c)(10)?**

Yes ☐ No ☐

If yes, explain in detail. Should the Relevant Party or Foreign Party, wish to confer with the Foreign Agent Registration Act Unit, National Security Division, United States Department of Justice, to determine whether registration is required, contact the Foreign Investment Review Section.

- 14) Is any Relevant Party or Foreign Party presently engaged in, or anticipate engaging in, any of the following on behalf of a Foreign Principal, foreign country, Foreign Government, or foreign agent of a Foreign Principal?**

- a) Within the United States, engaging in political activities for, or in the interests of, such a Foreign Principal, foreign country, or Foreign Government;
- b) Within the United States, soliciting, collecting, disbursing, or dispensing contribution, loans, money, or other things of value for, or in the interest of, such Foreign Principal, foreign country, or Foreign Government; or
- c) Within the United States, representing the interests of such Foreign Principal, foreign country, or Foreign Government before any agency, or official, of the Government of the United States.

If yes to any question above, explain each answer in detail.

- 15) Is any Relevant Party or Foreign Party presently engaged in, or anticipate engaging in, any of the following on behalf of a Foreign Principal, foreign country, Foreign Government, or foreign agent of a Foreign Principal?**

- a) Undertaking, or directing, an act within the United States as a Publicity Agent or Information-Service Employee for, or in the interests of, such Foreign Principal, foreign country, or Foreign Government; or
- b) Undertaking, or directing, an act within the United States as a Public Relations Counsel or Political Consultant for, or in the interests of, such Foreign Principal, foreign country, or Foreign Government.

If yes to any question above, explain each answer in detail.

- 16) Whether or not the answer to any of the questions above is “yes,” has any Relevant Party or Foreign Party received, or anticipate receiving, any funding from any Foreign Government, or Foreign Political Party, directly or indirectly?**

Yes ☐ No ☐

If yes:

- a) Explain the nature of the current/planned relationships with, or funding by, all foreign Entities in detail;
- b) Provide all funding amounts, whether provided directly or indirectly, including amounts itemized and aggregated for the prior ten years; and
- c) Provide copies of any and all contracts, or agreements, with the foreign Entities. If not memorialized in writing, explain the understanding between the Petitioner, or Foreign Party, and the foreign Entity or government.

- 17) Whether or not the answer to any of the questions above is “yes,” will any Foreign Government or Foreign Political Party, directly or indirectly, have any direction, control, or influence of any activity of any Relevant Party or Foreign Party?

Yes ☐ No ☐

If yes to any question above, explain each answer in detail.

- 18) Identify the Individuals who will be responsible for adhering to the FCC’s political advertising rules and maintaining a Political File pursuant to 47 CFR 73.1943, and describe that Individual’s role with the Relevant Party or Foreign Party.

Provide the responsive information in the chart below:

Responsible Person	Title/Role of the Responsible Person	Applicable TV/Radio Station	Call Sign

- 19) Will any non-U.S. Individual, owners, or management, including independent or third-party Individuals/Entities of the Relevant Party or Foreign Party have access to one or more of the following:

- a) Physical facilities or equipment under the Relevant Party’s or Foreign Party’s control; or
- b) Electronic interfaces that allow control, or monitoring, of the facilities or infrastructure under the Relevant Party’s or Foreign Party’s control, including access to actual programming content and content distribution.

Yes ☐ No ☐

If yes to either (a) or (b), explain the type of access and control that will be provided, and provide the following information:

- i) Full name(s) and alias(es);
- ii) Country(ies) of citizenship (If multiple countries of citizenship, list all countries.);
- iii) Employer name and relationship to either party;
- iv) Date of birth;
- v) Place of birth;
- vi) Social Security Number (SSN) (if applicable);
- vii) U.S. Alien Number (if applicable);
- viii) Passport Number(s) and complete name of country(ies) of issuance (If multiple passports, list all passport numbers and the complete name of the country of issuance.);
- ix) Cellular/mobile phone number(s);
- x) Home phone number(s);
- xi) Email address(es) used (including business and personal);
- xii) Residence address(es);
- xiii) Business address(es); and
- xiv) Business phone number(s).

20) Does the Relevant Party or any Foreign Party have any screening or vetting procedures that will be applied to U.S. or non-U.S. Individuals who have access, remote or otherwise, to communications facilities, broadcast-network facilities, equipment, or data?

Yes ☐ No ☐

If yes, explain all such procedures in detail.

21) Does the Relevant Party or any Foreign Party currently operate a website?

Yes ☐ No ☐

If yes, provide all URL addresses for any current or known future websites and describe whether the information therein is up to date.

22) Identify the total number of current employees of the Relevant Parties and the total number of planned employees for the next 12 months, and provide the following information:

a) Where are, or will, those employees be located for purposes of work?

- b) Describe the access each category of employee (e.g., Publicity Agent, Information-Service Employee, remote sales force, billing support, executives, technical support, content review, content approval) will have to:
- i) The Licensee's network;
 - ii) The Licensee's business locations;
 - iii) The physical facilities, equipment, or network elements owned, controlled, or leased by the Licensee;
 - iv) Any production facilities, or equipment, whether under the direct control of either the Licensee or under the control of independent third parties tasked or contracted for services; and
 - v) Customer/listener records of any kind, including billing records, listening platform used (e.g., app, online, subscription service), and other listener profile information, such as geolocation information, listening habits, political or national affiliation, and aggregated or compiled data of customers obtained as a result of the provision of services or acquired from third parties for any purpose.

Section IV: Licensee Operations

- 23) Has the Licensee been operational over the course of the current and/or previous year?

Yes ☐ No ☐

If yes, provide financial statements and records for the Licensee and Petitioner for the current and preceding year.

- 24) Name each of the Relevant Party's Corporate Officers, Senior Officers, and Directors and for each provide the following:

- a) Explain the nature and extent of each Corporate Officer's, Senior Officer's, and Director's involvement in the Entity's business; and
- b) Provide all countries of citizenship, date and place of birth, U.S. alien number (indicate whether the Individual is a U.S. Lawful Permanent Resident) and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. PII may be provided in Appendix G.

- 25) Identify the Senior Officer or employee (who is a U.S. citizen residing in the United States with an active security clearance or who is eligible to obtain one) who will be the Licensee's authorized law enforcement point of contact responsible for accepting and responding to requests or compulsory processes from U.S. law enforcement or other U.S. government agencies.

- a) Explain the Individual's relationship to the Licensee and provide name, all countries of citizenship, date and place of birth, U.S. social security number, all passport identifying

information (including number and country), all residence addresses, all business addresses, and all phone numbers. Also identify whether the Individual has an active U.S. Government security clearance. PII may be provided in Appendix G.

23) Provide all U.S. and foreign addresses (complete postal addresses) of the present and anticipated locations of the Relevant Party's and any Foreign Party's:

- a) Facilities, whether owned, leased, used or shared;
- b) Broadcast locations;
- c) Editorial locations;
- d) Data storage locations; and
- e) Locations where content is reviewed, whether or not content is edited.

Section V: Licensee Services

26) List the types of broadcast licenses held (or applied for) by the Licensee (e.g. radio, television) including the geographic area of service for each type of license.

27) Provide a general summary of the nature of the Licensee's current and planned services and operations, to include an explanation of the Licensee's intended overall business model and its relationship with any sister and/or partner companies.

Explain why the Licensee and/or Petitioner is seeking foreign investment/ownership.

28) Will programming be rebroadcast via satellite or cable?

Yes ☐ No ☐

If yes, provide details.

29) Will programming be available online?

Yes ☐ No ☐

If yes, describe the streaming business operation (including what platform(s) will be used to make the programming available online).

30) Describe 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, Petitioner, or any Foreign Party.

- 31)** Does any Relevant Party, any Foreign Party, or any of its subsidiaries or parents provide broadcast services of any kind in any foreign country or in the United States?

Yes ☐ No ☐

If yes, list all services provided in each country where those services are provided.

- 32)** Does any Relevant Party, any foreign Owner (or its affiliates), or any Foreign Party intend to allow Non-U.S. Individuals, investors, Entities, or governments to provide any influence, direction, control, commentary, or guidance on the content of programming to be broadcast?

- a) If yes, does any Relevant Party, any foreign Owner (or its affiliates), or any Foreign Party intend to place any restrictions, or limitations, on how Non-U.S. Individuals, investors, Entities, or governments may influence, direct, control, comment, or guide the content of programming to be broadcast?
- b) What, if any, policies, procedures, and protocols does any Relevant Party, any foreign Owner (or its affiliates), or any Foreign Party intend to put in effect to restrict, limit, or prohibit Non-U.S. Individuals, investors, Entities, or governments from providing influence, direction, control, commentary, or guidance on the content of programming to be broadcast?
- c) To the extent that any Relevant Party, any foreign Owner (or its affiliates), or any Foreign Party has any such policies, procedures, and protocols in effect now, produce copies of those materials.

- 33)** Indicate whether any Relevant Party, any Foreign 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.

- a) Indicate where any U.S. subscriber data identified here is stored and who serves as the custodian for such data. Also indicate who has access to such data and whether each individual with access is a U.S. or non-U.S. citizen.
- b) If U.S. subscriber data is disclosed/will be disclosed to third parties (service providers, third party advertisers, etc.) please identify which companies it is disclosed to (i.e., company name, address, and business relationship to Licensee)?
 - i) What U.S. customer data is disclosed?
 - ii) What, if any, limitations are placed on the third party's use of the data?
 - iii) What, if any, limitations are placed on third party's further disclosure of the data?
 - iv) What, if any, data security/storage standards does Licensee require of third parties?
- c) Indicate whether any Relevant Party, any Foreign Party, or its subsidiaries have deployed any security measures, protocols, or policies to protect subscriber data identified here from unauthorized access or disclosure. Describe each measure, protocol, or policy in

place to protect U.S. subscriber data. If the measures have been audited, provide the results of the audits.

WARNING

If the Petitioner or Licensee knowingly and willfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, the Petitioner or Licensee may be subject to prosecution under Title 18, United States Code, Section 1001. The FCC may terminate, revoke, or render null and void any license or authorization granted in this matter if any responses provided are false or intentionally misleading.

Licensee Certification

Pursuant to Title 28, United States Code, Section 1746, I, an authorized representative of the Licensee, declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this _____ day of _____, year of _____.

Representative Name: _____

Representative Title: _____

Representative Signature: _____

Petitioner Certification

Pursuant to Title 28, United States Code, Section 1746, I, an authorized representative of the Petitioner, declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this _____ day of _____, year of _____.

Representative Name: _____

Representative Title: _____

Representative Signature: _____

Appendix F

Standard Questions for Section 310(b) Petition for Declaratory Ruling Involving a Common Carrier Wireless or Common Carrier Earth Station Licensee

Petitioner:**FCC File Number(s):**

Purpose: This list of standard questions solicits the initial information that the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (Committee) will review in connection with any referral of the above-referenced application by the Federal Communications Commission (FCC) in order to assess any national security and law enforcement concerns raised by the application. After review, the Committee may request additional information, including through tailored questions. The 120-day initial review period will typically start on the date the Chair of the Committee determines that your responses to these standard questions and any tailored questions, when required, are complete. If the Committee determines no tailored questions are necessary, the 120-day initial review period will start no more than 30 days after the FCC's referral, on the date the Committee informs the FCC that the responses to the standard questions are complete and that no tailored questions are required. If you fail to provide timely responses to any Committee requests for information, the Committee may recommend that the FCC dismiss the application without prejudice.

Dissemination of Information: The information received by the Committee pursuant to 47 CFR 1.40003 and any subsequent requests for information by the Committee may be shared and used in accordance with Section 8 of Executive Order 13913 of April 4, 2020, Establishing the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector, 85 FR 19643 (Apr. 8, 2020).

Instructions

- 1) Who Must Respond to this Questionnaire:** A Petitioner that seeks to obtain (a) a section 310(b)(3) or 310(b)(4) foreign ownership ruling in connection with an application for a new common carrier wireless or common carrier earth station license(s), or (b) a new or modified 310(b)(3) or 310(b)(4) foreign ownership ruling in connection with an application for assignment, transfer of control, or other change in ownership or control of the Licensee must respond to this questionnaire. In the case of (b), a Petitioner must provide information pertaining to the post-transaction ownership, structure, and operations of the Licensee and Relevant Parties. As used in this questionnaire, the term "Licensee" refers to both an Applicant for a common carrier wireless or common carrier earth station license and an existing licensee.
- 2) Complete all Sections:** When a "Yes" answer is indicated, provide further information as appropriate. The questions seek further details regarding the Applicant and security-related practices and some questions are particularly directed at identifying and assessing the complete scope of the equipment that the Applicant will be operating and the services the Applicant will be offering should the FCC grant those authorities.

- 3) **Response Format:** Uniquely and sequentially Bates-number your responses to the standard questions, including any attachments, with an endorsement on each page. The Bates number must be a unique, consistently formatted identifier; the number of digits in the numeric portion of the format should not change in subsequent productions, if any, nor should spaces, hyphens, or other separators be added or deleted. Produce any Excel documents in native format (if desired, you may also produce a PDF version for record keeping purposes).
- 4) **Identify Sensitive Information:** Specifically 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. If 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. Personally Identifiable Information (PII) may be submitted in a separate attachment. The PII Supplement is Appendix G.
- 5) **Individuals' names:** For names that follow different naming conventions, such as the use of surnames as first names (e.g., Korean names), or the use of mother's last name as one of two last names that are often hyphenated (e.g., Spanish names), follow standard English convention for purposes of completing this information. For example, if the name is Kim Chul-su, write "Chul-su Kim" in the form. If the name in Spanish is Juan Garcia-Reyes, write "Juan Garcia Reyes."
- 6) **Residential Addresses:** Contract mail receipt locations, post office boxes, co-working or shared virtual locations may not be used in lieu of residence addresses.
- 7) **Business Addresses:** For each business address, clearly indicate whether the address is a shared business venue, co-working location, virtual office, or traditional physical office.
- 8) **Obligation to Update:** The Applicant must inform the Committee if there is any material change to any of the information provided in the Applicant's responses while the Committee's review is ongoing, including, but not limited to, changes in ownership, equipment, and Communications Assistance for Law Enforcement Act (CALEA) compliance.
- 9) **Definitions** – These terms, as used in this questionnaire, have the following definitions:
 - A "Controlling Interest" is generally a 50% or greater Ownership Interest (either equity or voting). Also, a Controlling Interest shall be determined on a case-by-case basis considering the distribution of ownership, and the relationships of the owners, including family relationships. The term Controlling Interest includes Individuals or Entities with positive or negative *de jure* or *de facto* control of the Applicant/Licensee. *De jure* control includes holding 50% or more of the voting stock of a corporation or holding a general partnership interest in a partnership. Ownership Interests that are held indirectly by any party through one or more intervening corporations may be determined by successive multiplication of the ownership percentages for each link in the vertical ownership chain except that if the ownership percentage for an interest in any link in the chain is equal to or exceeds 50% or represents actual control, it may be treated as if it were a 100% interest. *De facto* control is determined on a case-by-case basis. Examples of *de facto*, or actual, control include constituting or appointing 50% or greater of the board of directors

or management committee; having authority to appoint, promote, demote, and fire senior executives that control the day-to-day activities of the Applicant/Licensee; or playing an integral role in management decisions. In the case of a consortium, each member of the consortium shall be considered to have a Controlling Interest in the consortium.

- “Ultimate Owner” and “Ultimate Parent” refer to the Entity or Individual that ultimately owns and controls the Applicant/Licensee.
- “Immediate Owner” refers to the Entity or Individual in the vertical ownership chain that immediately owns and controls the Applicant/Licensee. In other words, the Immediate Owner is the Entity or Individual in the ownership chain that is closest to the Applicant/Licensee.
- An Entity or Individual with an “Ownership Interest” is any entity in the ownership chain with more than a 5% attributable interest in the Applicant/Licensee, including the “Ultimate Owner/Parent” to the “Immediate Owner,” and all Controlling Interest holders. Note that Controlling Interests include *de facto* control, for which equity and/or voting ownership may be below 5%.
- “Corporate Officer” refers to any Individual hired or appointed by the Entity’s board of directors that has actual or apparent authority to exercise day-to-day management responsibilities over an Entity.
- “Director” refers to any Individual serving on an Applicant’s board of directors or similar governing body organized to set policies for corporate management of or oversight for an Applicant/Licensee.
- “Entity” includes a partnership, association, estate, trust, corporation, limited liability company, consortium, joint venture, governmental authority, or other organization.
- An “Equity Interest Holder” is any Individual or Entity that has the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, a share or other ownership stake in the Applicant/Licensee.
- The term “Foreign Government” includes any person or group of persons exercising sovereign *de facto* or *de jure* political jurisdiction over any country, other than the United States, or over any part of such country, and includes any subdivision of any such group and any group or agency to which such sovereign *de facto* or *de jure* authority or functions are directly or indirectly delegated. Such term shall include any faction or body of insurgents within a country assuming to exercise governmental authority whether such faction or body of insurgents has or has not been recognized by the United States.
- “Individual” refers to a natural person, as distinguished from an Entity.
- A “Non-U.S. Individual” is an Individual who is not a U.S. citizen.
- An “Owner” is an Individual or Entity that holds an Ownership Interest in the Applicant/Licensee.
- An “Ownership Interest” is 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 (i.e., all entities that exist in the ownership structure between the Applicant itself and its ultimate parent).
- “Senior Officer” refers to the Chief Executive Officer, President, Chief Financial Officer, Chief Information Officer, Chief Technical Officer, Chief Operating Officer, or any other similarly situated Individual that has actual or apparent authority to act on behalf of the Entity.

Section I: Identification of Relevant Parties

- 1) Provide the name, address, principal place of business, and place of incorporation of Relevant Parties. For the purposes of the following questions “Relevant Parties” means the following:
 - a) Current or Proposed Common Carrier Wireless or Common Carrier Earth Station Licensee (“**Licensee**”)
 - b) Controlling U.S. Parent of the Licensee (“**Petitioner**”)
 - c) Any Individual or Entity with an Ownership Interest in either the Licensee or the Petitioner (“**Owner(s)/Controller(s)**”).

Section II: Petitioner/Licensee Ownership

- 2) To the extent not otherwise identified in response to Question 1, identify each Individual or Entity that holds an Ownership Interest in the Relevant Parties, specifically listing any foreign Entities or Foreign Government-controlled Entities, including the Ultimate Parent Entity of the Licensee and the Petitioner and any other companies/Individuals holding an Ownership Interest in the chain of ownership.
 - a) For each Individual or Entity with Ownership Interest in any of the Relevant Parties (identified in response to either Question 1 or Question 2), include a clear explanation of its involvement in the Relevant Party, including whether the Individual or Entity will have a management role in the Petitioner or Licensee.
 - b) For each Individual or Entity with Ownership Interest in any of the Relevant Parties (identified in response to either Question 1 or Question 2), provide all identifying information, as follows:
 - i) For Individuals, provide name (including all names and aliases used by that person), country of citizenship (indicate whether the Individual is a dual citizen and all countries where citizenship is held), date and place of birth, U.S. alien number (indicate whether the Individual is a U.S. Lawful Permanent Resident) and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. PII may be provided in Appendix G, a PII Supplement to the Standard Questions.
 - ii) For Entities, provide country of incorporation (if United States, include state of incorporation), principal place of business, general business type (e.g., holding company, investment firm, etc.), all business addresses, email addresses, and related phone numbers.

Section III: Petitioner/Licensee Details

- 3) Does any of the Relevant Parties have existing, planned, or prior relationships, partnerships, funding arrangements, or service contracts, directly or indirectly, with any of the following:

- a) Foreign companies or foreign Entities;
- b) Any Foreign Government or any entity owned or controlled by a Foreign Government; or
- c) An Individual or Entity outside the United States, not a citizen of, or domiciled within, the United States, or not subject to the jurisdiction of the United States, and not having as a principal place of business or presence in the United States.
Yes ☐ No ☐

If yes to any question above, explain each answer in detail.

- 4) Identify the total number of current employees of the Licensee and the Petitioner, and planned number of employees for the next 12 months.
- 5) Does the Licensee or Petitioner currently operate or plan to operate a website?
Yes ☐ No ☐

If yes, provide all URL addresses for any current or known future websites and describe whether the information therein is up to date.

- 6) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers or Directors been involved in bankruptcy proceedings, or any other legal proceeding undertaken for the purpose of liquidating, reorganizing, refinancing, or otherwise seeking relief from all or some of their debts in any jurisdiction over the past 5 years?
Yes ☐ No ☐

If yes, provide details.

- 7) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers or Directors ever been involved or associated with a previous application to the FCC?
Yes ☐ No ☐

If yes, provide application identifying information.

- 8) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers or Directors ever been involved or associated with a previous filing with the Committee on Foreign Investment in the United States (CFIUS)?
Yes ☐ No ☐

If yes, provide filing identifying information.

- 9) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers or Directors ever been blocked, sanctioned, penalized, or had an authorization or other permission revoked by the FCC?
Yes ☐ No ☐

If yes, provide details.

- 10) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers or Directors ever been blocked, sanctioned, penalized, or had an authorization or other permission prohibited, suspended, or revoked by CFIUS?

Yes ☐ No ☐

If yes, provide details.

- 11) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers or Directors ever been convicted of any felony (an offense carrying a maximum potential sentence of a term of imprisonment of more than a year) in the United States or any other country? This includes any settlements or negotiated resolutions, non-prosecution agreements, or deferred prosecution agreements. Yes ☐ No ☐

If yes, , provide details, including name(s) of the Individual or Entity involved, dates, offenses, jurisdiction/court, and sentence.

- 12) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers or Directors ever been subject to any criminal, administrative, or civil penalties imposed for violating the regulations of the FCC, U.S. Department of State, U.S. Department of the Treasury (including, but not be limited to, the Internal Revenue Service, Office of Foreign Assets Control, Financial Crimes Enforcement Network (FinCEN), or the Office of the Comptroller of the Currency), U.S. Department of Energy, U.S. Department of Commerce, U.S. Federal Trade Commission, U.S. Securities and Exchange Commission, U.S. Environmental Protection Agency, the World Bank Group, or U.S. Commodity Futures Trading Commission, or for violating the regulations of any comparable state or foreign agency? This includes any settlements or negotiated resolutions, non-prosecution agreements, or deferred prosecution agreements.

Yes ☐ No ☐

If yes, provide details, including name(s) of the Individual or Entity involved, dates, violations, agency, penalty, and if a fine was imposed, status of payment.

- 13) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers or Directors, or any associated foreign Entities ever been on the Specially Designated Nationals And Blocked Persons List (SDN List), the BIS Unverified List or Entity List in 15 CFR part 744, or equivalent list of the United Nations Security Council or European Union?

Yes ☐ No ☐

If yes, provide details.

- 14) Have any of the Relevant Parties or any of their Corporate Officers, Senior Officers or Directors ever been investigated, arraigned, arrested, indicted, or convicted of any of the following:

- a) Criminal violations of U.S. law, including espionage-related acts or criminal violations of the International Trade in Arms Regulations (ITAR) or the Export Administration Regulations (EAR)?

Yes ☐ No ☐

- b) Deceptive sales practices, violations of the Consumer Fraud Act and regulations, and/or other fraud or abuse practices whether pursuant to Federal, state, or local law?

Yes ☐ No ☐

- c) Violations of Federal, state, or local law in connection with the provision of telecommunications services, equipment and/or products, and/or any other practices regulated by the Telecommunications Act of 1996 and/or by state public utility commissions?

Yes ☐ No ☐

If yes to any of the above, describe in detail, including name(s) of Individuals and entities involved, date(s), and current status or final disposition of matter, including any terms of settlement. Provide any available supporting documentation.

Section IV: Licensee Operations

- 15) Has the Licensee been operational over the course of the current or previous year?

Yes ☐ No ☐

If yes, answer the following:

- a) Provide separately for each year its gross revenue;
- b) Provide separately for each year the Cost of Goods Sold (COGS);
- c) Provide the total amount of COGS allocated for telecommunications equipment and service types; and
- d) Describe the customer base of the Licensee (business, residential, carrier, enterprise, etc.). Is this expected to change, and if so, how?; and
- e) Describe, for all services provided to each category of customer (e.g., enterprise, residential, carrier, etc.):
 - i) Total number of subscribers;
 - ii) Total annual gross revenue for preceding fiscal year; and
 - iii) Percentage of total gross revenue per category of customer for preceding fiscal year.
 - iv) Is this expected to change, and if so, how?

- 16) List all expected and actual Federal, state, and local government customers, including pursuant to any classified contracts, and include a description of all services to be provided, or services that are currently being provided, to such customers.

- 17) Name each of the Licensee's and Petitioner's Corporate Officers, Senior Officers, and Directors, and for each provide the following:

- a) Explain the nature and extent of each Corporate Officer's, Senior Officer's or Director's involvement in the Entity's business; and

- b) Provide all countries of citizenship, date and place of birth, U.S. alien number and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. PII may be provided in Appendix G.
- 18) Identify the Senior officer or employee (who is a U.S. citizen residing in the United States with an active security clearance or who is eligible to obtain one) who will be the Licensee's authorized law enforcement point of contact responsible for accepting and responding to requests or compulsory processes from U.S. law enforcement or other U.S. government agencies.
- a) Explain the Individual's relationship to the Licensee and provide name, all countries of citizenship, date and place of birth, U.S. social security number, all passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. Also identify whether the Individual has an active U.S. Government security clearance. PII may be provided in Appendix G.
- 19) Identify whether, if required by law, regulation, or license condition, the Licensee will report the following to the appropriate law enforcement agencies, immediately upon discovery:
- a) Any act of compromise of a lawful interception of communications?
Yes ☐ No ☐
- b) Any unauthorized access to customer information and/or call-identifying information?
Yes ☐ No ☐
- c) Any artificially inflated or fraudulent call traffic detected on your network?
Yes ☐ No ☐
- d) Any felony (an offense carrying a maximum potential sentence of a term of imprisonment of more than a year) conviction, U.S. or foreign, of the Licensee, any company officers/directors, or any Individual/company with 5% or greater direct or indirect ownership interest in the Licensee?
Yes ☐ No ☐
- e) Any act of unlawful electronic surveillance that occurred on its premises or via electronic systems under its control?
Yes ☐ No ☐
- 20) Will the Licensee store and/or maintain any U.S. communications content, transactional data, call-associated data, billing records, or other subscriber information?
Yes ☐ No ☐
- If yes, answer the following:
- a) Describe the types of records that will be stored;
- b) Provide all addresses of locations where such records will be stored and/or remotely accessed/managed via electronic systems;

- c) If any storage location differs from the Licensee's address, explain the general purpose of the location and its function within the Licensee's business;
- d) If any of the records will be accessible from outside the United States, explain where, how, and who will have access to them; and
- e) Describe all physical/electronic security measures utilized for all locations/systems to protect the confidentiality of records.

21) Will any Non-U.S. Individual have access to one or more of the following:

- a) Physical facilities and/or equipment under the Licensee's control?

Yes ☐ No ☐

If yes, provide identity of person(s) and explain the type of access that will be provided.

- a) Customer records, including Customer Proprietary Network Information (CPNI), billing records, and/or Call Detail Records (CDRs)?

Yes ☐ No ☐

If yes, provide identity of person(s) and explain the type of access and records that will be provided.

- b) Network control, monitoring, and/or auditing features?

Yes ☐ No ☐

If yes, explain the type of access that will be provided, and how access will be logged and archived.

- c) Electronic interfaces that allow control and/or monitoring of the infrastructure under the Licensee's control, including, but not limited to, access to actual communications content and data?

Yes ☐ No ☐

If yes, provide identity of person(s) and explain the type of access and control that will be provided.

For each Individual identified in response to these questions, provide the following information: name, countries of citizenship, date and place of birth, U.S. alien number and/or social security number (if applicable), passport identifying information (including number and country), all residence addresses, all business addresses, and all phone numbers. PII may be provided in Appendix G, a Supplement to the Standard Questions.

22) What access control/security policies (physical and cyber) are in place, or will be in place prior to commencing operations, for your network? If the policies exist and are available in writing, provide copies of these policies.

23) What encryption products/technologies have been installed on this network, or will be installed prior to commencing operations?

- 24) Does/will the Licensee have any screening and/or vetting procedures which will be applied to U.S. or non-U.S. persons who have access, remote or otherwise, to the Licensee's communications network facilities, equipment, or data?

Yes ☐ No ☐

If yes, explain all such procedures.

- 25) Identify whether, if required by law, regulation, or a license condition, the Licensee will inform the National Security Division (NSD) of the U.S. Department of Justice if, in the future, any record storage/access location is transferred and/or newly established outside of the United States.
- 26) Explain how the Licensee, in accordance with U.S. law, regulation, or a license condition, would make any and all records not stored in the United States electronically available in the United States within five (5) business days pursuant to a lawful request to the authorized law enforcement point of contact identified above if such a point of contact is maintained or intended to be maintained.
- 27) Describe all lawful intercept capabilities of the Licensee. Will they be changing, if so, how?
- 28) What, if any, outside capabilities via remote access will exist within the Licensee to control or monitor operations over the network (e.g., audit mechanisms, record access monitoring)? Will they be changing, if so, how?
- 29) Do/will any third-party vendors, associated companies, or Owners have remote access to the Licensee's network, systems, or records to provide managed services?

Yes ☐ No ☐

If yes, provide a detailed explanation.

- 30) Do/will any third parties have access, post-transaction, to the Licensee's network, systems, or records for any other reason (e.g., sharing subscriber data for marketing purposes)?

Yes ☐ No ☐

If yes, provide a detailed explanation.

Section V: Licensee Services

- 31) List the types of common carrier wireless licenses (e.g. cellular, microwave) and/or common carrier earth station licenses held (or applied for) by the Relevant Parties including the geographic area of service for each type of license.
- 32) Provide a general summary of the nature of the Licensee's current and planned services and operations, to include an explanation of the Licensee's intended overall business model and its relationship with any sister and/or partner companies. Will they be changing, if so, how?
- 33) Why is the Petitioner seeking foreign investment/ownership?
- 34) Provide all addresses of the present and anticipated physical locations for all of the Licensee's network equipment, data centers, and infrastructure (e.g. towers, earth stations).

Will they be changing, if so, how? Advise whether these locations are owned or leased – if leased, provide details of the owner(s) and a list of goods/services the owner(s) provides – and the make and model of the principal equipment used, including, but not be limited to, the portions of the network covered below:

- a) Describe the carrier transport facilities (e.g., T1, DS3, Optical Carrier) that will enable customer data flow into and out of owned and/or leased equipment.
- b) Will the Licensee be operating any physical and/or virtual telecommunications switching platforms (e.g., TDM and/or VoIP switches)?
Yes ☐ No ☐

If yes, provide a network architecture diagram that shows all switches and connection points.

- c) Provide a description of any other intended network equipment and/or proposed infrastructure (e.g., routers, media gateways, multiplexing/cross-connect facilities, signaling devices, data centers, other equipment).
- d) Does the Licensee have a network topology map that shows its Points of Presence (POPs), Network Operation Centers (NOC), towers, and other network elements?
Yes ☐ No ☐

If yes, attach to your response.

- e) Is the Licensee or its affiliates able to control operations at any POP and/or Network Operations Center (NOC) from any overseas locations?
Yes ☐ No ☐

If yes, what is the nature of the foreign-based control? Where is it? Who has it? How? Will it be changing, if so, how?

- 35) Will the Licensee use interconnecting carriers and/or peering relationships?
Yes ☐ No ☐

If yes, provide details and list the carriers.

- 36) Will the Licensee rely on underlying carrier(s) to furnish services to its customers and/or resell any services?
Yes ☐ No ☐

If yes, provide details and list whose services and what services will be resold.

- 37) In what manner will services be delivered to customers?

- 38) Does/will the Licensee serve any sectors of U.S. critical infrastructure?
Yes ☐ No ☐

If yes, check all that apply:

s. ☐ Defense Industrial Base

aa. ☐ Information Technology

- | | |
|---|--|
| t. <input type="checkbox"/> U.S. Intelligence Community | bb. <input type="checkbox"/> Chemical |
| u. <input type="checkbox"/> Emergency Services
(i.e., Federal, state, local law enforcement,
fire,
police) | cc. <input type="checkbox"/> Commercial Facilities |
| v. <input type="checkbox"/> Government Facilities
(i.e., Federal, state, local entities) | dd. <input type="checkbox"/> Agriculture and Food Supply |
| w. <input type="checkbox"/> Banking and Finance | ee. <input type="checkbox"/> Health Care |
| x. <input type="checkbox"/> Nuclear Reactors, Materials, or Waste | ff. <input type="checkbox"/> National Monuments |
| y. <input type="checkbox"/> Drinking Water and Water Supply | gg. <input type="checkbox"/> Transportation |
| z. <input type="checkbox"/> Energy | hh. <input type="checkbox"/> Postal Shipping |
| | ii. <input type="checkbox"/> Dams |
| | jj. <input type="checkbox"/> Other (explain in detail) |

Will this be changing, if so, how?

Section VI: Licensee Services Portfolio Checklist and Reference Questions

Instructions: Check all applicable boxes that reflect the types of telecommunication services the Licensee intends to provide in the United States only. Do not select any services that will be provided outside the United States.

For each checked box: (1) provide a **separate and full explanation** at the end of this questionnaire and (2) answer the Reference Questions below the table regarding the services you have indicated in the checklist.

PROPOSED LICENSEE SERVICES	
VoIP (Voice over Internet Protocol)	<input type="checkbox"/>
POTS (Plain Old Telephone Service)	<input type="checkbox"/>
TDM (Time Division Multiplexing)	<input type="checkbox"/>
Voicemail	<input type="checkbox"/>
PBX (Private Branch Exchange)	<input type="checkbox"/>
Centrex (Hosted/Managed PBX)	<input type="checkbox"/>
Callback Service	<input type="checkbox"/>
Calling Card	<input type="checkbox"/>
Dial Tone Service	<input type="checkbox"/>
Issue DID (Direct Inward Dial) Local Telephone Numbers	<input type="checkbox"/>
Local Exchange Service	<input type="checkbox"/>
Local Toll Service	<input type="checkbox"/>
Domestic/International Long Distance (Interexchange Service)	<input type="checkbox"/>
Tollfree Service	<input type="checkbox"/>
IVR (Interactive Voice Response)	<input type="checkbox"/>
Conference Calling	<input type="checkbox"/>
Operator Service	<input type="checkbox"/>
Directory Assistance	<input type="checkbox"/>
Dial Around Service (1010XXX Casual Calling)	<input type="checkbox"/>
Switched Access	<input type="checkbox"/>
Special Access (Dedicated Line)	<input type="checkbox"/>
Mobile Top Up/Reload Services	<input type="checkbox"/>

Mobile Network Operator Services (MNO)	<input type="checkbox"/>
Mobile Virtual Network Operator Services (MVNO)	<input type="checkbox"/>
Automatic Call Distribution (ACD)	<input type="checkbox"/>
Other	<input type="checkbox"/>
	<input type="checkbox"/>
Data/Private Line	<input type="checkbox"/>
ISP (Internet Service Provider)	<input type="checkbox"/>
VPN (Virtual Private Network)	<input type="checkbox"/>
Web Hosting	<input type="checkbox"/>
LAN (Local Area Network)	<input type="checkbox"/>
WAN (Wide Area Network)	<input type="checkbox"/>
ISDN (Integrated Services Digital Network) BRI (Basic Rate Interface)	<input type="checkbox"/>
ISDN PRI (Primary Rate Interface)	<input type="checkbox"/>
DSL (Digital Subscriber Line)	<input type="checkbox"/>
Frame Relay	<input type="checkbox"/>
Email	<input type="checkbox"/>
International Voice/Data Service	<input type="checkbox"/>
Wireless/Mobile Voice/Data Services	<input type="checkbox"/>
Satellite Services	<input type="checkbox"/>
RF (Radio Frequency), Microwave	<input type="checkbox"/>
Video	<input type="checkbox"/>
Cloud Services	<input type="checkbox"/>
Other	<input type="checkbox"/>
Routing, Signaling Services	<input type="checkbox"/>
Transport Facilities	<input type="checkbox"/>
Leased Lines	<input type="checkbox"/>
Collocation Services	<input type="checkbox"/>
Other	<input type="checkbox"/>

Reference Questions:

Instructions: Answer each question below as it relates to each of the services selected in the above table.

- 1) In what manner will the service(s) be delivered to your customers?
- 2) What kind of network infrastructure will be utilized to deliver the service(s)?
- 3) What equipment (manufacturer, make, and model) and software version will be utilized to provide the service(s)? Will the software be regularly updated?
- 4) Will the service(s) be facilities based, resold, or both? Provide description.
- 5) Are you planning to implement and deploy 5G? If so, describe the plans, approach, anticipated services, and the intended vendors.

WARNING

If the Petitioner or Licensee knowingly and willfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, the Petitioner or Licensee may be subject to prosecution under Title 18, United States Code, Section 1001. The FCC may also terminate, revoke, or render null and void any license or authorization granted in this matter if any responses provided are false or intentionally misleading.

Licensee Certification

Pursuant to Title 28, United States Code, Section 1746, I, an authorized representative of the Licensee, declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this _____ day of _____, year of _____.

Representative Name: _____

Representative Title: _____

Representative Signature: _____

Petitioner Certification

Pursuant to Title 28, United States Code, Section 1746, I, an authorized representative of the Petitioner, declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this _____ day of _____, year of _____.

Representative Name: _____

Representative Title: _____

Representative Signature: _____

[illegible]

[FR Doc. 2021-03410 Filed 3-2-21; 8:45 am]

BILLING CODE 6712-01-C

FEDERAL COMMUNICATIONS COMMISSION**47 CFR Part 9****[PS Docket Nos. 20-291 and 09-14; FCC 21-25; FRS 17515]****911 Fee Diversion; New and Emerging Technologies 911 Improvement Act of 2008****AGENCY:** Federal Communications Commission.**ACTION:** Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (the FCC or Commission) proposes rules to implement the Don't Break Up the T-Band Act of 2020, which is Section 902 of the Consolidated Appropriations Act, 2021, Division FF, Title IX (Section 902). Section 902 directs the Commission to issue final rules, not later than 180 days after the date of enactment of Section 902, designating the uses of 911 fees by states and taxing jurisdictions that constitute 911 fee diversion for purposes of certain sections of the United States Code, as amended by Section 902. The intended effect of this notice of proposed rulemaking (NPRM) is to propose rules that implement Section 902 and help to identify those uses of 911 fees by states and other jurisdictions that support the provision of 911 services.

DATES: Comments are due on or before March 23, 2021, and reply comments are due on or before April 2, 2021.

ADDRESSES: You may submit comments, identified by PS Docket Nos. 20-291 and 09-14, by any of the following methods:

- *Federal Communications Commission's website:* <https://www.fcc.gov/ecfs/>. Follow the instructions for submitting comments.

- *Mail:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050

Junction Drive, Annapolis Junction, MD 20701. U.S. Postal Service first-class, Express, and Priority mail must be addressed to 45 L Street NE, Washington, DC 20554.

- Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID-19. See *FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Policy*, Public Notice, DA 20-304 (March 19, 2020), <https://www.fcc.gov/document/fcc-closes-headquarters-open-window-and-changes-hand-delivery-policy>.

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

FOR FURTHER INFORMATION CONTACT:

Brenda Boykin, Attorney Advisor, Policy and Licensing Division, Public Safety and Homeland Security Bureau, (202) 418-2062, Brenda.Boykin@fcc.gov, or John A. Evanoff, Deputy Division Chief, Policy and Licensing Division, Public Safety and Homeland Security Bureau, (202) 418-0848, John.Evanoff@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's notice of proposed rulemaking (NPRM), FCC 21-25, in PS Docket Nos. 20-291 and 09-14, adopted and released on February 17, 2021. The full text of this document is available at <https://www.fcc.gov/edocs/search-results?t=quick&fccdaNo=21-25>.

Initial Paperwork Reduction Act of 1995 Analysis

This notice of proposed rulemaking may contain new or modified information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA). If the Commission adopts any new or modified information collection requirements, they will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies will be invited to comment on the new or modified information collection requirements contained in this proceeding. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, we seek specific comment on how we might further reduce the information

collection burden for small business concerns with fewer than 25 employees.

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated in the **DATES** section above. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). See *Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121 (1998), <https://transition.fcc.gov/Bureaus/OGC/Orders/1998/fcc98056.pdf>.

The Commission will treat this proceeding as a "permit-but-disclose" proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within 2 business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda, or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule § 1.1206(b). In proceedings governed by rule § 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (e.g., .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Synopsis

Background

Congress has had a longstanding concern about the practice by some states and local jurisdictions of diverting 911 fees for non-911 purposes. In the ENHANCE 911 Act of 2004, Congress required states and local jurisdictions receiving Federal 911 grants to certify that they were not diverting 911 funds.¹ In the New and Emerging Technologies 911 Improvement Act of 2008 (NET 911 Act), Congress enacted additional measures to limit 911 fee diversion, codified in 47 U.S.C. 615a–1 (section 615a–1).² Specifically, section 615a–1(f)(1) provided that nothing in the NET 911 Act, the Communications Act of 1934, or any Commission regulation or order “shall prevent the imposition and collection of a fee or charge applicable to commercial mobile services or IP-enabled voice services specifically designated by a State, political subdivision thereof, Indian tribe, or village or regional corporation . . . for the support or implementation of 9–1–1 or enhanced 9–1–1 services, provided that the fee or charge is obligated or expended only in support of 9–1–1 and enhanced 9–1–1 services, or enhancements of such services, as specified in the provision of State or local law adopting the fee or charge.”³

The NET 911 Act also required the Commission to begin reporting annually on the status in each state of the collection and distribution of fees for the support or implementation of 911 or E911 services, including findings on the amount of revenues obligated or expended by each state “for any purpose other than the purpose for which any such fees or charges are

specified.”⁴ Pursuant to this provision, the Commission has reported annually to Congress on 911 fee diversion every year since 2009.⁵ All 12 of the annual reports issued to date have identified some states that have diverted 911 fees to other uses.

In October 2020, the Commission released a Notice of Inquiry seeking comment on the effects of fee diversion and the most effective ways to dissuade states and jurisdictions from continuing or instituting the diversion of 911/E911 fees.⁶ Noting that publicly identifying diverting states in the Commission’s annual reports has helped discourage the practice but has not eliminated fee diversion, the Commission sought comment on whether it could take other steps to discourage fee diversion, such as conditioning state and local eligibility for FCC licenses, programs, or other benefits on the absence of fee diversion.⁷ The Commission received eight comments and seven reply comments in response to the Notice of Inquiry.⁸

Section 902

On December 27, 2020, the President signed the Don’t Break Up the T-Band Act of 2020 as part of the Consolidated Appropriations Act, 2021.⁹ Section 902 of the new legislation requires the Commission to take action to help address the diversion of 911 fees by states and other jurisdictions for purposes unrelated to 911. Specifically, Section 902(c)(1)(C) adds a new paragraph (3)(A) to section 615a–1(f) that directs the Commission to adopt rules “designating purposes and functions for which the obligation or expenditure of 9–1–1 fees or charges, by any State or taxing jurisdiction authorized to impose such a fee or charge, is acceptable” for purposes of Section 902 and the Commission’s rules.¹⁰ The newly added section 615a–1(f)(3)(B) states that these purposes and functions shall be limited to “the

support and implementation of 9–1–1 services” provided by or in the state or taxing jurisdiction imposing the fee or charge, and “operational expenses of public safety answering points” within such state or taxing jurisdiction.¹¹ The new section also states that, in designating such purposes and functions, the Commission shall consider the purposes and functions that states and taxing jurisdictions specify as the intended purposes and functions for their 911 fees or charges, and “determine whether such purposes and functions directly support providing 9–1–1 services.”¹²

Section 902 also amends section 615a–1(f)(1) to provide that the rules adopted by the Commission for these purposes will apply to states and taxing jurisdictions that impose 911 fees or charges. Whereas the prior version of section 615a–1(f)(1) referred to fees or charges “obligated or expended only in support of 9–1–1 and enhanced 9–1–1 services, or enhancements of such services, as specified in the provision of State or local law adopting the fee or charge,” the amended version provides that nothing in the Act, the Communications Act of 1934 (47 U.S.C. 151 *et seq.*), the New and Emerging Technologies 911 Improvement Act of 2008, or any Commission regulation or order shall prevent the imposition and collection of a fee or charge applicable to commercial mobile services or IP-enabled voice services specifically designated by a State, political subdivision thereof, Indian tribe, or village or regional corporation serving a region established pursuant to the Alaska Native Claims Settlement Act, as amended (85 Stat. 688) for the support or implementation of 911 or enhanced 911 services, provided that the fee or charge is obligated or expended only in support of 911 and enhanced 911 services, or enhancements of such services, “consistent with the purposes and functions designated in the final rules issued under paragraph (3) as purposes and functions for which the obligation or expenditure of such a fee or charge is acceptable.”¹³

In addition, Section 902(c) establishes a process for states and taxing jurisdictions to seek a determination that a proposed use of 911 fees should be treated as having such an acceptable purpose or function even if it is for a purpose or function that has not been designated as such in the Commission’s

¹ Ensuring Needed Help Arrives Near Callers Employing 911 Act of 2004, Public Law 108–494, 118 Stat. 3986 (*ENHANCE 911 Act*) (relevant grant provisions codified at 47 U.S.C. 942). Congress provided another round of 911 grant funding, with similar non-diversion requirements, in the NG911 Act, Middle Class Tax Relief and Job Creation Act of 2012, Public Law 112–96, 126 Stat. 237, Title VI, Subtitle E, Next Generation 9–1–1 Advancement Act of 2012 (*NG911 Act*) (relevant grant provisions codified at 47 U.S.C. 942).

² New and Emerging Technologies 911 Improvement Act of 2008, Public Law 110–283, 122 Stat. 2620 (*NET 911 Act*). The NET 911 Act enacted 47 U.S.C. 615a–1 and also amended 47 U.S.C. 222, 615a, 615b, and 942. See 47 U.S.C. 615a–1 Editorial Notes.

³ 47 U.S.C. 615a–1(f)(1) (prior version). Under the NET 911 Act, the Commission’s annual 911 fee report covers states, as well as U.S. territories and the District of Columbia. See 47 U.S.C. 615a–1(f)(2) (directing the Commission to report on the status “in each State” of the collection and distribution of 911 fees and charges); *id.* at 615b(2) (definition of “State”).

⁴ 47 U.S.C. 615a–1(f)(2) (prior version).

⁵ These annual reports can be viewed at <https://www.fcc.gov/general/911-fee-reports>.

⁶ 911 Fee Diversion; New and Emerging Technologies 911 Improvement Act of 2008, PS Docket Nos. 20–291 and 09–14, Notice of Inquiry, 35 FCC Rcd 11010, 11010, para. 1 (2020) (*Fee Diversion NOI*).

⁷ *Fee Diversion NOI*, 35 FCC Rcd at 11011, 11016, paras. 5, 16.

⁸ These filings can be viewed in the FCC’s electronic comment filing system (ECFS) at <https://www.fcc.gov/ecfs/>, under PS Docket Nos. 20–291 and 09–14.

⁹ Consolidated Appropriations Act, 2021, Public Law 116–260, Division FF, Title IX, Section 902, Don’t Break Up the T-Band Act of 2020 (Section 902).

¹⁰ 47 U.S.C. 615a–1(f)(3)(A) (as amended); sec. 902(c)(1)(C).

¹¹ 47 U.S.C. 615a–1(f)(3)(B) (as amended); sec. 902(c)(1)(C).

¹² 47 U.S.C. 615a–1(f)(3)(B) (as amended); sec. 902(c)(1)(C).

¹³ 47 U.S.C. 615a–1(f)(1) (as amended) (emphasis added); sec. 902(c)(1)(A).

rules.¹⁴ Specifically, newly added section 615a–1(f)(5) provides that a state or taxing jurisdiction may submit to the Commission a petition for a determination that an obligation or expenditure of a 911 fee or charge “for a purpose or function other than a purpose or function designated under [section 615a–1(f)(3)(A)] should be treated as such a purpose or function,” *i.e.*, as acceptable for purposes of this provision and the Commission’s rules. The new section 615a–1(f)(5) provides that the Commission shall grant the petition if the state or taxing jurisdiction provides sufficient documentation that the purpose or function “(i) supports public safety answering point functions or operations,” or “(ii) has a direct impact on the ability of a public safety answering point to—(I) receive or respond to 9–1–1 calls; or (II) dispatch emergency responders.”

8. Section 902(d) requires the Commission to create an “interagency strike force” to study “how the Federal Government can most expeditiously end diversion” by states and taxing jurisdictions and to report to Congress on its findings within 270 days of the statute’s enactment.¹⁵ Section 902(d)(1) provides that if the Commission obtains evidence that “suggests the diversion by a State or taxing jurisdiction of 9–1–1 fees or charges,” the Commission shall submit such information to the strike force, “including any information regarding the impact of any underfunding of 9–1–1 services in the State or taxing jurisdiction.”¹⁶ Section 902(d)(2) provides that the Commission shall also include evidence it obtains of diversion and underfunding in future annual fee reports, beginning with the first report “that is required to be submitted after the date that is 1 year after the date of the enactment of this Act.”¹⁷ In addition, Section 902(c)(1)(C) provides that if a state or taxing jurisdiction receives a grant under section 158 of the National Telecommunications and Information Administration Organization Act (47 U.S.C. 942) after the date of the enactment of the new legislation, “such State or taxing jurisdiction shall, as a condition of receiving such grant, provide the information requested by

the Commission to prepare the [annual report to Congress on 911 fees].”¹⁸

Finally, Section 902(d)(4) prohibits any state or taxing jurisdiction identified as a fee diverter in the Commission’s annual report from participating or sending a representative to serve on any committee, panel, or council established to advise the First Responder Network Authority (FirstNet) under 47 U.S.C. 1425(a) or any advisory committee established by the Commission.

Section 902 does not impose any requirement on states or taxing jurisdictions to impose any fee in connection with the provision of 911 service. As revised, the proviso to section 615a–1 states that nothing in the Act or the Commission’s rules “shall prevent the imposition and collection of a fee or charge applicable to commercial mobile services or IP-enabled voice services” specifically designated by the taxing jurisdiction “for the support or implementation of 9–1–1 or enhanced 9–1–1 services, provided that the fee or charge is obligated or expended only in support of 9–1–1 and enhanced 9–1–1 services, or enhancements of such services, consistent with the purposes and functions designated in [the Commission’s forthcoming rules] as purposes and functions for which the obligation or expenditure of such a fee or charge is acceptable.”¹⁹

In this notice of proposed rulemaking, we propose measures to implement Section 902. We seek comment on these measures, which are designed to identify those uses of 911 fees by states and other jurisdictions that support the provision of 911 services.

Definitions and Applicability

As a preliminary matter, we note that Section 902 defines certain terms relating to 911 fees and fee diversion. To promote consistency, we propose to codify these definitions in our rules with certain modifications, as described below. We seek comment on these proposed definitions.

911 fee or charge. Section 902 defines “9–1–1 fee or charge” as “a fee or charge applicable to commercial mobile services or IP-enabled voice services specifically designated by a State or taxing jurisdiction for the support or implementation of 9–1–1 services.”²⁰ We propose to codify this definition in our rules. However, we note that the statutory definition in Section 902 does

not address services that may be subject to 911 fees other than Commercial Mobile Radio Services (CMRS) and IP-enabled voice services. The reason for this omission is unclear. For example, virtually all states impose 911 fees on wireline telephone services and have provided information on such fees for inclusion in the Commission’s annual fee reports. In addition, as 911 expands beyond voice to include text and other non-voice applications, states could choose to extend 911 fees to such services in the future.²¹

To promote regulatory parity and avoid gaps that could inadvertently frustrate the rapid deployment of effective 911 services, including advanced Next Generation 911 (NG911) services, we propose to define “911 fee or charge” in our rules to include fees or charges applicable to “other emergency communications services” as defined in section 201(b) of the NET 911 Act. Under the NET 911 Act, the term “other emergency communications service” means “the provision of emergency information to a public safety answering point via wire or radio communications, and may include 9–1–1 and enhanced 9–1–1 service.”²² The proposed modification will make clear that the rules in subpart I extend to all communications services regulated by the Commission that provide emergency communications, including wireline services, and not just to commercial mobile services and IP-enabled voice services.

²¹ For example, the Commission has extended 911 obligations to providers of text messaging services. See *Facilitating the Deployment of Text-to-911 and Other Next Generation 911 Applications; Framework for Next Generation 911 Deployment*, PS Docket Nos. 10–255 and 11–153, Report and Order, 78 FR 32169 (May 29, 2013), 28 FCC Rcd 7556 (2013) (requiring covered text providers to provide consumers attempting to send a text to 911 with an automatic bounce-back message when the service is unavailable); *Facilitating the Deployment of Text-to-911 and Other Next Generation 911 Applications; Framework for Next Generation 911 Deployment*, PS Docket Nos. 11–153 and 10–255, Second Report and Order and Third Further Notice of Proposed Rulemaking, 79 FR 55367 (Sept. 16, 2014) and 79 FR 55413 (Sept. 16, 2014), 29 FCC Rcd 9846 (2014) (requiring covered text providers to implement text-to-911 service no later than June 30, 2015 or six months from the date of a public safety answering point’s (PSAP’s) request, whichever is later). Further, in RAY BAUM’S Act, which directed the Commission to consider adopting rules to ensure that dispatchable location is conveyed with 911 calls, Congress specifically defined the term “9–1–1 call” to include a voice call “or a message that is sent by other means of communication.” See Consolidated Appropriations Act, 2018, Public Law 115–141, 132 Stat. 348, Division P, Repack Airwaves Yielding Better Access for Users of Modern Services Act of 2018 (RAY BAUM’S Act) sec. 506(c)(1) (codified at 47 U.S.C. 615 Notes).

²² NET 911 Act sec. 201(b), codified at 47 U.S.C. 615b(8).

¹⁴ 47 U.S.C. 615a–1(f)(5) (as amended); sec. 902(c)(1)(C).

¹⁵ Sec. 902(d)(3).

¹⁶ Sec. 902(d)(1).

¹⁷ Sec. 902(d)(2). Based on the December 27, 2020 enactment date of Section 902, this requirement will apply beginning with the next annual fee report, due to Congress by December 31, 2021.

¹⁸ 47 U.S.C. 615a–1(f)(4) (as amended); sec. 902(c)(1)(C).

¹⁹ 47 U.S.C. 615a–1(f)(1) (as amended); sec. 902(c)(1)(A).

²⁰ 47 U.S.C. 615a–1(f)(3)(D)(i) (as amended); sec. 902(c)(1)(C), (f)(1).

We tentatively conclude that adoption of this proposed expanded definition of “911 fee or charge” is reasonably ancillary to the Commission’s effective performance of its statutorily mandated responsibilities under Section 902 and other Federal 911-related statutes that, taken together, establish an overarching Federal interest in ensuring the effectiveness of the 911 system. The Commission’s general jurisdictional grant includes the responsibility to set up and maintain a comprehensive and effective 911 system, encompassing a variety of communication services in addition to CMRS and IP-enabled voice services. Section 251(e)(3) of the Communications Act of 1934, which directs the Commission to designate 911 as the universal emergency telephone number, states that the designation of 911 “shall apply to both wireline and wireless telephone service,” which evidences Congress’s intent to grant the Commission broad authority over different types of communications services in the 911 context.²³ Similarly, RAY BAUM’S Act directed the Commission to consider adopting rules to ensure that dispatchable location is conveyed with 911 calls “regardless of the technological platform used.”²⁴ In addition, section 615a–1(e)(2) provides that the Commission “shall enforce this section as if this section was a part of the Communications Act of 1934 [47 U.S.C. 151 *et seq.*]” and that “[f]or purposes of this section, any violations of this section, or any regulations promulgated under this section, shall be considered to be a violation of the Communications Act of 1934 or a regulation promulgated under that Act, respectively.”²⁵

Based on the foregoing, we tentatively conclude that including “other emergency communications services” within the scope of the definition of 911 fees we propose is also reasonably ancillary to the Commission’s effective performance of its statutorily mandated responsibilities for ensuring that the 911 system, including 911, E911, and NG911 calls and texts from any type of service,

is available, that these 911 services function effectively, and that 911 fee diversion by states and other jurisdictions does not detract from these critical, statutorily recognized purposes. Diverting fees collected for 911 service of any type, whether it be wireline, wireless, IP based, or text, undermines the purpose of these Federal statutes by depriving the 911 system of the funds it needs to function effectively and to modernize 911 operations.²⁶ We seek comment on this tentative conclusion and on the extent to which our proposed rules would strengthen the effectiveness of a nationwide 911 service.

In addition, we seek comment on extending the definition of “911 fee or charge” to include fees or charges designated for the support of “public safety,” “emergency services,” or similar purposes if the purposes or allowable uses of such fees or charges include the support or implementation of 911 services.²⁷ This would be consistent with the approach taken in the agency’s annual fee reports, which found that the mere labelling of a fee is not dispositive and that one must examine the underlying purpose of the

fee to determine whether it is (or includes) a 911 fee within the meaning of the NET 911 Act.²⁸ We seek comment on these conclusions.

We propose that for purposes of implementing Section 902, our definition of “911 fee or charge” should similarly extend to fees or charges that are expressly identified by the state or taxing jurisdiction as supporting 911, even if the fee is not labelled as a 911 fee. We tentatively conclude that this is consistent with the purpose of Section 902 with respect to diversion of 911 fees and charges. We seek comment on this proposal. Does the proposed definition of 911 fees or charges capture the universe of 911 fees or charges that can be diverted? Is the definition overinclusive or underinclusive? Are there other modifications to the definition that would help to prevent 911 fee diversion?

Diversion. Section 902(f)(4) defines “diversion” as, with respect to a 911 fee or charge, the obligation or expenditure of such fee or charge for a purpose or function other than the purposes and functions designated in the final rules issued under paragraph (3) of section 6(f) of the Wireless Communications and Public Safety Act of 1999, as added by this Act, as purposes and functions for which the obligation or expenditure of such a fee or charge is acceptable.

We propose to codify this definition, with minor changes to streamline it. Specifically, we propose to define diversion as “[t]he obligation or expenditure of a 911 fee or charge for a purpose or function other than the purposes and functions designated by the Commission as acceptable pursuant to [the applicable rule section in subpart I].” In addition, we propose to clarify that diversion also includes distribution of 911 fees to a political subdivision that obligates or expends such fees for a purpose or function other than those designated by the Commission. We believe this provision will clarify that states and taxing jurisdictions are also responsible for diversion of 911 fees by political subdivisions, such as counties, that may receive 911 fees. We seek comment on these proposals.

²³ 47 U.S.C. 251(e)(3). Section 251(e)(3) was added as part of the Wireless Communications and Public Safety Act of 1999, Public Law 106–81, 113 Stat. 1286 (1999) (911 Act), which established 911 as the national emergency number and required the Commission to provide for appropriate transition periods for areas in which 911 was not in use. Congress broadly stated the purpose of the 911 Act as “to encourage and facilitate the prompt deployment throughout the United States of a seamless, ubiquitous, and reliable end-to-end infrastructure for communications, including wireless communications, to meet the Nation’s public safety and other communications needs.” 911 Act sec. 2(b), codified at 47 U.S.C. 615 Notes.

²⁴ RAY BAUM’S Act sec. 506(a).

²⁵ 47 U.S.C. 615a–1(e)(2).

²⁶ The 2016 report of the Task Force on Optimal PSAP Architecture (TFOPA) recounted how fee diversion practices have “delayed plans in several states to meet the deployment schedule for the transition to an NG9–1–1 system.” See FCC, Task Force on Optimal PSAP Architecture, Adopted Final Report at 154 (2016) (TFOPA Report), https://transition.fcc.gov/pshs/911/TFOPA/TFOPA_FINALReport_012916.pdf; see generally FCC, Legal and Regulatory Framework for Next Generation 911 Services, Report and Recommendations, at Sec. 4.1.4 (2013), https://www.911.gov/pdf/FCC_Report_Legal_Regulatory_Framework_NG911_Services_2013.pdf. Other commenters have noted instances of fee diversion resulting in the delay of 911 improvements. See New Jersey Wireless Association Reply Comments to Tenth Report, PS Docket No. 09–14, at 2 (rec. Feb. 12, 2019) (noting that instead of upgrading to NG911 technology, New Jersey is maintaining a 911 selective router system that is “past its useful life and is now costing more to maintain from previous years, due to its obsolescence”); Letter from Matthew Grogan, 1st Vice President, Nevada APCO at 1 (Feb. 15, 2019) (noting that Nevada 911 funds have been used to purchase police body cameras at a time when “several counties and jurisdictions . . . are still not equipped with enhanced 9–1–1 services”), https://www.leg.state.nv.us/App/NELIS/REL/80th2019/ExhibitDocument/OpenExhibitDocument?exhibitId=36516&fileDownloadName=SB%2025_Testimony%20in%20Opposition_Matthew%20Grogan%20Nevada%20Fee%20Diversion.pdf.

²⁷ We also propose a safe harbor in the rules providing that the obligation or expenditure of such fees or charges will not constitute diversion so long as the state or taxing jurisdiction: (1) Specifies the amount or percentage of such fees or charges that is dedicated to 911 services; (2) ensures that the 911 portion of such fees or charges is segregated and not commingled with any other funds; and (3) obligates or expends the 911 portion of such fees or charges for acceptable purposes and functions as defined under this section.

²⁸ E.g., FCC, Twelfth Annual Report to Congress on State Collection and Distribution of 911 and Enhanced 911 Fees and Charges at 51–52, para. 31 (2020) (Twelfth Report), <https://www.fcc.gov/files/12thannual911feereport2020pdf> (“We do not agree that a fee or charge must be exclusively designated for 911 or E911 purposes in order to constitute a fee or charge ‘for the support or implementation of 9–1–1 or enhanced 9–1–1 services’ under section 6(f)(1) of the NET 911 Act.”); see also FCC, Eleventh Annual Report to Congress on State Collection and Distribution of 911 and Enhanced 911 Fees and Charges at 43, para. 34 (2019) (Eleventh Report), <https://www.fcc.gov/files/11thannual911feereport2019pdf>.

State or taxing jurisdiction. Section 902 defines a state or taxing jurisdiction as “a State, political subdivision thereof, Indian Tribe, or village or regional corporation serving a region established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601 *et seq.*).”²⁹ We propose to codify this definition in our rules. We note that the existing language in section 615a–1 directs the Commission to submit an annual report to Congress on the use of 911 fees by “each State or political subdivision thereof,” and Section 902 does not revise this language. We also note that Section 902 does not alter the definition of “State” in the existing legislation. Under section 615b, the term “State” means “any of the several States, the District of Columbia, or any territory or possession of the United States.”³⁰ Accordingly, provisions in subpart I that apply to any “State or taxing jurisdiction” would apply to the District of Columbia and any United States territory or possession as well. To clarify this and to assist users of the regulations, we propose to add the definition of “State” to subpart I.

Regarding the scope of proposed subpart I, we propose that the rules apply to states or taxing jurisdictions that collect 911 fees or charges (as defined in that subpart) from commercial mobile services, IP-enabled voice services, and other emergency communications services. And as the proposed definitions make clear, such fees or charges would include fees or charges designated for the support of public safety, emergency services, or similar purposes if the purposes or allowable uses of such fees or charges include the support or implementation of 911 services. We seek comment on these proposals.

A. Designation of Obligations or Expenditures Acceptable for Purposes of Section 902

Section 902 requires the Commission to issue rules “designating purposes and functions for which the obligation or expenditure of 9–1–1 fees or charges, by any State or taxing jurisdiction authorized to impose such a fee or charge, is acceptable” for purposes of the statute. In addition, Section 902 provides that the purposes and functions designated as acceptable for such purposes “shall be limited to the support and implementation of 9–1–1 services provided by or in the State or taxing jurisdiction imposing the fee or charge and operational expenses of

public safety answering points within such State or taxing jurisdiction.”³¹ Section 902 also provides that the Commission shall consider the purposes and functions that states and taxing jurisdictions specify as their intended purposes and “determine whether such purposes and functions directly support providing 9–1–1 services.”³² Moreover, Section 902 provides states and taxing authorities with the right to file a petition with the Commission for a determination that an obligation or expenditure of a 911 fee or charge that is imposed for a purpose or function other than those designated as acceptable for purposes of the statute in the Commission rules should nevertheless be treated as having an acceptable purpose or function for such purposes.³³

We propose to codify the statutory standard for acceptable purposes and functions for the obligation or expenditure of 911 fees or charges by providing that acceptable purposes and functions for purposes of the statute are limited to (1) support and implementation of 911 services provided by or in the state or taxing jurisdiction imposing the fee or charge, and (2) operational expenses of PSAPs within such state or taxing jurisdiction. This proposed language tracks the language in Section 902. In addition, we propose to specify in the rules that examples of such acceptable purposes and functions include, but are not limited to, the following, provided that the state or taxing jurisdiction can adequately document that it has obligated or spent the fees or charges in question for these purposes and functions:

- (1) PSAP operating costs, including lease, purchase, maintenance, and upgrade of customer premises equipment (CPE) (hardware and software), computer aided dispatch (CAD) equipment (hardware and software), and the PSAP building/facility;
- (2) PSAP personnel costs, including telecommunicators’ salaries and training;
- (3) PSAP administration, including costs for administration of 911 services

³¹ 47 U.S.C. 615a–1(f)(3)(B) (as amended); sec. 902(c)(1)(C).

³² 47 U.S.C. 615a–1(f)(3)(B) (as amended); sec. 902(c)(1)(C).

³³ 47 U.S.C. 615a–1(f)(5)(A) (as amended); Section 902(c)(1)(C). Such a petition must be granted if the Commission finds that the State or taxing jurisdiction has provided sufficient documentation to demonstrate that the purpose or function in question supports PSAP functions or operations, or that the purpose or function has a direct impact on the ability of a PSAP to receive or respond to 911 calls or to dispatch emergency responders. *Id.*

and travel expenses associated with the provision of 911 services;

(4) Integrating public safety/first responder dispatch and 911 systems, including lease, purchase, maintenance, and upgrade of CAD hardware and software to support integrated 911 and public safety dispatch operations; and

(5) Providing for the interoperability of 911 systems with one another and with public safety/first responder radio systems.

We believe these purposes and functions are consistent with the general standard for designating acceptable uses of 911 fees and charges set out in Section 902. They also are consistent with the Commission’s past analysis of 911 fee diversion in its annual fee reports, and, as required under Section 902, they reflect the Commission’s consideration of the purposes and functions that states have specified for their 911 fees and charges. In particular, the Commission has stated in its annual fee reports that the requisite nexus to 911 includes expenditures that (1) support PSAP functions or operations, (2) have a reasonable nexus to PSAPs’ ability to receive 911 calls and/or dispatch emergency responders, or (3) relate to communications infrastructure that connects PSAPs (or otherwise ensures the reliable reception and processing of emergency calls and their dispatch to first responders).³⁴ In addition, the Commission has stated that expenses associated with integrating public safety dispatch and 911 systems (*e.g.*, purchase of CAD hardware and software to support integrated 911 and dispatch operations) may be 911 related, provided the state or other jurisdiction can document a connection to 911.³⁵ We seek comment on our proposed inclusion of these examples of acceptable purposes and functions and any additional examples that should be specified in the rules.

We also seek comment on specifying certain examples of purposes and

³⁴ See FCC, Tenth Annual Report to Congress on State Collection and Distribution of 911 and Enhanced 911 Fees and Charges at 49, para. 40 (2018) (*Tenth Report*), <https://www.fcc.gov/files/10thannual911feereporttocongresspdf>. Under this analysis, funding for 911 dispatcher salaries and training would have a sufficient nexus to 911, but equipment and infrastructure for law enforcement, firefighters, and other first responders generally would not. See also *Eleventh Report* at 74, para. 59 (“CTIA supports the Commission in requiring documentation sufficient to demonstrate that the expenditures (1) support PSAP functions or operations, (2) have a reasonable nexus to PSAPs’ ability to receive 9–1–1 calls and/or dispatch emergency responders, or (3) relate to communications infrastructure that connects PSAPs.”).

³⁵ See *Twelfth Report* at 48–49, para. 26; *Eleventh Report* at 39, para. 26; *Tenth Report* at 42, para. 26.

²⁹ 47 U.S.C. 615a–1(f)(3)(D)(iii) (as amended); sec. 902(c)(1)(C), (f)(5).

³⁰ 47 U.S.C. 615b(2).

functions that are *not* acceptable for the obligation or expenditure of 911 fees or charges for purposes of the statute. These would include, but are not limited to:

(1) Transfer of 911 fees into a state or other jurisdiction's general fund or other fund for non-911 purposes;

(2) Equipment or infrastructure for constructing or expanding non-public safety communications networks (*e.g.*, commercial cellular networks); and

(3) Equipment or infrastructure for law enforcement, firefighters, and other public safety/first responder entities, including public safety radio equipment and infrastructure, that does not have a direct impact on the ability of a PSAP to receive or respond to 911 calls or to dispatch emergency responders.

Identifying these examples as unacceptable expenditures for purposes of the statute is consistent with the manner in which such expenditures were analyzed in our annual 911 fee reports. For example, the fee reports have repeatedly found that transferring 911 fees to the state's general fund or using 911 fees for the expansion of commercial cellular networks constitutes fee diversion.³⁶ The fee reports also have found that expenditures to support public safety radio systems, including maintenance, upgrades, and new system acquisitions, are not 911 related.³⁷ The Eleventh Report explained that the purchase or upgrade of public safety radio equipment was not considered to be 911 related because "radio networks used by first responders are technically and operationally distinct from the 911 call-handling system."³⁸ We seek comment on whether we should reexamine any of these prior findings in light of the impact of the coronavirus pandemic on public safety and emergency communications services, if any.

Our proposed designation of acceptable purposes and functions for purposes of the statute is also consistent with the legislative history of the NET 911 Act. In its report on H.R. 3403 (the bill that was enacted as the NET 911 Act), the House Committee on Energy and Commerce noted that several states were known to be using 911 fees for "purposes other than 911 or emergency

communications services."³⁹ The Report also noted that under subsection 6(f) of the proposed legislation, "[s]tates and their political subdivisions should use 911 or E-911 fees only for direct improvements to the 911 system. Such improvements could include improving the technical and operational aspects of PSAPs; establishing connections between PSAPs and other public safety operations, such as a poison control center; or implementing the migration of PSAPs to an IP-enabled emergency network." Further, "[t]his provision is not intended to allow 911 or E-911 fees to be used for other public safety activities that, although potentially worthwhile, are not directly tied to the operation and provision of emergency services by the PSAPs."⁴⁰

We seek comment on our proposed designation of acceptable purposes and functions under the statute. Are the proposed purposes and functions that would be deemed acceptable overinclusive or underinclusive? If the proposed purposes are overinclusive, commenters should explain how and why. What purposes and functions have states and taxing jurisdictions specified as the intended functions for 911 fees and charges, and how should we take these specifications into account as we designate acceptable purposes and functions under Section 902? CTIA contends that allowable 911 expenditures should include the nonrecurring costs of establishing a 911 system, the costs of emergency telephone and dispatch equipment, and costs for training for maintenance and operation of the 911 system but should exclude costs for leasing real estate, cosmetic remodeling of facilities, salaries or benefits, or emergency vehicles.⁴¹ The Commission has found in its 911 fee reports, however, that some PSAP overhead costs, such as 911 telecommunicator salaries, are 911 related.⁴² To the extent that the proposed purposes and functions are underinclusive, commenters should identify what additional purposes and functions should be deemed acceptable, and why.

³⁹ House of Representatives Committee on Energy and Commerce, Report on 911 Modernization and Public Safety Act of 2007, H. Rept. 110-442 at 11 (2007) (*H. Rept. 110-442*), <https://www.congress.gov/110/crpt/hrpt442/CRPT-110hrpt442.pdf> ("The most recent data available indicate that four states use 911 fees, including wireless and wireline fees, for purposes other than 911 or emergency communications services.").

⁴⁰ *H. Rept. 110-442* at 15.

⁴¹ CTIA Comments on *Fee Diversion NOI* at 5-6 (rec. Nov. 2, 2020).

⁴² See, *e.g.*, *Eleventh Report* at 21, para. 18; *Tenth Report* at 44-45, para. 33.

We also propose to define acceptable purposes and functions under Section 902 for states and taxing jurisdictions that impose multi-purpose fees or charges intended to support 911 services as well as other public safety purposes. In such instances, we believe states and taxing jurisdictions should have the flexibility to apportion the collected funds between 911 related and non-911 related programs, but that safeguards are needed to ensure that such apportionment is not subject to manipulation that would constitute fee diversion. We therefore propose to adopt a safe harbor in our rules providing that the obligation or expenditure of such fees or charges will not constitute diversion so long as the state or taxing jurisdiction: (1) Specifies the amount or percentage of such fees or charges that is dedicated to 911 services; (2) ensures that the 911 portion of such fees or charges is segregated and not commingled with any other funds; and (3) obligates or expends the 911 portion of such fees or charges for acceptable purposes and functions as defined under this section. This provision would provide transparency in the use of 911 fees when a state or taxing jurisdiction collects a fee for both 911 and non-911 purposes. It would also enable the Commission to verify through the annual fee report data collection that the 911 portion of such fees or charges is not being diverted.

We seek comment on our proposal for determining whether there is diversion of a fee or charge collected for both 911 and non-911 purposes. Are the measures we propose sufficient to provide transparency with respect to diversion in the use of such fees? Are there other measures that would help ensure that 911 fees or charges are fully traceable in states or taxing jurisdictions with such funding mechanisms? In addition, some state laws and regulations provide that any excess 911 funds left over after all 911 expenditures have been covered can be used for non-911 related purposes.⁴³ Similarly, some state laws and regulations provide that if the 911 service is *discontinued*, the remaining 911 funds can be disbursed to non-911 uses, such as a general fund. Does the existence or implementation of

⁴³ The TFOPA Report noted, "The legislative practice of sweeping uncommitted balances of 9-1-1-related accounts, especially those intended to fund NG9-1-1 system infrastructure generally occurs quietly without much public scrutiny." *TFOPA Report* at 153-54. The TFOPA Report proposed measures to deter such sweeps and advised that "there should ultimately be consequences for repeated diversions." *Id.* at 162.

³⁶ *E.g.*, *Twelfth Report* at 52-54, paras. 32, 35, 37; *Eleventh Report* at 40, 42-43, paras. 28, 32, 35; *Tenth Report* at 43-44, 46-47, paras. 30, 32, 35, 37.

³⁷ See *Twelfth Report* at 48-49, para. 26; *Eleventh Report* at 39, para. 26; *Tenth Report* at 42, para. 26.

³⁸ See *Eleventh Report* at 42, para. 32; see also *Eleventh Report* at 44, para. 37 (finding that there was no 911 fee diversion where Virginia allocated a portion of its wireless E911 funding to the Virginia State Police for costs incurred for answering wireless 911 telephone calls and to support sheriff's 911 dispatchers).

such provisions for non-911 related disbursements constitute diversion?

B. Petition for Determination

Section 902(c)(1)(C) provides that a state or taxing jurisdiction may petition the Commission for a determination that “an obligation or expenditure of a 9–1–1 fee or charge . . . by such State or taxing jurisdiction for a purpose or function other than a purpose or function designated under paragraph (3)(A) [support for 911 services/PSAP expenditures] should be treated as such a purpose or function.”⁴⁴ The state or taxing jurisdiction must demonstrate that the expenditure: (1) “supports public safety answering point functions or operations,” or (2) has a direct impact on the ability of a public safety answering point to “receive or respond to 9–1–1 calls” or to “dispatch emergency responders.”⁴⁵ If the Commission finds that the state or taxing jurisdiction has provided sufficient documentation to make this demonstration, Section 902 provides that the Commission shall grant the petition.⁴⁶

We propose to codify these provisions in new subpart I of the rules. We believe Congress intended this petition process to serve as a safety valve allowing states to seek further refinement of the definition of obligations and expenditures that are considered 911 related. At the same time, the proposed rule would set clear standards for what states must demonstrate to support a favorable ruling, including the requirement to provide sufficient documentation. To promote efficiency in reviewing such petitions, we also propose that states or taxing jurisdictions seeking such a determination must do so by filing a petition for declaratory ruling under § 1.2 of the Commission’s rules.⁴⁷ The declaratory ruling process would promote transparency regarding the ultimate decisions about 911 fee revenues that legislatures and executive officials make and how such decisions promote effective 911 services and deployment of NG911. Consistent with the declaratory ruling process outlined in § 1.2(b), we anticipate docketing the petition within an existing or new proceeding. In addition, we anticipate the Public Safety and Homeland Security Bureau will seek comment on petitions via public notice and with a

comment and reply comment cycle. We propose to delegate authority to the Bureau to rule on these petitions. We seek comment on these proposals and on any possible alternative processes for entertaining such petitions.

C. Other Section 902 Provisions

Pursuant to Section 902(d)(4), any state or taxing jurisdiction identified by the Commission in the annual 911 fee report as engaging in diversion of 911 fees or charges “shall be ineligible to participate or send a representative to serve on any committee, panel, or council established under section 6205(a) of the Middle Class Tax Relief and Job Creation Act of 2012 . . . or any advisory committee established by the Commission.”⁴⁸ We propose to codify this restriction as it applies to any advisory committee established by the Commission in subpart I and seek comment on this proposal. We also seek comment on the extent to which state and local governments currently diverting 911 fees (based on the Commission’s most recent report) now participate in such Commission advisory committees and the impact on them from being prohibited from doing so. Would it be helpful to provide a mechanism for states and taxing jurisdictions to raise questions regarding their eligibility to serve on an advisory committee?

Section 902(c)(1)(C) also provides that if a state or taxing jurisdiction receives a grant under section 158 of the National Telecommunications and Information Administration Organization Act (47 U.S.C. 942) after the date of enactment of Section 902, “such State or taxing jurisdiction shall, as a condition of receiving such grant, provide the information requested by the Commission to prepare [the annual report to Congress on 911 fees].”⁴⁹ We propose to codify this provision in subpart I and seek comment on this proposal. What effect does this statutory provision and its proposed codification in the Commission’s rules have on states or taxing jurisdictions that receive such grants? Does this provision, combined with other statutory anti-diversion restrictions that already apply to 911 grant recipients, increase the likelihood that diverting states and taxing jurisdictions will change their diversion

practices? Are there any aspects of our proposed implementation of Section 902 that might create obstacles to state fiscal needs?

Finally, Section 902(d)(2) provides that, beginning with the first annual fee report “that is required to be submitted after the date that is 1 year after the date of the enactment of this Act,” the Commission shall include in each report “all evidence that suggests the diversion by a State or taxing jurisdiction of 9–1–1 fees or charges, including any information regarding the impact of any underfunding of 9–1–1 services in the State or taxing jurisdiction.” Given that the Commission is similarly required to provide the interagency strike force with any information regarding underfunding of 911 services,⁵⁰ in addition to the proposals discussed above, we seek comment on how the Commission can emphasize this aspect of its information collection reports.

Procedural Matters

Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in the notice of proposed rulemaking (NPRM). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments provided on the first page of the NPRM. The Commission will send a copy of the NPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the NPRM and IRFA (or summaries thereof) will be published in the **Federal Register**.

A. Need for, and Objectives of, the Proposed Rules

The NPRM proposes and seeks comment on ways to implement Section 902 of the Consolidated Appropriations Act of 2021. On December 27, 2020, the President signed the Don’t Break Up the T-Band Act of 2020, which is Division FF, Title IX, Section 902 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260). Section 902 directs the Commission to issue final rules 180 days after enactment on December 27, 2020 designating acceptable purposes and functions for the obligation or expenditure of 911 fees by states and taxing jurisdictions. Section 902 also provides that the use of 911 fees for any

⁴⁸ Sec. 902(d)(4) (internal citations omitted).

⁴⁹ 47 U.S.C. 615a–1(f)(4) (as amended); Section 902(c)(1)(C). The National Highway Traffic Safety Administration and National Telecommunications and Information Administration will review the regulations for the 911 Grant Program at 47 CFR part 400 in order to determine how best to implement the new obligation under the law. The Commission will work with these Agencies to ensure a coordinated compliance regime.

⁵⁰ Sec. 902(d)(1).

⁴⁴ 47 U.S.C. 615a–1(f)(5)(A) (as amended); sec. 902(c)(1)(C).

⁴⁵ 47 U.S.C. 615a–1(f)(5)(B) (as amended); sec. 902(c)(1)(C).

⁴⁶ 47 U.S.C. 615a–1(f)(5)(A) (as amended); sec. 902(c)(1)(C).

⁴⁷ See 47 CFR 1.2.

purpose or function other than those designated by the Commission constitutes 911 fee diversion.

To implement Section 902 of the Act, the NPRM seeks comment on the Commission's proposals to amend part 9 of the rules to establish a new subpart I regarding "911 Fees." Section 902 defines several terms, and the NPRM proposes to codify these definitions in the new subpart I of the rules. In addition, Section 902 directs the Commission to issue final rules designating purposes and functions for which the obligation or expenditure of 911 fees is acceptable. It also provides that the purposes and functions identified by the Commission as acceptable "shall be limited to the support and implementation of 9–1–1 services provided by or in the State or taxing jurisdiction imposing the fee or charge and operational expenses of public safety answering points within such State or taxing jurisdiction." The NPRM seeks comments on proposals to develop an illustrative, non-exhaustive list of permissible and non-permissible uses for purposes of Section 902.

Section 902 provides that a state or taxing jurisdiction may petition the FCC for a determination that an obligation or expenditure of a 911 fee for a purpose or function other than those deemed acceptable by the Commission should be treated as an acceptable expenditure. Per Section 902, the petition must demonstrate that the expenditure: (1) Supports public safety answering point (PSAP) functions or operations, or (2) has a direct impact on the ability of a PSAP to receive or respond to 911 calls or to dispatch emergency responders. If the Commission finds that a state or taxing jurisdiction has provided sufficient documentation to make this demonstration, the statute provides that it shall grant the petition. In addition, the Commission seeks comment on amending the rules to require that if a state or taxing jurisdiction receives a grant under section 158 of the National Telecommunications and Information Administration Organization Act (47 U.S.C. 942) after December 27, 2020, such state or taxing jurisdiction shall provide the information requested by the Commission to prepare the annual report to Congress required by the NET 911 Act. The NPRM seeks comment on proposals to codify these provisions in subpart I of part 9 of the rules.

B. Legal Basis

This action was taken pursuant to Sections 1, 4(i), 4(j), 4(o), 201(b), 251(e), 301, 303(b), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j),

154(o), 201(b), 251(e), 301, 303(b), and 303(r), the Don't Break Up The T-Band Act of 2020, Section 902 of Title IX, Division FF of the Consolidated Appropriations Act, 2021, Public Law 116–260, Section 101 of the New and Emerging Technologies 911 Improvement Act of 2008, Public Law 110–283, 47 U.S.C. 615a–1, and the Wireless Communications and Public Safety Act of 1999, Public Law 106–81, 47 U.S.C. 615 note, 615, 615a, and 615b.

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

The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small-business concern" under the Small Business Act. A "small-business concern" is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

Small Businesses, Small Organizations, Small Governmental Jurisdictions. Our actions, over time, may affect small entities that are not easily categorized at present. We therefore describe here, at the outset, three broad groups of small entities that could be directly affected herein. First, while there are industry-specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the Small Business Administration's (SBA's) Office of Advocacy, in general a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States, which translates to 30.7 million businesses.

Next, the type of small entity described as a "small organization" is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field." The Internal Revenue Service (IRS) uses a revenue benchmark of \$50,000 or less to delineate its annual electronic filing requirements for small exempt organizations. Nationwide, for tax year 2018, there were approximately 571,709 small exempt organizations in the U.S. reporting revenues of \$50,000 or less according to the registration and

tax data for exempt organizations available from the IRS.

Finally, the small entity described as a "small governmental jurisdiction" is defined generally as "governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand." U.S. Census Bureau data from the 2017 Census of Governments indicate that there were 90,075 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States. Of this number there were 36,931 general purpose governments (county, municipal and town or township) with populations of less than 50,000 and 12,040 special purpose governments— independent school districts with enrollment populations of less than 50,000. Accordingly, based on the 2017 U.S. Census of Governments data, we estimate that at least 48,971 entities fall into the category of "small governmental jurisdictions."

Wireless Telecommunications Carriers (except Satellite). This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The appropriate size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. For this industry, U.S. Census Bureau data for 2012 show that there were 967 firms that operated for the entire year. Of this total, 955 firms employed fewer than 1,000 employees and 12 firms employed 1000 employees or more. Thus, under this category and the associated size standard, the Commission estimates that the majority of Wireless Telecommunications Carriers (except Satellite) are small entities.

Wired Telecommunications Carriers. The U.S. Census Bureau defines this industry as "establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony

services, including voice over internet protocol (VoIP) services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.” The SBA has developed a small business size standard for Wired Telecommunications Carriers, which consists of all such companies having 1,500 or fewer employees. U.S. Census Bureau data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this size standard, the majority of firms in this industry can be considered small.

All Other Telecommunications. The “All Other Telecommunications” category is comprised of establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing internet services or VoIP services via client-supplied telecommunications connections are also included in this industry. The SBA has developed a small business size standard for “All Other Telecommunications,” which consists of all such firms with annual receipts of \$35 million or less. For this category, U.S. Census Bureau data for 2012 show that there were 1,442 firms that operated for the entire year. Of those firms, a total of 1,400 had annual receipts less than \$25 million, and 15 firms had annual receipts of \$25 million to \$49,999,999. Thus, the Commission estimates that the majority of “All Other Telecommunications” firms potentially affected by our action can be considered small.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

As indicated in Section A above, the NPRM seeks comment on proposed rules to implement Section 902. The NPRM generally does not propose specific reporting or recordkeeping requirements. The NPRM does, however, propose and seek comment on codifying the requirement that states or taxing jurisdictions seeking a Commission determination on 911 fee

diversion satisfy certain criteria established in Section 902. In such cases, a state or taxing jurisdiction would have to show that a proposed expenditure: (1) Supports PSAP functions or operations, or (2) has a direct impact on the ability of a PSAP to receive or respond to 911 calls or to dispatch emergency responders. If the Commission finds that a state or taxing jurisdiction has provided sufficient documentation to make this demonstration, the statute provides that it shall grant the petition. The information and documentation that a state or taxing jurisdiction will have to provide the Commission to make the requisite showing will impact the reporting and recordkeeping requirements for small entities and others subject to the requirements. The Commission proposes to apply the existing declaratory ruling procedures and obligations under § 1.2 of the Commission’s rules, which small entities may already be familiar with, to petitions for determination.

In addition, the NPRM seeks comment on amending the rules to require that if a state or taxing jurisdiction receives a grant under section 158 of the National Telecommunications and Information Administration Organization Act (47 U.S.C. 942) after December 27, 2020, such state or taxing jurisdiction shall provide the information requested by the Commission to prepare the report required under section 6(f)(2) of the Wireless Communications and Public Safety Act of 1999 (47 U.S.C. 615a–1(f)(2)). This proposed requirement is consistent with the requirements of Section 902. Under OMB Control No. 3060–1122, the Office of Management and Budget previously approved and renewed the information collection requirements associated with filing annual 911 fee reports as mandated by the NET 911 Act.

E. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

The RFA requires an agency to describe any significant specifically small business alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for 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 small entities.

In the NPRM, the Commission seeks to implement the provisions of Section 902 that require Commission action by proposing changes to part 9 of our rules that would achieve the stated objectives of Congress’s mandated rules in a cost-effective manner that is not unduly burdensome to providers of emergency telecommunication services or to states and taxing jurisdictions. Using this approach, we inherently take steps to minimize any significant economic impact or burden for small entities. Specifically, we propose to adopt and codify the definitions in Section 902 for certain terms relating to 911 fees and fee diversion in part 9 of our rules. For a few terms, we make limited modifications to the definition to avoid gaps and promote the apparent intent of the new statute. In addition to promoting consistency, we believe our proposals will help small entities and others who will be subject to Section 902 and our rules avoid additional expenses for compliance which may have resulted if the Commission in the alternative proposed and adopted different definitions for certain terms in Section 902 relating to 911 fees and fee diversion.

Similarly, to fulfill the Commission obligations associated with issuing rules designating acceptable purposes and functions, for consistency we propose to use language from Section 902 codifying the statutory standard for which the obligation or expenditure of 911 fees or charges by any state or taxing jurisdiction is considered acceptable. We also propose to specify in the rules examples of both acceptable and unacceptable purposes and functions for the obligation or expenditure of 911 fees or charges. If adopted, identifying and including these examples in the Commission’s rules should enable small entities to avoid unacceptable expenditures in violation of our rules, which could impact eligibility for Federal grants and participation in Federal advisory committees.

Finally, the Commission expects to more fully consider the economic impact on small entities, as identified in comments filed in response to the NPRM and this IRFA, in reaching its final conclusions and taking action in this proceeding.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

None.

Ordering Clauses

Accordingly, *it is ordered*, pursuant to Sections 1, 4(i), 4(j), 4(o), 201(b), 251(e), 301, 303(b), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 154(o), 201(b), 251(e), 301, 303(b), and 303(r), the Don't Break Up the T-Band Act of 2020, Section 902 of Title IX, Division FF of the Consolidated Appropriations Act, 2021, Public Law 116–260, Section 101 of the New and Emerging Technologies 911 Improvement Act of 2008, Public Law 110–283, 47 U.S.C. 615a–1, and the Wireless Communications and Public Safety Act of 1999, Public Law 106–81, 47 U.S.C. 615 note, 615, 615a, and 615b, that this notice of proposed rulemaking is hereby *adopted*.

It is further ordered that, pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's Rules, 47 CFR 1.415, 1.419, interested parties may file comments on the notice of proposed rulemaking on or before 20 days after publication in the **Federal Register**, and reply comments on or before 30 days after publication in the **Federal Register**.

It is further ordered that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this notice of proposed rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 9

Communications common carriers, Communications equipment, Radio, Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 9 as follows:

PART 9—911 REQUIREMENTS

■ 1. The authority citation for part 9 is revised to read as follows:

Authority: 47 U.S.C. 151–154, 152(a), 155(c), 157, 160, 201, 202, 208, 210, 214, 218, 219, 222, 225, 251(e), 255, 301, 302, 303, 307, 308, 309, 310, 316, 319, 332, 403, 405, 605, 610, 615, 615 note, 615a, 615b, 615c, 615a–1, 616, 620, 621, 623, 623 note, 721, and 1471, and Section 902 of Title IX, Division FF, Pub. L. 116–260, 134 Stat. 1182, unless otherwise noted.

■ 2. Add subpart I, consisting of §§ 9.21 through 9.26, to read as follows:

Subpart I—911 Fees

Sec.

9.21 Applicability.

9.22 Definitions.

9.23 Designation of acceptable obligations or expenditures.

9.24 Petition regarding additional purposes and functions.

9.25 Participation in annual fee report data collection.

9.26 Advisory committee participation.

§ 9.21 Applicability.

The rules in this subpart apply to States or taxing jurisdictions that collect 911 fees or charges (as defined in this subpart) from commercial mobile services, IP-enabled voice services, and other emergency communications services.

§ 9.22 Definitions.

For purposes of this subpart, the terms in this section have the following meaning:

911 fee or charge. A fee or charge applicable to commercial mobile services, IP-enabled voice services, or other emergency communications services specifically designated by a State or taxing jurisdiction for the support or implementation of 911 services. A 911 fee or charge shall also include a fee or charge designated for the support of public safety, emergency services, or similar purposes if the purposes or allowable uses of such fee or charge include the support or implementation of 911 services.

Diversion. The obligation or expenditure of a 911 fee or charge for a purpose or function other than the purposes and functions designated by the Commission as acceptable pursuant to § 9.23. Diversion also includes distribution of 911 fees to a political subdivision that obligates or expends such fees for a purpose or function other than those designated as acceptable by the Commission pursuant to § 9.23.

Other emergency communications services. The provision of emergency information to a public safety answering point via wire or radio communications, and may include 911 and E911 service.

State. Any of the several States, the District of Columbia, or any territory or possession of the United States.

State or taxing jurisdiction. A State, political subdivision thereof, Indian Tribe, or village or regional corporation serving a region established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601 *et seq.*)

§ 9.23 Designation of acceptable obligations or expenditures.

(a) Acceptable purposes and functions for the obligation or expenditure of 911 fees or charges are limited to:

(1) Support and implementation of 911 services provided by or in the State or taxing jurisdiction imposing the fee or charge; and

(2) Operational expenses of public safety answering points within such State or taxing jurisdiction.

(b) Examples of acceptable purposes and functions include, but are not limited to, the following, provided that the State or taxing jurisdiction can adequately document that it has obligated or spent the fees or charges in question for these purposes and functions:

(1) PSAP operating costs, including lease, purchase, maintenance, and upgrade of customer premises equipment (CPE) (hardware and software), computer aided dispatch (CAD) equipment (hardware and software), and the PSAP building/facility;

(2) PSAP personnel costs, including telecommunicators' salaries and training;

(3) PSAP administration, including costs for administration of 911 services and travel expenses associated with the provision of 911 services;

(4) Integrating public safety/first responder dispatch and 911 systems, including lease, purchase, maintenance, and upgrade of CAD hardware and software to support integrated 911 and public safety dispatch operations; and

(5) Providing for the interoperability of 911 systems with one another and with public safety/first responder radio systems.

(c) Examples of purposes and functions that are not acceptable for the obligation or expenditure of 911 fees or charges include, but are not limited to, the following:

(1) Transfer of 911 fees into a State or other jurisdiction's general fund or other fund for non-911 purposes;

(2) Equipment or infrastructure for constructing or expanding non-public safety communications networks (*e.g.*, commercial cellular networks); and

(3) Equipment or infrastructure for law enforcement, firefighters, and other public safety/first responder entities, including public safety radio equipment and infrastructure, that does not have a direct impact on the ability of a PSAP to receive or respond to 911 calls or to dispatch emergency responders.

(d) If a State or taxing jurisdiction collects fees or charges designated for "public safety," "emergency services," or similar purposes that include the support or implementation of 911 services, the obligation or expenditure of such fees or charges shall not constitute diversion provided that the State or taxing jurisdiction:

(1) Specifies the amount or percentage of such fees or charges that is dedicated to 911 services;

(2) Ensures that the 911 portion of such fees or charges is segregated and not commingled with any other funds; and

(3) Obligates or expends the 911 portion of such fees or charges for acceptable purposes and functions as defined under this section.

§ 9.24 Petition regarding additional purposes and functions.

(a) A State or taxing jurisdiction may petition the Commission for a determination that an obligation or expenditure of 911 fees or charges for a purpose or function other than the purposes or functions designated as acceptable in § 9.23 should be treated as an acceptable purpose or function. Such

a petition must meet the requirements applicable to a petition for declaratory ruling under § 1.2 of this chapter.

(b) The Commission shall grant the petition if the State or taxing jurisdiction provides sufficient documentation to demonstrate that the purpose or function:

(1) Supports public safety answering point functions or operations; or

(2) Has a direct impact on the ability of a public safety answering point to:

- (i) Receive or respond to 911 calls; or
- (ii) Dispatch emergency responders.

§ 9.25 Participation in annual fee report data collection.

If a State or taxing jurisdiction receives a grant under section 158 of the National Telecommunications and Information Administration Organization Act (47 U.S.C. 942) after December 27, 2020, such State or taxing

jurisdiction shall provide the information requested by the Commission to prepare the report required under section 6(f)(2) of the Wireless Communications and Public Safety Act of 1999 (47 U.S.C. 615a–1(f)(2)).

§ 9.26 Advisory committee participation.

Notwithstanding any other provision of law, any State or taxing jurisdiction identified by the Commission in the report required under section 6(f)(2) of the Wireless Communications and Public Safety Act of 1999 (47 U.S.C. 615a–1(f)(2)) as engaging in diversion of 911 fees or charges shall be ineligible to participate or send a representative to serve on any advisory committee established by the Commission.

[FR Doc. 2021–04250 Filed 3–1–21; 4:15 pm]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 86, No. 40

Wednesday, March 3, 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 COMMERCE

Economic Development Administration; Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice and opportunity for public comment.

SUMMARY: The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms' workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

SUPPLEMENTARY INFORMATION:

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE [2/13/2021 through 2/23/2021]

Firm name	Firm address	Date accepted for investigation	Product(s)
B T M Industries, Inc	604 Washington Street, Woodstock, IL 60098.	2/16/2021	The firm manufactures miscellaneous metal parts.
Byan Systems, Inc	413 South Linden Street, Lusk, WY 82225.	2/22/2021	The firm manufactures automatic gates.
J D Machine Corporation d/b/a J D Machine.	2744 North Parkland Boulevard, Ogden, UT 84404.	2/22/2021	The firm manufactures aerospace parts.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which

these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Bryan Borlik,
Director.

[FR Doc. 2021-04405 Filed 3-2-21; 8:45 am]

BILLING CODE 3510-WH-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XA812]

Recommendations for More Resilient Fisheries and Protected Resources Due to Climate Change

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

ACTION: Notice; request for information.

SUMMARY: On January 27, 2021, the White House issued an Executive Order on Tackling the Climate Crisis at Home and Abroad. As part of this effort, NOAA is collecting recommendations on how to make fisheries and protected resources more resilient to climate change, including changes in management and conservation measures, and improvements in science, monitoring, and cooperative research. NOAA requests written input from interested parties on how best to achieve these objectives described in the Executive Order.

DATES: Responses must be received by April 2, 2021.

ADDRESSES: Responses should be submitted via email to OceanResources.Climate@noaa.gov. Include "Climate: Recommendations for

Fisheries and Protected Resources” in the subject line of the message.

Instructions: Response to this request for information (RFI) is voluntary. Respondents may comment on fisheries, protected resources or both. For all submissions, clearly indicate which issue(s) are being addressed. Email attachments will be accepted in plain text, Microsoft Word, or Adobe PDF formats only. Each individual or institution is requested to submit only one response. The Department of Commerce may post responses to this RFI, without change, on a Federal website. NOAA, therefore, requests that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFI. Please note that the U.S. Government will not pay for response preparation, or for the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT: Heather Sagar, heather.sagar@noaa.gov, 301-427-8019.

SUPPLEMENTARY INFORMATION: On January 27, 2021, the President signed a new Executive Order on Tackling the Climate Crisis at Home and Abroad. Section 216(c) of the Executive Order requires the Secretary of Commerce, through the Administrator of the National Oceanic and Atmospheric Administration, to collect input from fishermen, regional ocean councils, fishery management councils, scientists, and other stakeholders on how to make fisheries and protected resources more resilient to climate change, including changes in management and conservation measures, and improvements in science, monitoring, and cooperative research.

Dated: February 24, 2021.

Benjamin Friedman,

Deputy Under Secretary for Operations, Performing the Duties of Under Secretary of Commerce for Oceans and Atmosphere and NOAA Administrator.

[FR Doc. 2021-04137 Filed 3-2-21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XA810]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Berth III New Mooring Dolphins Project in Ketchikan, Alaska

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to the City of Ketchikan, Alaska (COK) to incidentally harass, by Level A and B harassment, marine mammals during construction activities associated with the Berth III New Mooring Dolphins Project in Ketchikan, AK.

DATES: This Authorization is effective for a period of one year, from October 1, 2021 through September 30, 2022.

FOR FURTHER INFORMATION CONTACT: Robert Pauline, Office of Protected Resources, NMFS, (301) 427-8401. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act>. In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the “take” of marine mammals, with certain exceptions, sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed incidental take authorization may be provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the

taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other “means of effecting the least practicable adverse impact” on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as “mitigation”); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth.

The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

Summary of Request

On May 14, 2020, NMFS received a request from COK for an IHA to take marine mammals incidental to construction activities associated with the Berth III Mooring Dolphin Project in Ketchikan, Alaska. After several revisions, the application was deemed adequate and complete on September 22, 2021. COK’s request is for take of nine species of marine mammals by harassment, including Level A harassment of three of these species. Neither COK nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of the Specified Activity

COK plans to make improvements to Berth III, in order to accommodate a new fleet of large cruise ships (*i.e.* Bliss class) and to meet the needs of the growing cruise ship industry and its vessels in Southeast Alaska. Expansion activities include vibratory pile removal, vibratory pile driving, impact pile driving and down-the-hole (DTH) pile installation. Underwater sound generated by these in-water activities may result in harassment including Level B harassment and Level A harassment of marine mammal species. In-water work is scheduled to occur over approximately 120 days between October 1, 2021 and March 13, 2022 although the IHA would be effective until September 30, 2022.

The proposed project would install three new mooring dolphins (MD) with one at the north end of Berth III (MD#2) and two at the south end (MD#3 & MD#4) as shown in Figure 2 in COK’s IHA application (available online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/>

incidental-take-authorizations-construction-activities). A total of 20 piles will be installed. Eight of the piles are temporary template piles and would be removed as shown in Table 1. Pile driving will be conducted from an anchored barge, utilizing vibratory and impact hammers to install and remove piles and DTH pile installation to position rock sockets and tension

anchors. Rock socketing is a process where a pile is driven by conventional vibratory and impact hammers until reaching solid bedrock. If at that point the pile cannot support the needed load, a hole can be drilled into the rock with a DTH system to allow the pile to be anchored up to 10 or more feet into the solid rock. Tension anchoring involves creating an anchor hole that is smaller

in diameter than the pile. The holes extend 10 to 20 feet or more below the bottom of the pile. A steel bar or other anchoring structure (*e.g.*, rebar frame) is then grouted or cemented in place from the bottom of the anchor hole and extending up to the top of the pile. Attaching the anchor bar or frame to the pile then helps anchor the pile in place to support the required project loads.

TABLE 1—PROJECT PILE TYPES AND QUANTITIES

Location	Item	Size and type	Qty
MD#2	Dolphin and Fender Piles	48-inch (1.22 m) steel pipe piles	6
	Temporary Template Piles	30-inch (0.76 m) steel pipe piles	8
MD#3	Dolphin Piles	36-inch (0.9 m) steel pipe piles	3
MD#4	Dolphin Piles	36-inch (0.9 m) steel pipe piles	3

A detailed description of the planned Berth III New Mooring Dolphins Project is provided in the **Federal Register** notice for the proposed IHA (85 FR 71612; November 10, 2020). Since that time, no changes have been made to the planned activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity.

Mitigation, monitoring, and reporting measures are described in detail later in this document (please see Mitigation and Monitoring and Reporting sections).

Comments and Responses

A notice of NMFS's proposal to issue an IHA to COK was published in the **Federal Register** on November 12, 2020 (85 FR 71612). That notice described, in detail, COK's activity, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals. During the 30-day public comment period, NMFS received comments from the Marine Mammal Commission (Commission). Please see the Commission's letter for full details regarding their recommendations and rationale. The letter is available online at: <https://www.fisheries.noaa.gov/action/incidental-take-authorization-berth-iii-new-mooring-dolphins-project-ketchikan-alaska>. A summary of the Commission's recommendations as well as NMFS' responses is below.

Comment 1: The Commission inquired about the methodology used to extrapolate the source level for DTH installation of 48-inch piles and recommended that NMFS publish a revised authorization for public comment that fully describes its extrapolation method before issuing any final authorization to COK.

Response: The extrapolation technique and software packages employed by NMFS and described

below are commonly used and widely accepted by the scientific community. In summary, NMFS ran regressions in the R programming language (version 3.5.1) using the R Commander Graphical User Interface. Data were average source levels from recordings of single piles and available covariates (*e.g.*, water depth, pile depth, hole size, distance of sound source measurement) where NMFS had access to published and unpublished DTH monitoring data. The Generalized Linear Model routine in R Commander was used to assess the fit of linear and non-linear multiple regression models of the data. Model assumptions were assessed graphically and mathematically and the best fit of models that fit statistical assumptions and retained statistically significant covariates was chosen mathematically. The best fit model was used to calculate the source level for the extrapolated hole size. The calculated source level was then rounded to the next highest integer decibel for use in this action. NMFS does not concur that the notice of proposed authorization needs to be re-published given that a re-published notice would utilize the same extrapolation methodology and arrive at the same source level for DTH installation of 48-inch piles.

Comment 2: The Commission recommended that NMFS use a repetition rate of 13 strikes/second and the proxy source level of 146 dB re 1 μ Pa₂-sec at 10 m from Guan and Miner (2020) to re-estimate the Level A harassment and shutdown zones for DTH pile installation of 12-inch piles.

Response: NMFS did utilize a proxy source level of 146 dB re 1 μ Pa₂-sec for DTH pile installation of 12-inch piles. NMFS does not agree with the recommendation to use a strike rate of 13 strikes per second as strike rates can be highly variable. While it appears that

strike rates may decrease as hole sizes become smaller, there is no specific strike rate data available for 12-inch piles. Therefore, NMFS used a strike rate across all DTH activities of 10 strikes per second.

Comment 3: The Commission recommended that NMFS require COK to conduct sound source and sound propagation measurements of DTH pile installation.

Response: NMFS agrees that there would be value in conducting sound source testing on some of the piles for which DTH installation data is not available. However, the City of Ketchikan has not budgeted for sound source verification and propagation measurements and a requirement of this nature would not be practicable. Therefore, NMFS does not concur with the Commission's recommendation.

Comment 4: The Commission recommended that NMFS employ alternate methodologies to estimate take of harbor seals. They recommended either basing take estimates on survey data from a local haulout location or on observations made during a COK-sponsored rock blasting project (84 FR 36891; July 30, 2019).

Response: There are a number of ways to estimate take in the absence of density data. NMFS based take on observed harbor seal group size near the project area. This methodology has previously been employed by NMFS at other locations in Ketchikan (84 FR 36891; July 30, 2019 and 85 FR 673; January 7, 2020). Applying the available haulout data would likely overestimate take since it assumed that all 83 seals at the haulout would be taken during each day of construction. NMFS did use the data from the COK-sponsored rock blasting project but interpreted the results differently than the Commission. Given that harbor seals are known to

follow fishing vessels into the marina, COK and NMFS assumed that more seals would be found in or near the harbor, while the Commission assumed that the animals would be evenly distributed across the entire 12.5-km Level B harassment zone. Since NMFS believes seal concentrations are likely to be greater near the harbor, we do not concur with the Commission's recommendation.

Comment 5: The Commission recommended that NMFS revise condition 6(b)(ix) in the final authorization to require COK to report the number of individuals of each species detected within the Level A and B harassment zones, and estimates of number of marine mammals taken by Level A and B harassment, by species. The Commission recommended NMFS include requirements that COK include in its monitoring report (1) the estimated percentages of the Level A and B harassment zones that were not visible, (2) an extrapolation of the estimated takes by Level A and B harassment based on the number of observed exposures within the Level A and B harassment zones and the percentages of the Level A and B harassment zones that were not visible (*i.e.*, extrapolated takes) consistent with other authorizations, and (3) the total number of Level A and B harassment takes based on both the observed and extrapolated takes for each species.

Response: We do not fully concur with the Commission's recommendation and do not adopt it as stated. NMFS agrees with the recommendation to require COK to report the number of individuals of each species detected within the harassment zones and has included this requirement in both the proposed and final authorizations. (See condition 6(b)(ix).) NMFS does not agree with the recommendation to require COK to report estimates of the numbers of marine mammals taken by Level B harassment. The Commission does not explain why it believes this requirement is necessary, nor does it provide recommendations for methods of generating such estimates in a manner that would lead to credible results. NMFS does agree COK should report the estimated percentage(s) of the Level B harassment zones that were not visible, and has included this requirement in both the proposed and final authorizations. (See condition 6(b)(iii).) These pieces of information—numbers of individuals of each species detected within the harassment zones and the estimated percentage(s) of the harassment zones that were not visible—may be used to glean an approximate understanding of whether

COK may have exceeded the amount of take authorized. Although the Commission does not explain its reasoning for offering these recommendations, NMFS recognizes the basic need to understand whether an IHA-holder may have exceeded its authorized take. The need to accomplish this basic function of reporting does not require that NMFS require applicants to use methods we do not have confidence in to generate estimates of “total take” that cannot be considered reliable.

Comment 6: The Commission recommended that NMFS include in the final authorization an additional table that specifies the extents of the Level A harassment zones that exceed the shut-down zones, particularly for HF cetaceans and phocids.

Response: The table described by the Commission has been used very infrequently and only in situations with there are limited pile types, pile sizes, and/or pile installation methods employed. Such a table would be cumbersome and unwieldy in this instance given the numerous pile types, pile sizes and pile installation methods planned for use in which different Level A harassment isopleths are dependent on either varying duration or strike rate for both impact and DTH installation. The information that the Commission desires is readily available in Table 7 and Table 10.

Comment 7: The Commission recommended that NMFS reinforce that COK must keep a running tally of the total Level A and B harassment takes, both observed and extrapolated, for each species consistent with condition 4(g) of the final authorization.

Response: The IHA indicates the number of takes authorized for each species. We agree that COK must ensure they do not exceed authorized takes, but do not concur with the Commission's repeated recommendations regarding the need for NMFS to oversee IHA-holders' compliance with issued IHAs, including the use of a “running tally” of takes. Regardless of the Commission's substitution of the word “reinforce” for the word “ensure,” as compared with its prior recommendations for other actions, compliance with the terms of an issued IHA remains the responsibility of the IHA-holder.

Comment 8: The Commission recommended that NMFS refrain from issuing a renewal for any authorization unless it is consistent with the procedural requirements specified in section 101(a)(5)(D)(iii) of the MMPA.

Response: In prior responses to comments about IHA Renewals (*e.g.*, 84 FR 52464; October 02, 2019 and 85 FR 53342, August 28, 2020), NMFS has

explained how the Renewal process, as implemented, is consistent with the statutory requirements contained in section 101(a)(5)(D) of the MMPA, provides additional efficiencies beyond the use of abbreviated notices, and, further, promotes NMFS' goals of improving conservation of marine mammals and increasing efficiency in the MMPA compliance process. Therefore, we intend to continue implementing the Renewal process.

Changes From the Proposed IHA to Final IHA

NMFS increased authorized take of harbor porpoise from 40 to 80 and authorized take of minke whale from 2 to 8 based on informal comments from the Commission. Authorized take of humpback whales was also increased from 68 to 119 due to the daily occurrence of a single humpback whale in Tongass Narrows after the notice of proposed IHA (85 FR 71612; November 12, 2020) had published in the **Federal Register**. These changes are described in detail in the Estimated Take section. The source level for DTH installation of 12-inch anchors was reduced from 166.2 dB to 162 dB based on data from Guan and Miner (2020) where 18-inch piles were measured. Anchor holes for COK will be 12-inch. Therefore, it is more accurate to use the 18-inch SL as the proxy sound source level for 12-inch anchors compared to 30-, 36- and 48-inch piles from Reyff & Heyvaert (2019), Reyff (2020), and Denes et al. (2019) which were used to derive 166.2 dB SL value. Therefore, the Level B harassment isopleth for DTH installation of 12-inch anchors was reduced from 12,023 m to 6,310 m. In the Monitoring and Reporting section, NMFS has added language stating that PSOs must work in rotating shifts of 4 hours and individual PSOs must not perform duties for more than 12 hours in a 24-hour period. New language has also been added requiring PSOs to use elevated platforms at observation points to the extent practicable.

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SARs; <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>) and more general information about these species

(e.g., physical and behavioral descriptions) may be found on NMFS's website (<https://www.fisheries.noaa.gov/find-species>).

Table 2 lists all species or stocks for which take is expected and authorized for this action, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2020). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal

stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of

individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's U.S. Alaska SARs (Muto *et al.* 2020). All values presented in Table 2 are the most recent available at the time of publication and are available in the 2019 SARs (Muto *et al.*, 2020) and draft 2020 SARs (available online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports>).

TABLE 2—MARINE MAMMALS THAT COULD OCCUR IN THE PROJECT AREA

Common name	Scientific name	MMPA stock	ESA/ MMPA status; strategic (Y/N) ¹	Stock abundance Nbest (CV, N _{min} , most recent abundance survey) ²	PBR	Annual M/SI ³
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Eschrichtiidae						
Gray Whale	<i>Eschrichtius robustus</i>	Eastern North Pacific	- , -, N	26,960 (0.05, 25,849, 2016) ..	801	139
Family Balaenidae						
Humpback whale	<i>Megaptera novaeangliae</i>	Central North Pacific	- , -, Y	10,103 (0.3; 7,891; 2006)	83	25
Minke whale	<i>Balaenoptera acutorostrata</i> ...	Alaska	- , -, N	N.A.	N.A.	0
Order Cetartiodactyla—Cetacea—Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae						
Killer whale	<i>Orcinus orca</i>	Alaska Resident	- , -, N	2,347 (N.A.; 2,347; 2012)	24	1
		West Coast Transient	- , -, N	243 (N.A., 243, 2009)	2.4	0
		Northern Resident	- , -, N	302 (N.A.; 302, 2018)	2.2	0.2
		Gulf of Alaska, Aleutian Is- lands, and Bering Sea Transient.	- , -, N	587 (N.A.; 587; 2012)	5.87	1
Pacific white-sided dolphin	<i>Lagenorhynchus obliquidens</i>	North Pacific	- , -, N	26,880 (N.A.; N.A.; 1990)	N.A.	0
Family Phocoenidae						
Harbor porpoise	<i>Phocoena phocoena</i>	Southeast Alaska	- , -, Y	1,354 (0.10; 896; 2012)	8.95	34
Dall's porpoise	<i>Phocoenoides dalli</i>	Alaska	- , -, N	83,400 (0.097; N.A.; 1991)	N.A.	38
Order Carnivora—Superfamily Pinnipedia						
Family Otariidae (eared seals and sea lions)						
Steller sea lion	<i>Eumetopias jubatus</i>	Eastern U.S.	- , -, N	43,201 (N.A.; 43,201; 2017) ..	2,592	112
Family Phocidae (earless seals)						
Harbor seal	<i>Phoca vitulina richardii</i>	Clarence Strait	- , -, N	27,659 (N.A.; 24,854; 2015) ..	746	40

¹ Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

² NMFS marine mammal stock assessment reports online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>. CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable (N.A.).

³ These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

As indicated above, all nine species (with 12 managed stocks) in Table 2 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur, and we are authorizing it.

A detailed description of the of the species likely to be affected by the project, including brief introductions to the species and relevant stocks as well as available information regarding population trends and threats, and

information regarding local occurrence, were provided in the **Federal Register** notice for the proposed IHA (85 FR 71612); since that time, we are not aware of any changes in the status of these species and stocks; therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice for these descriptions. Please also refer to NMFS' website (<https://www.fisheries.noaa.gov/find-species>) for generalized species accounts.

species) for generalized species accounts.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals

are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (e.g., Richardson *et al.*, 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.*, (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges based on available behavioral response data, audiograms

derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (i.e., low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel

(dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.*, (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in Table 3.

TABLE 3—MARINE MAMMAL HEARING GROUPS
[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, <i>Kogia</i> , river dolphins, cephalorhynchid, <i>Lagenorhynchus cruciger</i> & <i>L. australis</i>)	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (i.e., all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.*, 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.*, 2006; Kastelein *et al.*, 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Nine mammal species (seven cetacean and two pinniped (one otariid and one phocid) species) have the reasonable potential to co-occur with the planned survey activities. Of the cetacean species that may be present, three are classified as low-frequency cetaceans (i.e., all mysticete species), two are classified as mid-frequency cetaceans (i.e., all delphinid and ziphiid species and the sperm whale), and two are classified as high-frequency cetaceans (i.e., porpoise spp.).

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

The effects of underwater noise from pile removal activities have the potential to result in behavioral harassment of marine mammals in the vicinity of the survey area. The notice of proposed IHA (85 FR 71602; November 10, 2020) included a discussion of the effects of anthropogenic noise on marine mammals and the potential effects of underwater noise from WSDOT's vibratory pile removal on marine

mammals and their habitat. That information and analysis is incorporated by reference into this final IHA determination and is not repeated here; please refer to the notice of proposed IHA (85 FR 71602; November 10, 2020).

Estimated Take

This section provides an estimate of the number of incidental takes authorized through this IHA, which will inform both NMFS' consideration of "small numbers" and the negligible impact determination.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines "harassment" as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would primarily be by Level B harassment, as use of the acoustic sources (i.e., vibratory or impact pile driving or DTH pile installation) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for high frequency cetacean species and phocid pinnipeds. Auditory injury is unlikely to occur in low-frequency and

mid-frequency cetacean species and otariid pinnipeds. The planned mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no mortality is anticipated or authorized for this activity. Below we describe how the take is estimated.

Generally speaking, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these basic factors can contribute to a basic calculation to provide an initial prediction of takes, additional information that can qualitatively inform take estimates is also sometimes available (e.g., previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the authorized take estimate.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment for non-explosive sources—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (e.g., frequency, predictability, duty cycle), the environment (e.g., bathymetry), and the receiving animals (e.g., hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.*, 2007, Ellison *et al.*, 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine

mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 dB re 1 μ Pa (rms) for continuous (e.g., vibratory pile-driving, drilling) and above 160 dB re 1 μ Pa (rms) for non-explosive impulsive (e.g., seismic airguns) or intermittent (e.g., scientific sonar) sources.

COK's planned activity includes the use of continuous (vibratory pile driving, DTH pile installation) and impulsive (impact pile driving), sources, and therefore the 120 and 160 dB re 1 μ Pa (rms) criteria are applicable.

Level A harassment for non-explosive sources—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0)

(Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). COK's planned activity includes the use of impulsive (impact pile driving, DTH pile installation) and non-impulsive (vibratory pile driving/removal, DTH pile installation) sources.

These thresholds are provided in Table 4. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2018 Technical Guidance, which may be accessed at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance>.

TABLE 4—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset acoustic thresholds* (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	Cell 1: $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	Cell 2: $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	Cell 3: $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	Cell 4: $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	Cell 5: $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	Cell 6: $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	Cell 7: $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	Cell 8: $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	Cell 9: $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	Cell 10: $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered. *Note:* Peak sound pressure (L_{pk}) has a reference value of 1 μ Pa, and cumulative sound exposure level (L_E) has a reference value of 1 μ Pa²s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (i.e., varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the planned project. Marine mammals are expected to be affected via sound generated by the primary components of the project (i.e., vibratory pile driving, vibratory pile removal, impact pile driving, and DTH pile installation).

Vibratory hammers produce constant sound when operating, and produce vibrations that liquefy the sediment surrounding the pile, allowing it to penetrate to the required seating depth. An impact hammer would then generally be used to place the pile at its intended depth through rock or harder substrates. An impact hammer is a steel

device that works like a piston, producing a series of independent strikes to drive the pile. Impact hammering typically generates the loudest noise associated with pile installation. The actual durations of each installation method vary depending on the type of pile, size of the pile, and substrate characteristics (e.g. bedrock).

In order to calculate distances to the Level A harassment and Level B harassment sound thresholds for piles of various sizes being used in this project, NMFS used acoustic monitoring data from other locations to inform selection of representative source levels (see Table 5).

Sound source levels for vibratory installation of 30-inch steel piles were obtained by Denes *et al.* (2016) during the installation of 30-inch steel pipe piles at the Ketchikan Ferry Terminal. Vibratory removal of 30-inch piles is expected to be quieter than installation,

so this value is used as a proxy. Sound levels for vibratory installation of 48-inch steel piles were obtained by Austin *et al.* (2016) during the installation of test piles at the Port of Anchorage. The applicant elected to conservatively employ sound source levels for the 48-inch piles as a proxy to calculate harassment isopleths for 36-inch piles.

Sound levels for impact installation of 30-inch steel piles were taken from Denes *et al.* (2016) during the installation of piles at the Ketchikan Ferry Terminal. Sound levels for impact installation of 48-inch steel piles were obtained by Austin *et al.* (2016) during the installation of test piles at the Port of Anchorage. Overall median levels were not reported for peak and single strike SEL values. Therefore, the highest values reported for peak and single strike SEL were used. The highest levels reported were a peak of 213.2 dB re: 1 μ Pa at 14 m and a single strike SEL of 186.7 dB re: 1 μ Pa²-sec on pile IP5 at

11 m (Austin *et al.* 2016). Sound source levels for 48-inch piles are used as a proxy to calculate harassment isopleths for 36-inch piles.

DTH pile installation includes drilling (non-impulsive sound) and hammering (impulsive sound) to penetrate rocky substrates (Denes *et al.* 2016; Denes *et al.* 2019; Reyff and Heyvaert 2019). DTH pile installation was initially thought to be a primarily non-impulsive noise source. However, Denes *et al.* (2019) concluded from their study in Virginia that DTH should be characterized as impulsive based on a >3 dB difference in sound pressure level in a 0.035-second window (Southall *et al.* 2007) compared

to a 1-second window. Therefore, DTH pile installation is treated as both an impulsive and non-impulsive noise source. In order to evaluate Level A harassment, DTH pile installation activities are evaluated according to the impulsive criteria and the User Spreadsheet may be employed. Level B harassment isopleths are determined by applying non-impulsive criteria and using the 120 dB threshold which is also used for vibratory driving. This approach ensures that the largest ranges to effect for both Level A and Level B harassment are accounted for in the take estimation process.

The source level employed to derive Level B harassment isopleths for DTH pile installation (socketing) of all pile sizes was derived from the Denes *et al.* (2016) study at Kodiak, Alaska. The reported median source value for drilling was determined to be 166.2 dB RMS.

For DTH anchoring of 12-inch holes, COK used a sound source level from 18-inch piles from Guan and Miner (2020) as a proxy (146 dB SEL) for Level A harassment calculations. For DTH installation of 30 and 36-inch sockets, source levels from 42-inch holes from Reyff & Heyvaert (2019), Reyff (2020), and Denes *et al.* (2019) were employed.

TABLE 5—ESTIMATES OF MEAN UNDERWATER SOUND LEVELS GENERATED DURING VIBRATORY PILE REMOVAL, VIBRATORY PILE INSTALLATION, IMPACT PILE INSTALLATION, AND DTH PILE INSTALLATION

Method and pile type	Sound source level at 10 meters			Literature source
	SPL rms	SPL _{PK}	SS _{SEL}	
Vibratory Hammer				
30-inch steel piles	161.9	Denes <i>et al.</i> 2016.
36-and 48-inch steel piles	168.2	Austin <i>et al.</i> 2016.
Impact Hammer				
30-inch diameters	195	208.5	180.7	Denes <i>et al.</i> 2016.
36- and 48-inch ¹	198.6	213.2 ²	186.7 ³	Austin <i>et al.</i> 2016.
DTH Pile Installation				
DTH Sockets (48-inch) ⁴	166.2	168	Extrapolated from DTH SSV studies listed below; Denes <i>et al.</i> (2016).
DTH Sockets (30-, 36-inch) ⁴	166.2	194	164	Reyff & Heyvaert (2019); Reyff (2020); Denes <i>et al.</i> (2016, Denes <i>et al.</i> 2019).
DTH Anchors (12-inch) ⁵	162	172	146	Guan and Miner (2020).

¹ Sound source levels for 48-inch piles are used as a proxy to calculate harassment isopleths for 36-inch piles.

² Represents maximum value measured at 14 m.

³ Represents maximum value measured at 11 m.

⁴ DTH drilling source levels for 24-inch piles from Denes *et al.* (2016) was used as a proxy for 30-inch to 48-inch piles. SL was revised to 166.2 dB from 166 dB utilized in notice of proposed IHA to more accurately reflect averaged results of DTH installation of 30-, 36- and 48-inch piles from Reyff & Heyvaert (2019); Reyff (2020); Denes *et al.* (2019).

⁵ The pile/hole size from Guan and Miner (2020) measured 18-inches and anchor holes for COK will be 12-inches. Therefore, it is more accurate to use the 18-inch SL as the proxy sound source level for 12-inch anchors.

SS SEL = single strike sound exposure level; dB peak = peak sound level; rms = root mean square.

Level A harassment Zones

When the NMFS Technical Guidance (2016) was published, in recognition of the fact that ensonified area/volume could be more technically challenging to predict because of the duration component in the new thresholds, we developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to help predict takes. We note that because of some of the assumptions included in the methods used for these tools, we anticipate that isopleths produced are typically going to be overestimates of some degree,

which may result in some degree of overestimate of Level A harassment take. However, these tools offer the best way to predict appropriate isopleths when more sophisticated 3D modeling methods are not available, and NMFS continues to develop ways to quantitatively refine these tools, and will qualitatively address the output where appropriate. For stationary sources such as impact driving, vibratory driving and DTH pile installation example from project, NMFS User Spreadsheet predicts the distance at which, if a marine mammal remained at that distance the whole

duration of the activity, it would incur PTS.

Inputs used in the User Spreadsheet (Table 6) and the resulting isopleths are reported below (Table 7). Level A harassment thresholds for impulsive sound sources (impact pile driving, DTH pile installation) are defined for both SEL_{cum} and Peak SPL, with the threshold that results in the largest modeled isopleth for each marine mammal hearing group used to establish the effective Level A harassment isopleth. Note that the peak SPL for DTH installation of 48-inch piles is unknown as no sound source verification testing has been conducted

on piles of that size. The single strike SEL was extrapolated using data points measured for smaller piles during DTH

installation. In this project, Level A harassment isopleths based on SELcum

were always larger than those based on Peak SPL.

TABLE 6—PARAMETERS OF PILE DRIVING AND DRILLING ACTIVITY USED IN USER SPREADSHEET

Equipment type	Vibratory pile driver (installation/removal of 30-inch steel piles)	Vibratory pile driver (installation of 36 and 48-inch steel piles)	Impact pile driver (30-inch steel piles)	Impact pile driver (36 and 48-inch steel piles)	DTH sockets		DTH anchor (12-inch steel piles) ²
					30-, 36-in ¹	48-in	
Source Level	161.9 RMS	168.2 RMS	180.7 SS SEL	186.7 SS SEL	164 SS SEL/ 194 SPLpk.	168 SS SEL	146 SS SEL/ 172 SPLpk.
Weighting Factor Adjustment (kHz).	2.5	2.5	2	2	2		2.
(a) Activity duration (time) within 24 hours.	(a) Up to 6 hrs OR >6–8 hrs(c) 1.	(a) Up to 6 hrs OR >6–8 hrs (c) 1.	(a) 1–10 minutes (b) Up to 500 strikes (c) 1.	(a) 1–10 minutes (b) Up to 500 strikes (c) 1.	(a) Up to 3 hrs OR >3–6 hrs.	(a) Up to 2 hrs OR >2–3 hrs OR >3–4 hrs.	(a) Up to 6 hrs OR >6–8 hrs.
(b) Number of strikes per pile (impact) OR number of strikes per second (DTH).	(a) >10–20 minutes. (b) 501–1,000 strikes (c) 1.	(a) >10–20 minutes. (b) 501–1,000 strikes (c) 1.	(b) 10 strike/sec.	(b) 10 strike/sec.	(b) 10 strikes/sec.
(c) Number of piles per day.	(a) >20–30 minutes (b) 1,001–1,500 strikes (c) 1.	(a) >20–30 minutes (b) 1,001–1,500 strikes (c) 1.	(c) 1	(c) 1	(c) 1.
Propagation (xLogR).	15	15	15	15	15		15.
Distance of source level measurement (meters).	10	10	10	11	10		10.

¹ DTH drilling source levels for 42-inch piles from Reyff and Heyvaert (2019), (Reyff 2020), and Denes et al. (2019) were used as a proxy for 30- and 36-inch piles.

² DTH drilling source levels for 18-inch piles from Guan and Miner (2020) were used as a proxy for 12-inch piles.

TABLE 7—CALCULATED DISTANCES TO LEVEL A HARASSMENT ISOPLETHS (m) DURING VIBRATORY PILE INSTALLATION/REMOVAL, IMPACT INSTALLATION AND DTH PILE INSTALLATION FOR EACH HEARING GROUP

Source	Daily duration	PTS onset isopleth (m)				
		Cetaceans			Pinnipeds	
		Low-frequency	Mid-frequency	High-frequency	Phocid	Otariid
30-inch Vibratory (Installation or Removal)	Up to 6 hours	25.9	2.3	38.3	15.7	1.1
	7 to 8 hours	31.4	2.8	46.4	19.1	1.3
36- and 48-inch Vibratory	Up to 6 hours	68.1	6	100.7	41.4	2.9
	7 to 8 hours	82.5	7.3	122	50.1	3.5
Down-the-Hole Socket (30-, 36-inch)	Up to 3 hours	1,225.6	43.6	1,459.9	655.9	47.8
	4 to 6 hours	1,945.5	69.3	2,317.4	1,041.2	75.8
Down-the-Hole Socket (48-inch)	Up to 2	1,728.3	61.5	2,058.7	924.9	67.3
	>2 to 3 hours	2,264.8	80.5	2,697.7	1,212	88.2
	>3 to 4 hours	2,743.6	97.6	3,268	1,468.2	106.9
Down the Hole Anchor (12-inch)	Up to 6 hours	122.8	4.4	146.2	65.7	4.8
	7 to 8 hours	148.7	5.3	177.1	79.6	5.8
30-inch Diesel Impact	Up to 500 strikes (1–10 minutes).	442	15.7	526.4	236.5	17.2
	501–1,000 strikes (11–20 minutes).	701.6	25	835.7	375.4	27.3
	1,001–1,500 strikes (21–30 minutes).	919.3	32.7	1,095	492	35.8
36- and 48-inch Diesel Impact	Up to 500 strikes (1–10 minutes).	1,221.2	43.4	1,454.6	653.5	47.9
	501–1,000 strikes (11–20 minutes).	1,938.5	68.9	2,309	1,037.4	75.5

TABLE 7—CALCULATED DISTANCES TO LEVEL A HARASSMENT ISOPLETHS (m) DURING VIBRATORY PILE INSTALLATION/REMOVAL, IMPACT INSTALLATION AND DTH PILE INSTALLATION FOR EACH HEARING GROUP—Continued

Source	Daily duration	PTS onset isopleth (m)				
		Cetaceans			Pinnipeds	
		Low-frequency	Mid-frequency	High-frequency	Phocid	Otariid
	1,001–1,500 strikes (21–30 minutes).	2,540.1	90.3	3,025.7	1,359.4	99

Level B Harassment Zones

Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

$$TL = B * \log_{10} (R1/R2),$$

Where

TL = transmission loss in dB

B = transmission loss coefficient; for practical spreading equals 15

R1 = the distance of the modeled SPL from the driven pile, and

R2 = the distance from the driven pile of the initial measurement

The recommended TL coefficient for most nearshore environments is the, practical spreading value of 15. This value results in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions, which is the most appropriate assumption for COK's planned activity.

Using the practical spreading model, COK determined underwater noise would fall below the behavioral effects threshold of 120 dB rms for marine mammals at a maximum radial distance of 16,343 m for vibratory pile driving of 36 and 48-inch diameter piles. Other activities, including rock anchoring and impact pile driving, have smaller Level B harassment zones. All Level B harassment isopleths are reported in Table 8 below. It should be noted that based on the geography of Tongass Narrows and the surrounding islands, sound will not reach the full distance of the Level B harassment isopleth. The largest Level B Harassment isopleth will be truncated by land masses at approximately 12,500 m to the southeast and approximately 3,590 m northwest of the project area. Constraining land masses include Revillagigedo Island, Gravina Island, Pennock Island and Spire Island.

TABLE 8—CALCULATED LEVEL B HARASSMENT ISOPLETHS

Source	Behavioral disturbance isopleth (m) 120 dB
30-inch Vibratory (Installation or Removal)	6,213
36- and 48-inch Vibratory	16,343
DTH installation ¹ (Socket) ...	12,023
DTH installation (anchor) ² ...	6,310
30-inch Diesel Impact	2,154
36- and 48-inch Diesel Impact	3,744

¹ SL of 166.2 dB was used for socket installation instead of 166 as used in notice of proposed IHA.

² SL of 162 dB (Guan and Miner 2020) was used for 12-inch anchor installation.

Marine Mammal Occurrence and Take Calculation and Estimation

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations. Note that there is no density data for any of the species near the Berth III mooring dolphin project area, therefore the take estimate is informed by qualitative data.

The number of marine mammals that may be exposed to harassment thresholds is calculated by estimating the likelihood of a marine mammal being present within a harassment zone during the associated activities. Estimated marine mammal abundance is determined by reviewing local and regional reports, surveys, permits and observations of abundance and frequency near the planned project action. For example, for species that are common with the potential to occur daily, the take calculations are based on the group size multiplied by the projected number of days of underwater noise activities. For species that are less common, take estimates are based on group size multiplied by the frequency (e.g. weekly, monthly). The estimated number of takes are based upon reasonable ranges from the best information currently available for these species near the project area.

Authorization of Level A harassment takes was requested by COK for harbor seal, harbor porpoise, and Dall's porpoise. Harbor seals are habituated to fishing vessels and may follow vessels that enter the marina. Dall's and harbor porpoises' small size and speed make it possible that these animals could occur within the Level A harassment zones and potentially incur injury prior to detection.

Humpback Whale

Humpback whales occur frequently in Tongass Narrows and the adjacent Clarence Strait during summer and fall months to feed, but are less common during winter and spring. The average group size during the fall surveys was two whales according to Dalheim *et al.* (2009). Local reports of humpback whale group size in Tongass Narrows are similar, with the typical size being between 1 and 3. During the spring months, humpback whales tend to congregate in areas outside of the Ketchikan area, such as Lynn Canal and Fredrick Sound. Therefore, it is assumed that the occurrence of humpback whales in the project area is two individuals twice per week throughout the project. A group size of two was also assumed in the Biological Opinion provided to the US Army Corp of Engineers (USACE) for the Alaska Department of Transportation & Public Ferries (ADOT&PF) Berth improvement project in Tongass Narrows (NMFS 2019).

In the notice of proposed IHA (85 FR 71612; November 12, 2020) NMFS estimated that up to 2 individuals could be exposed to underwater noise twice a week during the 17 weeks of the project's in-water work, for a total of 68 incidents of take from the Central North Pacific stock. Wade *et al.* (2016) determined that 6.1 percent of all humpback whales in Southeast Alaska and northern British Columbia were members of the Mexico DPS, while all others are assumed to be members of the Hawaii DPS. Therefore, NMFS had proposed to authorize 68 incidents of take by Level B harassment from the Central North Pacific Stock with 64

instances from the Hawaii DPS and four instances from the endangered Mexico DPS. However, NMFS has increased authorized take by Level B harassment due to the daily presence of a single humpback whale close to Ketchikan during the month of November (USA Today, December 1, 2020). NMFS assumed that one whale would be present in the project area daily throughout the duration of the project. Based on the recent occurrence information, we estimate that one humpback whale will be within the Level B harassment zone daily for 17 weeks.

Therefore:

$(7 \times 17) = 119$ exposures of Central North Pacific stock humpback whales to Level B harassment

As described above, an estimated 6.1 percent of humpback whales in Southeast Alaska are from the Mexico DPS (Wade *et al.* 2016). Therefore, of the 119 animals potentially exposed to Level B harassment due to Berth III pile driving activities, 6.1 percent or 7 of these 119 exposures would be ESA-listed Mexico DPS humpback whales, and the remaining 112 would most likely from the non-listed Hawaii DPS.

Take by Level A harassment is not expected for humpback whales because of the expected effectiveness of the monitoring and mitigation measures. While calculated Level A harassment zones are up to 2,800 m, multiple protected species observers (PSOs) will monitor Tongass Narrows which is < less than 600 m in width and represents a much smaller effective Level A harassment zone. Humpbacks are usually readily visible, therefore, shutdown measures can be implemented prior to any humpback whales incurring PTS within Level A harassment zones.

Steller Sea Lion

Steller sea lion abundance in the Tongass Narrows area is not well known and no systematic studies of Steller sea lions have been conducted in or near the Tongass Narrows area. However, sea lions are known to occur in the Tongass Narrows area throughout the year with peak numbers March through September (ADOT 2019). Sea lions may be present during salmon and herring runs and are known to visit hatcheries and fish processing facilities in the vicinity.

Group sizes are generally 6 to 10 individuals (Freitag 2017) but have been reported to reach 80 animals (Freitag 2017). COK assumed one large group of 10 individuals could be present each day in the project vicinity based on HDR

(2019) and Freitag (2017) (as cited in 83 FR 22009; May 11, 2018). NMFS agrees that this daily estimate is appropriate and therefore has authorized up to 1,200 takes by Level B harassment.

Take by Level A harassment is not expected for Steller sea lions because of the relatively small Level A harassment zones for otariids (Table 7) and the expected effectiveness of the monitoring and mitigation measures discussed below.

Harbor Seal

Harbor seal densities in the Tongass Narrows area are not well known. No systematic studies of harbor seals have been conducted in or near Tongass Narrows. Seals are known to occur year-round with little seasonal variation in abundance (Freitag 2017) and local experts estimate that there are about 1 to 3 harbor seals in Tongass Narrows every day, in addition to those that congregate near the seafood processing plants and fish hatcheries. COK conducted pinnacle rock blasting in December 2019 and January 2020 near the vicinity of the planned project and recorded a total of 21 harbor seal sightings of 24 individuals over 76.2 hours of pre- and post-blast monitoring (Sitkiewicz 2020). Harbor seals were observed in groups ranging from 1–3 animals throughout the 0.70-mile (1.12-kilometer) observation zone. Based on this knowledge, COK assumed an average group size in Tongass Narrows of three individuals. They anticipated that three groups of three harbor seals per group could be exposed to project-related underwater noise each day for 120 days of in-water work. Given that harbor seals are known to follow fishing vessels into the marina and may be difficult to detect, COK assumed that one group of three seals could be taken by Level A harassment daily, resulting in 360 Level A harassment takes. NMFS agreed with these assumptions and, therefore, has authorized 720 takes by Level B harassment and 360 takes by Level A harassment.

Dall's Porpoise

The mean group size of Dall's porpoise in Southeast Alaska is estimated at approximately three individuals (Dahlheim *et al.*, 2009; Jefferson *et al.*, 2019). However, in the Ketchikan vicinity, Dall's porpoises are reported to typically occur in groups of 10–15 animals, with an estimated maximum group size of 20 animals (Freitag 2017, as cited in 83 FR 22009, May 11, 2018). Overall, sightings of Dall's porpoise are infrequent near Ketchikan, but they could be present on

any given day during the construction period.

COK assumed that a maximum group size of 20 Dall's porpoise could occur in the project area each month. NMFS concurs with this assessment and has authorized 80 takes of Dall's porpoise over the anticipated four-month project duration.

Given the large size of the Level A harassment zone associated with impact pile driving for high-frequency cetaceans, it is possible Dall's porpoises may enter the Level A harassment zone undetected. Therefore, NMFS has authorized a total of 60 takes of Dall's porpoise by Level B harassment and 20 takes by Level A harassment over the course of the project.

Harbor Porpoise

Harbor porpoises are non-migratory; therefore, occurrence estimates are not dependent on season. Freitag (2017 as cited in 83 FR 37473; August 1, 2018) observed harbor porpoises in Tongass Narrows zero to one time per month. Harbor porpoises observed in the project vicinity typically occur in groups of one to five animals with an estimated maximum group size of eight animals (83 FR 37473, August 1, 2018, Solstice 2018). Based on this previous information from the Ketchikan Berth IV Expansion project and the AKDOT Tongass Narrows project, COK estimated that two groups of five harbor porpoise may enter the Tongass Narrows twice per month. NMFS agrees with this estimate and, therefore, has authorized 80 takes of harbor porpoise during the duration of the project.

Given that harbor porpoises are stealthy, having no visible blow and a low profile in the water making the species difficult for monitors to detect (Dahlheim *et al.* 2015), COK requested that a total of 20 takes of harbor porpoises by Level A harassment be authorized. Therefore, NMFS has authorized 20 takes of harbor porpoise by Level A harassment and 60 takes by Level B harassment. The number of proposed takes in the proposed IHA (40) was incorrect due to a mathematical error.

Killer Whale

Typical pod sizes observed within the project vicinity range from 1 to 10 animals. COK assumed that the frequency of killer whales passing through the action area is estimated to be once per month and also conservatively assumed a pod size of 10.

Therefore, NMFS has authorized 40 takes of killer whales by Level B harassment.

Take by Level A harassment is not expected for killer whales because of the small Level A harassment zones for mid-frequency cetaceans and the expected effectiveness of the monitoring and mitigation measures discussed below.

Gray Whale

Gray whales have not been reported within the Tongass Narrows; however, their presence cannot be entirely discounted. Since the largest Level B harassment zone extends beyond Tongass Narrows, COK assumed that up to two gray whales may be taken per month. Therefore, NMFS has authorized up to 8 takes of gray whale by Level B harassment.

Due to the unlikely occurrence of gray whales and the ability to shut down pile driving activities prior to a whale entering the Level A harassment zone, no Level A harassment takes of gray whales were requested or are authorized.

Minke Whale

There are no known occurrences of minke whales within the project area although they may be present in Tongass Narrows and Clarence Strait year-round. Their abundance throughout Southeast Alaska is low. However, minke whales are distributed throughout a wide variety of habitats and could occur near the project area. Minke whales are generally sighted as individuals (Dahlheim *et al.* 2009).

NMFS had proposed to authorize two minke whale takes by Level B harassment in the proposed IHA. However, based on an informal comment from the Commission, NMFS has increased to eight the authorized take of minke whales (two takes per month) since they are at least if not more likely to occur in Tongass Narrows compared to gray whales, which have never been observed in Tongass Narrows. No Level A harassment takes of minke whales are anticipated due to the very limited occurrence of minke whales and the ability to shut down pile driving activities prior to a whale entering the Level A harassment zone.

Pacific White-Sided Dolphin

Pacific white-sided dolphins have not been reported within the Tongass Narrows; however, the dolphin is within its range and thus its presence cannot be discounted. Pacific white-sided dolphin group sizes generally range from between 20 and 164 animals. For the purposes of this assessment, COK assumed one group of 30 dolphins may be present within the Level B harassment zone every tenth day, or about every other week, similar to what was estimated for a prior IHA (84 FR 36891; July 30, 2019). Therefore, NMFS has authorized 360 takes of Pacific white-sided dolphin by Level B harassment.

No Level A takes are expected due to the relatively small size of Level A harassment zone for mid-frequency cetaceans which can be readily monitored.

Table 9 below summarizes the authorized take for all the species described above as a percentage of stock abundance.

TABLE 9—AUTHORIZED TAKE BY LEVEL A AND B HARASSMENT AND AS A PERCENTAGE OF STOCK ABUNDANCE

Species	Level B takes	Level A takes	Stock abundance	Percent of stock
Humpback whale ¹	119	N/A	10,103	1.18
Stellar sea lion eDPS	1,200	N/A	43,201	2.78
Harbor seal	720	360	27,659	3.90
Dall's porpoise	60	20	83,400	0.09
Harbor porpoise	60	20	1,354	5.90
Killer whale ²				
AK resident	40	N/A	2,347	1.70
West coast transient			243	16.46
Northern resident			302	13.25
Gulf of Alaska, Aleutian Islands, and Bering Sea transient			587	6.81
Gray whale	8	N/A	26,960	0.03
Pacific white-sided Dolphin	360	N/A	26,880	1.34
Minke whale	8	N/A	N/A	N/A

¹ Assumes that 6.1 percent of humpback whales exposed are members of the Mexico DPS (Wade *et al.* 2016). Distribution of take by ESA status is 112 Level B takes for Hawaii DPS and 7 Level B take for Mexico DPS.

² These percentages assume all takes come from the same killer whale stock, thus the percentage should be adjusted down if multiple stocks are actually affected.

Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses. NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological)

of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is

expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat, as well as subsistence uses. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which

may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

The following mitigation measures are required for this IHA:

- For in-water heavy machinery work other than pile driving, if a marine mammal comes within 10 m, operations shall cease and vessels shall reduce speed to the minimum level required to maintain steerage and safe working conditions. This type of work could include the following activities: (1) Movement of the barge to the pile location; or (2) positioning of the pile on the substrate via a crane (*i.e.*, stabbing the pile);

- Briefings must be conducted between construction supervisors and crews and the marine mammal monitoring team prior to the start of all pile driving activity and when new personnel join the work, to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures;

- For those marine mammals for which take has not been authorized, in-water pile installation and removal will shut down immediately if such species are observed within or entering the Level A or Level B harassment zone; and

- If take reaches the authorized limit for an authorized species, pile installation and removal will be stopped as these species approach the Level A or Level B harassment zone to avoid additional take.

- COK is required to implement all mitigation measures described in the biological opinion (issued on DATE).

The following mitigation measures would apply to COK's in-water construction activities.

- **Establishment of Shutdown Zones**—COK will establish shutdown zones for all pile driving and removal activities. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Shutdown zones will vary based on the activity type and marine mammal hearing group (Table 10). Due to sediment

characteristics and variation in pile sizes, COK does not know how much time will be required for vibratory driving/removal and DTH installation at each pile or how many strikes will be required for impact installation. Given this uncertainty, COK will utilize a tiered system to identify and monitor appropriate shutdown zones based on activity duration or the number of strikes required for pile installation or removal. During vibratory driving/removal and DTH pile installation, the shutdown zone size will initially be set at the lowest tier, which represents the least amount of active installation/removal time. Shutdown zones will be expanded to the next largest zone after Tier 1 time period has elapsed. For those activities with three specified tiers (*i.e.*, impact driving, DTH socketing), the shutdown zone will be expanded to the largest isopleths identified in Tier 3 if the activity extends beyond the Tier 2 active time period. During impact driving, the shutdown zones associated with 0–500 strikes will be monitored until 500 strikes have occurred. The shutdown zones will increase to the next tier between 501–1,000 strikes. After 1,000 strikes the shutdown zones will subsequently be increased to the largest zone sizes.

- If a marine mammal is entering or is observed within an established shutdown zone, pile driving must be halted or delayed. Pile driving may not commence or resume until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or 15 minutes have passed without subsequent detections of small cetaceans and pinnipeds; or 30 minutes have passed without subsequent detections of large cetaceans.

- The placement of PSOs during all pile driving and removal activities (described in detail in the *Monitoring and Reporting* section) will ensure that the entire shutdown zone is visible during pile installation. Should environmental conditions deteriorate such that marine mammals within the entire shutdown zone would not be visible (*e.g.*, fog, heavy rain), pile driving and removal must be delayed until the PSO is confident marine mammals within the shutdown zone could be detected.

- **PSOs**—COK will employ PSOs who will be able to fully monitor Level A harassment zones. Placement of PSOs will allow observation of marine mammals within the large segments of the Level B harassment zones. However, due to the large size of some of the Level B harassment zones (Table 8), PSOs will not be able to effectively observe the entire zone.

- **Pre-activity Monitoring**—Prior to the start of daily in-water construction activity, or whenever a break in pile driving/removal of 30 minutes or longer occurs, PSOs will observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone will be considered cleared when a marine mammal has not been observed within the zone for that 30-minute period. If a marine mammal is observed within the shutdown zone, a soft-start cannot proceed until the animal has left the zone or has not been observed for 15 minutes. When a marine mammal for which take is authorized is present in the harassment zone, activities may begin. If work ceases for more than 30 minutes, the pre-activity monitoring of the shutdown zones will commence.

- **Soft Start**—Soft-start procedures are believed to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. For impact pile driving, COK will be required to provide an initial set of three strikes from the hammer at reduced energy, followed by a thirty-second waiting period. This procedure will be conducted three times before impact pile driving begins. Soft start will be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of thirty minutes or longer.

- **Scheduling**—Pile driving or removal activities must occur during daylight hours. If poor environmental conditions restrict visibility of the shutdown zones (*e.g.*, from excessive wind or fog, high Beaufort state), pile installation may not be initiated. Work that has begun with a fully cleared Level B harassment zone may continue during inclement weather (*e.g.*, fog, heavy rain) or periods of limited visibility.

TABLE 10—SHUTDOWN AND MONITORING ZONES FOR EACH DRIVING/REMOVAL ACTIVITY

Pile size	Low frequency cetacean shutdown area (m)	Mid frequency cetacean shutdown area (m)	High frequency shutdown area (m) (harbor porpoise, dall's porpoise) ¹	Phocid pinniped shutdown area (m) (harbor seal)	Otariid pinniped shutdown area (m) (steller sea lion)	Level B harassment zone (m)
Vibratory Pile Driving/Removal:						
30-inch piles up to 8 hrs	40	10	50	10		6,300
36- and 48-inch piles up to 8 hrs	90	10	50	10		12,500
Impact Pile Driving:						
30-inch piles up to 500 strikes	500	40	50	10	40	2,200
30-inch piles 501 to 1,000 strikes	700					
30-inch piles 1,001 to 1,500 strikes	1,000					
36- and 48-inch piles up to 500 strikes ...	1,300	50	50	10	50	3,800
36- and 48-inch piles 501 to 1,000 strikes	2,000	70			80	
36- and 48-inch piles 1,001 to 1,500 strikes	2,600	90			100	
DTH Socket:						
30-, 36-inch piles up to 3 hrs	1,300	50	50	10	50	12,500
30-, 36-inch piles 3 hrs—6 hrs	2,000	70				
48-inch piles up to 2 hours	1,750	65			70	
48-inch piles >2 to 3 hrs	2,300	85			100	
48-inch piles >3 to 4 hours	2,750	100			110	
DTH Anchor:						
12-inch hole up to 8 hours	150	10	50	10		6,350

¹ Represents largest Level B Harassment isopleth. Note that isopleth is truncated by land masses at 12,500 meters.

To minimize impacts to marine mammals and their prey vibratory installation will be used as the primary methods of pile installation. Impact driving will be minimized and used only as needed to seat the pile in its final position or to penetrate material that is too dense for a vibratory hammer.

Based on our evaluation of the applicant's planned measures, as well as other measures considered by NMFS, we have determined that the required measures provide the means effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the planned action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.*, presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.*, source characterization, propagation, ambient noise); (2) affected species (*e.g.*, life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.*, age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.*, marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Visual Monitoring

Monitoring must be conducted 30 minutes before, during, and 30 minutes after pile driving and removal activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven or removed. Marine mammal monitoring during pile driving and removal must be conducted by NMFS-approved PSOs in a manner consistent with the following:

- Independent PSOs (*i.e.*, not construction personnel) who have no other assigned tasks during monitoring periods must be used;
- At least one PSO must have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization;
- Other PSOs may substitute education (degree in biological science or related field) or training for experience;
- Where a team of two or more PSOs are required, a lead observer or monitoring coordinator must be designated. The lead observer must have prior experience working as a marine mammal observer during construction;
- COK must submit PSO Curriculum Vitae for approval by NMFS prior to the onset of pile driving;

- PSOs must work in rotating shifts of 4 hours and individual PSOs must not perform duties for more than 12 hours in a 24-hour period; and

- PSOs must use elevated platforms at observation points to the extent practicable.

PSOs should have the following additional qualifications:

- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;

- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;

- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and

- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

A minimum of three onshore observers will be stationed along Tongass Narrows at locations that provide optimal visual coverage for shutdown and monitoring zones. To maximize the visual coverage of shutdown and monitoring zones, observers will use elevated platforms at observation points to the extent practicable. Observers will be in contact with each other via two-way radio and with a cellular phone used as back-up communications. The primary purpose of this observer is to implement the shutdown zones and monitor the Level B harassment zones. PSOs must be positioned in order to focus on monitoring these zones. PSOs would scan the waters using binoculars, and/or spotting scopes, and would use a handheld global positioning system (GPS) or range-finder device to verify the distance to each sighting from the project site.

Monitoring will be conducted 30 minutes before, during, and 30 minutes after pile driving/removal activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving activities include

the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

Reporting

A draft marine mammal monitoring report would be submitted to NMFS within 90 days after the completion of pile driving and removal activities, or 60 days prior to a requested date of issuance of any future IHAs for projects at the same location, whichever comes first. It will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated marine mammal observation data sheets. Specifically, the report must include:

- Dates and times (begin and end) of all marine mammal monitoring;
- Construction activities occurring during each daily observation period, including how many and what type of piles were driven or removed and by what method (*i.e.*, impact or vibratory);
- Weather parameters and water conditions during each monitoring period (*e.g.*, wind speed, percent cover, visibility, sea state) and estimated observable distance (if less than the harassment zone distance).

- The number of marine mammals observed, by species, relative to the pile location and if pile driving or removal was occurring at time of sighting;

- Age and sex class, if possible, of all marine mammals observed;

- PSO locations during marine mammal monitoring;

- Distances and bearings of each marine mammal observed to the pile being driven or removed for each sighting (if pile driving or removal was occurring at time of sighting);

- Description of any marine mammal behavior patterns during observation, including direction of travel and estimated time spent within the Level A and Level B harassment zones while the source was active;

- Number of individuals of each species (differentiated by month as appropriate) detected within the harassment zones;

- Detailed information about any implementation of any mitigation triggered (*e.g.*, shutdowns and delays), a description of specific actions that ensued, and resulting behavior of the animal, if any;

- Description of attempts to distinguish between the number of individual animals taken and the number of incidences of take, such as ability to track groups or individuals; and

- Submit all PSO datasheets and/or raw sighting data (in a separate file from

the Final Report referenced immediately above).

If no comments are received from NMFS within 30 days, the draft final report will constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

Reporting Injured or Dead Marine Mammals

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, the IHA-holder shall report the incident to the Office of Protected Resources (OPR) (301-427-8401), NMFS and to the Alaska regional stranding coordinator (907-586-7209) as soon as feasible. If the death or injury was clearly caused by the specified activity, the IHA-holder must immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHA. The IHA-holder must not resume their activities until notified by NMFS.

The report must include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and
- General circumstances under which the animal was discovered.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be "taken" through harassment, NMFS considers other factors, such as the likely nature

of any responses (e.g., intensity, duration), the context of any responses (e.g., critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (e.g., as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

Vibratory pile removal, vibratory pile driving, impact pile driving, and DTH pile installation have the potential to disturb or displace marine mammals. Specifically, these planned project activities may result in take, in the form of Level A harassment and Level B harassment. Potential takes could occur if individuals are present in the ensonified zone when these activities are underway. No mortality is anticipated given the nature of the activity and measures designed to minimize the possibility of injury to marine mammals.

The Level A harassment zones identified in Table 7 are based upon an animal exposed to vibratory pile driving, impact pile driving, and DTH pile installation for periods of time ranging from 30 minutes for impact driving, up to 8 hours for vibratory driving, up to 6 hours for DTH socketing and 8 hours for DTH anchoring. Exposures of this length are unlikely for vibratory driving/removal and DTH pile installation scenarios given marine mammal movement throughout the area. Even during impact driving scenarios, an animal exposed to the accumulated sound energy would likely experience only limited PTS at the lower frequencies where pile driving energy is concentrated.

Behavioral responses of marine mammals to pile driving at the project site, if any, are expected to be mild and temporary. Given that the installation of 12 permanent piles and eight temporary piles would occur over 4 months, any harassment would be temporary and intermittent. Effects on individuals that are taken by Level B harassment, on the basis of reports in the literature as well as monitoring from other similar activities, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or

decreased foraging (if such activity were occurring) (Southall *et al.* 2007, ABR 2016). Most likely, individuals will simply move away from the sound source and be temporarily displaced from the areas of pile driving. These reactions and behavioral changes are expected to subside quickly when the exposures cease.

The potential for harassment is minimized through the implementation of the required mitigation measures. During all impact driving, implementation of soft start procedures and monitoring of established shutdown zones shall be required, significantly reducing any possibility of injury. Given sufficient notice through use of soft start (for impact driving), marine mammals are expected to move away from an irritating sound source prior to it becoming potentially injurious. To reduce the severity of in-water noise, vibratory pile driving will be the primary installation method for the project and impact hammers will only be used to seat pile tips into fractured bedrock ahead of the hammering operations or if material is encountered that is too dense to penetrate with a vibratory hammer.

The planned project is located within an active marine commercial and industrial area with no known pinniped haulouts or rookeries near the project area. While construction of mooring dolphins at Berth III would have some permanent removal of habitat available to marine mammals, the area lost is relatively small and not of particular importance to any marine mammals.

Any impacts on prey that would occur during in-water construction would have at most short-term effects on foraging of individual marine mammals, and likely no effect on the populations of marine mammals as a whole. Therefore, effects on marine mammal prey during the construction are expected to be minimal and, therefore, are unlikely to cause substantial effects on marine mammals at the individual or population level.

In addition, it is unlikely that minor noise effects in a small, localized area of habitat would have any effect on the stocks' ability to recover. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activities will have only minor, short-term effects on individuals. The specified activities are not expected to impact rates of recruitment or survival and will therefore not result in population-level impacts.

For all species except humpback whales, there are no known BIAs near

the project zone that would be impacted by COK's planned activities. For humpback whales, the whole of Southeast Alaska is a seasonal BIA from spring through late fall (Ferguson *et al.*, 2015). However, Tongass Narrows and Clarence Strait are not important portions of this habitat due to development and human presence. Tongass Narrows is also a small passageway and represents a very small portion of the total available habitat for humpback whales. Finally, there is no ESA-designated critical habitat for humpback whales.

In summary and as described above, the following factors primarily support our determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No mortality is anticipated or authorized;
- Authorized Level A harassment would be limited and of low degree;
- Mitigation measures such as employing vibratory driving to the maximum extent practicable, soft-starts, and shut downs will be implemented;
- Impacts to marine mammal habitat are anticipated to be minimal;
- The project area is located in an industrialized and commercial marina;
- The project area does not include any rookeries, or known areas or features of special significance for foraging or reproduction; and
- The anticipated incidents of Level B harassment consist of, at worst, temporary modifications in behavior.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the required monitoring and mitigation measures, NMFS finds that the total marine mammal take from the planned activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be

taken is fewer than one third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The number of instances of take for each species or stock authorized to be taken as a result of this project is included in Table 9. Our analysis shows that less than one-third of the best available population abundance estimate of each species or stock could be taken by harassment. The number of animals authorized to be taken for each authorized stock would be considered small relative to the relevant stock's abundances even if each estimated taking occurred to a new individual, which is an unlikely scenario.

The west coast transient stock of killer whales represents the highest percentage of a single stock (<17 percent) that is authorized take. This take percentage also assumes that all authorized killer whale takes would be from this stock, which is highly unlikely given the expansive range of the stock.

A lack of an accepted stock abundance value for the Alaska stock of minke whale did not allow for the calculation of an expected percentage of the population that would be affected. The most relevant estimate of partial stock abundance is 1,232 minke whales in coastal waters of the Alaska Peninsula and Aleutian Islands (Zerbini *et al.*, 2006). Given that two takes by Level B harassment are authorized for the stock, comparison to the best estimate of stock abundance shows less than 0.2 percent of the stock is expected to be impacted.

Based on the analysis contained herein of the planned activity (including the required mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

In order to issue an IHA, NMFS must find that the specified activity will not have an "unmitigable adverse impact" on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined "unmitigable adverse impact" in 50 CFR 216.103 as an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing

subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

Alaska Native hunters in the Ketchikan vicinity do not traditionally harvest cetaceans (Muto *et al.* 2020). Harbor seals are the most commonly targeted marine mammal that is hunted by Alaska Native subsistence hunters within the Ketchikan area. In 2012 an estimated 595 harbor seals were taken for subsistence uses, with 22 of those occurring in Ketchikan (Wolfe *et al.* 2012). This is the most recent data available. The harbor seal harvest per capita in both communities was low, at 0.02 for Ketchikan. ADF&G subsistence data for Southeast Alaska shows that from 1992 through 2008, plus 2012, from zero to 19 Steller sea lions were taken by Alaska Native hunters per year with typical harvest years ranging from zero to five animals (Wolfe *et al.* 2013). In 2012, it is estimated nine sea lions were taken in all of Southeast Alaska and only from Hoonah and Sitka. There are no known haulout locations in the project area. Both the harbor seal and the Steller sea lion may be temporarily displaced from the action area. However, neither the local population nor any individual pinnipeds are likely to be adversely impacted by the planned action beyond noise-induced harassment or slight injury. The planned project is anticipated to have no long-term impact on Steller sea lion or harbor seal populations, or their habitat no long term impacts on the availability of marine mammals for subsistence uses is anticipated.

Based on the description of the specified activity, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the required mitigation and monitoring measures, NMFS has determined that there will not be an unmitigable adverse impact on subsistence uses from COK's planned activities.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216-6A, NMFS must review our action (*i.e.*, the issuance of an incidental harassment authorization) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental

harassment authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216-6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS Office of Protected Resources consults internally whenever we propose to authorize take for endangered or threatened species, in this case with the NMFS Alaska Regional Office.

There is one marine mammal species (Mexico DPS humpback whale) with confirmed occurrence in the project area that is listed as endangered under the ESA. The NMFS Alaska Regional Office Protected Resources Division issued a Biological Opinion under section 7 of the ESA, on the issuance of an IHA to the City of Ketchikan under section 101(a)(5)(D) of the MMPA by the NMFS Permits and Conservation Division. The Biological Opinion concluded that the issuance of an IHA to COK is not likely to jeopardize the continued existence of Mexico DPS humpback whales or adversely modify critical habitat because none exists in the area.

Authorization

NMFS has issued an IHA to the City of Ketchikan for in-water construction activities associated with the Berth III Expansion Project in Ketchikan, Alaska between October 1, 2021 and September 30, 2022, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: February 26, 2021.

Donna S. Wieting,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2021-04368 Filed 3-2-21; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF EDUCATION**Applications for New Awards; Child Care Access Means Parents in School Program**

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The U.S. Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2021 for the Child Care Access Means Parents in School (CCAMPIS) Program, Assistance Listing Number 84.335A. This notice relates to the approved information collection under OMB control number 1840-0737.

DATES:

Applications Available: March 3, 2021.

Deadline for Transmittal of Applications: June 1, 2021.

Deadline for Intergovernmental Review: August 2, 2021.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.

FOR FURTHER INFORMATION CONTACT: Tanisha Hamblin-Johnson, Ed.D., U.S. Department of Education, 400 Maryland Avenue SW, Room 2C145, Washington, DC 20202-4260. Telephone: (202) 453-6090. Email: tanisha.johnson@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:**Full Text of Announcement****I. Funding Opportunity Description**

Purpose of Program: The CCAMPIS Program supports the participation of low-income parents in postsecondary education through the provision of campus-based child care services.

Priorities: This notice contains two absolute priorities and three invitational priorities. In accordance with 34 CFR 75.105(b)(2)(iv), the absolute priorities are from section 419N(d) of the Higher Education Act of 1965, as amended (HEA), 20 U.S.C. 1070e(d).

Absolute Priorities: For FY 2021, and any subsequent year in which we make awards from the list of unfunded applications from this competition,

these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet both priorities. These priorities are:

Absolute Priority 1: Projects that are designed to leverage significant local or institutional resources, including in-kind contributions, to support the activities assisted under section 419N of the HEA.

Absolute Priority 2: Projects that are designed to utilize a sliding fee scale for child care services provided under section 419N of the HEA in order to support a high number of low-income parents pursuing postsecondary education at the institution.

Invitational Priorities: For FY 2021, and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are invitational priorities. Under 34 CFR 75.105(c)(1) we do not give an application that meets these invitational priorities a competitive or absolute preference over other applications.

These priorities are:

Invitational Priority 1: Supporting Students Who Are Single Parents

Background: According to the Institute for Women's Policy Research (IWPR), there are nearly 2.1 million single mothers in college today, many of whom are women of color.¹ These mothers face nearly insurmountable odds against finishing their degrees, even as many of them are pursuing higher education in order to lift their families out of poverty. Only eight percent of single mothers who start college earn an associate or bachelor's degree within six years, compared with about half of women who are not mothers.

The IWPR research also finds that supports, such as free child care, financial assistance, and social skills training, would allow more student parents to graduate. According to the IWPR, offering free child care to a single mother pursuing a bachelor's degree improves success rates for community college students. Free child care may allow many student parents to finish school much quicker, meaning they would require fewer years of support and likely spend more years earning higher wages. Studies show that

¹ Institute for Women's Policy Research (IWPR) analysis of data from the U.S. Department of Education (September 2017), National Center for Education Statistics. National Postsecondary Student Aid Study and the Integrated Postsecondary Aid Survey (IPEDS). Retrieved from <https://iwpr.org/iwpr-issues/student-parent-success-initiative/single-mothers-in-college-growing-enrollment-financial-challenges-and-the-benefits-of-attainment/>.

students who utilize a campus child care center had more than triple the rate of on-time completion than that of parents who did not use the center.²

Priority:

Projects that propose to serve children of student-parents residing in a single parent home. An applicant should describe in its application how it will provide resources with institutional funds, in addition to child care assistance provided by CCAMPIS funds, that will enhance the student-parents' educational, personal, and financial growth.

Invitational Priority 2: Addressing Child Care Shortages Due to COVID

Background: Researchers from the Community College Research Center at Teachers College of Columbia University analyzed data collected on a bi-weekly basis from the U.S. Census Bureau. The data were collected from August to mid-October 2020 to determine the impact the pandemic has had on college enrollment. The survey revealed that the pandemic has had a strong negative influence on community college enrollment. According to the authors of the survey, "as of October 2020, more than 40% of households report that a prospective student is cancelling all plans for community college; another 15% are either taking fewer classes or switching programs."³ Another author writing on this topic notes that "community college students are cancelling their plans at more than twice the rate of four-year college students."⁴

Students list the Novel Coronavirus as being the main reason for cancelling their college enrollment plans. The numbers of college enrollment cancellations are largest in those demographic groups that have been impacted by the virus the hardest: Black and Latinx students and low-income households.⁵ These groups are the same

² Stewart, P. (2018). Campus Child Care Critical in Raising Single Mothers' Graduation Rates. *Diverse*. <https://diverseeducation.com/article/117704/>.

³ Belfield, C., and Brock, T. Behind the Enrollment Numbers: How COVID Has Changed Students' Plans for Community College. CCRC, November 19, 2020. Retrieved February 8, 2021. <https://ccrc.tc.columbia.edu/easyblog/covid-enrollment-community-college-plans.html>.

⁴ St. Amour, M. Analysis: Low-income Community College Students Most Likely to Report Canceling College Plans. *Inside Higher Ed*. December 10, 2020. Retrieved February 8, 2021. <https://www.insidehighered.com/news/2020/12/10/analysis-low-income-community-college-students-most-likely-report-canceling-college>.

⁵ Belfield, C., and Brock, T. Behind the Enrollment Numbers: How COVID Has Changed Students' Plans for Community College. CCRC, November 19, 2020. Retrieved February 8, 2021.

Continued

groups disproportionately served by community colleges.

Another finding suggests that income security is a major contributing factor to who cancels their community college plans. Studies show that low-income households, specifically those led by a single parent, exit community college at a higher rate.⁶ This is likely attributable to job loss, reduction of hours, and the need to take care of children now attending school in a virtual environment. As the impact of the virus is felt by everyone, regardless of socioeconomic background, the number of persons needing child care has grown exponentially. While the need for, and new restrictions on, child care centers have grown, the slots and space available for child care has decreased, creating child care deserts in communities hardest hit by the virus.⁷

The Center for American Progress defines “child care deserts” as areas with little or no access to quality child care or a ZIP code with more than three children for every licensed child care center slot.⁸ Without viable child care options, student parents in child care deserts—the areas most impacted by the Novel Coronavirus—will continue to face significant challenges in re-enrolling in community colleges.

Priority:

Projects that propose to increase the number of licensed, quality child care centers in areas most impacted by the Novel Coronavirus where under-resourced community colleges are located, by, for example, utilizing unused classrooms on campus, working with community partners to create space in neighboring buildings, and hiring and training child care staff.

Invitational Priority 3: Providing Wrap-Around Services for Low-Income Parents in Postsecondary Education

Background: One educational barrier that reduces a student's opportunity to enter, persist, and complete higher

education is poverty. Students from low-income backgrounds are more likely to delay enrollment, enroll in college in a part-time status, or drop out. And while large numbers of under-resourced students are attending college,⁹ many colleges and universities continue to struggle to address the total need of the under-resourced college student. Financial aid supports, like Pell Grants, provide important resources for under-resourced students to access college, but additional supports are needed to ensure students persist and complete. Studies in New York and Ohio, for example, show that comprehensive supports designed to help community college students stay enrolled and graduate have doubled three-year graduation rates for those students.¹⁰

Priority:

Projects that propose to develop high-impact community engagement strategies and partner with community organizations in order to leverage institutional and community resources to provide wrap-around services (such as public benefits and additional financial aid to cover textbook costs, transportation costs, mental health services, faculty mentoring, tutoring, peer support groups, and emergency grants) that meet the whole need of low-income parents in postsecondary education.

Application Requirements: For FY 2021 and any subsequent year in which we make awards from the list of unfunded applications from this competition, applicants must meet the following application requirements from section 419N of the HEA.

(a) An institution of higher education desiring a grant under this competition must submit an application that—

- (1) Demonstrates that the institution is an eligible institution;
- (2) Specifies the amount of funds requested;
- (3) Demonstrates the need of low-income students (as defined in this notice) at the institution for campus-based child care services by including in the application—

(i) Information regarding student demographics;

- (ii) An assessment of child care capacity on or near campus;

(iii) Information regarding the existence of waiting lists for existing child care;

(iv) Information regarding additional needs created by concentrations of poverty or by geographic isolation; and

(v) Other relevant data;

(4) Contains a description of the activities to be assisted, including whether the grant funds will support an existing child care program or a new child care program;

(5) Identifies the resources, including technical expertise and financial support, the institution will draw upon to support the child care program and the participation of low-income students in the program, such as accessing social services funding, using student activity fees to help pay the costs of child care, using resources obtained by meeting the needs of parents who are not low-income students, and accessing foundation, corporate, or other institutional support, and demonstrate that the use of the resources will not result in increases in student tuition;

(6) Contains an assurance that the institution will meet the child care needs of low-income students through the provision of services, or through a contract for the provision of services;

(7) Describes the extent to which the child care program will coordinate with the institution's early childhood education curriculum, to the extent the curriculum is available, to meet the needs of the students in the early childhood education program at the institution, and the needs of the parents and children participating in the child care program assisted under the applicant's project;

(8) In the case of an institution seeking assistance for a new child care program—

(i) Provides a timeline, covering the period from receipt of the grant through the provision of the child care services, delineating the specific steps the institution will take to achieve the goal of providing low-income students with child care services;

(ii) Specifies any measures the institution will take to assist low-income students with child care during the period before the institution provides child care services; and

(iii) Includes a plan for identifying resources needed for the child care services, including space in which to provide child care services, and technical assistance, if necessary;

(9) Contains an assurance that any child care facility assisted under this section will meet the applicable State or local government licensing,

⁶ <https://ccrc.tc.columbia.edu/easyblog/covid-enrollment-community-college-plans.html>.

⁷ St. Amour, M. Analysis: Low-income Community College Students Most Likely to Report Canceling College Plans. Inside Higher Ed. December 10, 2020. Retrieved February 8, 2021. <https://www.insidehighered.com/news/2020/12/10/analysis-low-income-community-college-students-most-likely-report-canceling-college>.

⁸ Malik, R., and Hamm, K. Mapping America's Child Care Deserts. Center for American Progress. August 30, 2017. Retrieved February 8, 2021. <https://www.americanprogress.org/issues/early-childhood/reports/2017/08/30/437988/mapping-americas-child-care-deserts/>.

⁹ Malik, R., and Hamm, K. Mapping America's Child Care Deserts. Center for American Progress. August 30, 2017. Retrieved February 8, 2021. <https://www.americanprogress.org/issues/early-childhood/reports/2017/08/30/437988/mapping-americas-child-care-deserts/>.

⁹ U.S. Department of Education/Federal Student Aid. (2020). 2018–2019 Award Year Grant Volume by School. <https://studentaid.gov/sites/default/files/fsawg/datacenter/library/grants-ay18-19-q4.xls>.

¹⁰ CUNY ASAP Doubles Graduation Rates in New York and Ohio. MDRG. February 2021. Retrieved February 23, 2021. <https://www.mdr.org/publication/cuny-asap-doubles-graduation-rates-new-york-city-and-ohio>.

certification, approval, or registration requirements; and

(10) Contains a plan for any child care facility assisted under this program to become accredited within three years of the date the institution first receives assistance under this program.

Definitions: The definition of “low-income student” and “early childhood education program” are from sections 419N and 103 (20 U.S.C. 1003) of the HEA, respectively.

Early childhood education program means—

(1) A Head Start program or an Early Head Start program carried out under the Head Start Act (42 U.S.C. 9831 *et seq.*), including a migrant or seasonal Head Start program, an Indian Head Start program, or a Head Start program or an Early Head Start program that also receives State funding;

(2) A State licensed or regulated child care program; or

(3) A program that—

(i) Serves children from birth through age six that addresses the children’s cognitive (including language, early literacy, and early mathematics), social, emotional, and physical development; and

(ii) Is—

(I) A State prekindergarten program;

(II) A program authorized under section 619 (20 U.S.C. 1419) or part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 *et seq.*); or

(III) A program operated by a local educational agency.

Low-income student means a student—

(1) Who is eligible to receive a Federal Pell Grant for the award year for which the determination is made; or

(2) Who would otherwise be eligible to receive a Federal Pell Grant for the award year for which the determination is made, except that the student fails to meet the requirements of—

(i) 20 U.S.C. 1070a(c)(1) because the student is enrolled in a graduate or first professional course of study; or

(ii) 20 U.S.C. 1091(a)(5) because the student is in the United States for a temporary purpose.

Program Authority: 20 U.S.C. 1070e.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and

Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

Note: Because there are no program-specific regulations for the CCAMPIS Program, applicants are encouraged to carefully read the authorizing statute: Title IV, part A, subpart 7, section 419N of the HEA (20 U.S.C. 1070e).

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: \$43,500,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: \$30,000 to \$443,492.

Estimated Average Size of Awards: \$167,116.

Maximum Award: In accordance with section 419N(b)(2)(A) of the HEA, the maximum annual amount an applicant may receive under this program is one percent of the total amount of all Federal Pell Grant funds awarded to students enrolled at the institution for FY 2020. In the event that an applicant’s maximum award amount is lower than the statutory minimum award of \$30,000, the grant will be \$30,000 for a single budget period of 12 months.

Estimated Number of Awards: 275.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 48 months.

III. Eligibility Information

1. **Eligible Applicants:** Institutions of higher education that awarded a total of \$250,000 or more of Federal Pell Grant funds during FY 2020 to students enrolled at the institution.

2. a. **Cost Sharing or Matching:** This competition does not require cost sharing or matching.

b. **Indirect Cost Rate Information:** This program uses an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see www2.ed.gov/about/offices/list/ocfo/intro.html.

c. **Administrative Cost Limitation:** This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform

to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. **Subgrantees:** A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

IV. Application and Submission Information

1. Application Submission

Instructions: Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf, which contain requirements and information on how to submit an application.

2. **Intergovernmental Review:** This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

3. **Funding Restrictions:** Funding restrictions are outlined in section 419N(b)(2)(B) of the HEA. We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. **Recommended Page Limit:** The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative, which includes the budget narrative, to no more than 50 pages and (2) use the following standards:

- A “page” is 8.5” × 11”, on one side only, with 1” margins.

- Double space all text in the application narrative, and single-space titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.

- Use a 12-point font.

- Use an easily readable font such as Times New Roman, Courier, Courier New, or Arial.

The recommended 50-page limit does not apply to the Application for Federal Assistance cover sheet (SF 424); the Budget Information Summary form (ED Form 524); the CCAMPIS Program Profile form and the one-page Project Abstract form; or the assurances and certifications. The recommended page limit also does not apply to a table of contents, which you should include in the application narrative. You must include your complete response to the

selection criteria in the application narrative.

We recommend that any application addressing the invitational priorities include no more than three additional pages for each priority.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from section 419N of the HEA and 34 CFR 75.210 and are listed below.

We will award up to 100 points to an application under the selection criteria. The maximum number of points available for each criterion is indicated in parentheses.

(a) *Need for the project.* (24 points)

In determining the need for the proposed project, the Secretary considers the extent to which the applicant demonstrates, in its application, the need for campus-based child care services for low-income students, by including the following (see section 419N(c)(3) of the HEA):

(i) Information regarding student demographics.

(ii) An assessment of child care capacity on or near campus, including information regarding the existence of waiting lists for existing child care.

(iii) Information regarding additional needs created by concentrations of poverty or by geographic isolation.

(iv) Other relevant data.

(b) *Quality of project design.* (36 points)

In determining the quality of the design of the proposed project, the Secretary considers the following:

(i) The extent to which the applicant describes in its application the activities to be assisted, including whether the grant funds will support an existing child care program or a new child care program (see section 419N(c)(4) of the HEA).

(ii) The extent to which the services to be provided by the proposed project are focused on those with greatest needs (see 34 CFR 75.210(d)(3)(xi)).

Note: When describing how the project is focused on those with greatest needs, applicants are encouraged to include, in their assessment of focus on service of those with the greatest needs, the extent to which services are available during all hours that classes are in session, including evenings and weekends, to part-time students, and to students who need only emergency drop-in child care in the event that regularly scheduled child care is unexpectedly unavailable.

(iii) The likely impact of the services to be provided by the proposed project on the intended recipients of those services (see 34 CFR 75.210(d)(3)(iv)).

(iv) The extent to which the application includes an assurance that the institution will meet the child care needs of low-income students through the provision of services, or through a contract for the provision of services (see section 419N(c)(6) of the HEA).

(v) The extent to which the child care program will coordinate with the institution's early childhood education curriculum, to the extent the curriculum is available, to meet the needs of the students in the early childhood education program at the institution, and the needs of the parents and children participating in the child care program assisted under this section (see section 419N(c)(7) of the HEA).

(vi) The extent to which the proposed project encourages parental involvement (see 34 CFR 75.210(c)(2)(xix)).

(vii) If the applicant is seeking assistance for a new child care program (see section 419N(c)(8) of the HEA).

(1) The extent to which the applicant's timeline, covering the period from receipt of the grant through the provision of the child care services, delineates the specific steps the institution will take to achieve the goal of providing low-income students with child care services;

(2) The extent to which the applicant specifies any measures the institution will take to assist low-income students with child care during the period before the institution provides child care services; and

(3) The extent to which the application includes a plan for identifying resources needed for the child care services, including space in which to provide child care services and technical assistance if necessary.

Note: The maximum available points for this selection criterion will be divided equally, for applications that seek assistance to support existing programs, among factors (i)–(vi), and, for applications that seek assistance to support new programs, among factors (i)–(vii).

(c) *Quality of management plan.* (21 points)

In determining the quality of the management plan for the proposed project, the Secretary considers the following:

(i) The extent to which the application identifies the resources, including technical expertise and financial support, the institution will draw upon to support the child care program and the participation of low-income students in the program, such as accessing social services funding, using student activity fees to help pay the costs of child care, using resources obtained by meeting the needs of

parents who are not low-income students, and accessing foundation, corporate or other institutional support, and demonstrates that the use of the resources will not result in increases in student tuition (see section 419N(c)(5) of the HEA).

(ii) The qualifications, including relevant training and experience, of key project personnel (see 34 CFR 75.210(e)(3)(ii)).

(iii) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (see 34 CFR 75.210(g)(2)(i)).

(d) *Quality of project evaluation.* (12 points)

In determining the quality of the project evaluation, the Secretary considers the following:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project (see 34 CFR 75.210(h)(2)(i)).

(ii) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible (see 34 CFR 75.210(h)(2)(iv)).

(iii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes (see 34 CFR 75.210(h)(2)(vi)).

(e) *Adequacy of resources.* (7 points)

In determining the adequacy of resources for the proposed project, the Secretary considers the following:

(i) The extent to which the budget is adequate to support the proposed project (see 34 CFR 75.210(f)(2)(iii)).

(ii) The extent to which the costs are reasonable in relation to the number of persons to be served and to the anticipated results and benefits (see 34 CFR 75.210(f)(2)(v)).

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

For this competition, a panel of non-Federal readers will review each application in accordance with the selection criteria. The individual scores of the reviewers will be added and the sum divided by the number of reviewers to determine the peer review score received in the review process.

If there are insufficient funds for all applications with the same total scores, the Secretary will choose among the tied applications so as to serve geographical areas that have been underserved by the CCAMPIS Program.

3. Risk Assessment and Specific Conditions: Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. Integrity and Performance System: If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently \$250,000), under 2 CFR 200.206(a)(2), we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds \$10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity

information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed \$10,000,000.

5. In General: In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. Award Notices: If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we will notify you.

2. Administrative and National Policy Requirements: We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. Open Licensing Requirements: Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created

in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. Reporting: (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to www.ed.gov/fund/grant/apply/appforms/appforms.html.

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. Performance Measures: The success of the CCAMPIS Program will be measured by the postsecondary persistence and degree completion rates of the CCAMPIS Program participants. All CCAMPIS Program grantees will be required to submit an annual performance report documenting the persistence and degree attainment of their participants. Although students may choose to use child care services at different points in their college enrollment, the goal is to measure the outcomes of student-parents based on their completion of their program within 150 percent or 200 percent of the published program length. The cohort model of evaluation will track the level

of utilization by a student-parent throughout their enrollment at the institution and will provide results based on the long-term academic success of the student-parent. The Department will aggregate the data provided in the annual performance reports from all grantees to determine the accomplishment level. The CCAMPIS reporting data collection is moving towards a semester-to-semester cohort model. This will not increase public reporting burden as CCAMPIS grantees are gathering and maintaining the data needed in completing and reviewing the collection of information currently.

6. *Continuation Awards:* In making a continuation grant under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package 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.

Tiwanda Burse,

Deputy Assistant Secretary for Management & Planning, Office of Postsecondary Education. Delegated authority to perform functions and duties of the Assistant Secretary for the Office of Postsecondary Education.

[FR Doc. 2021-04393 Filed 3-2-21; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2021-SCC-0031]

Agency Information Collection Activities; Comment Request; Campus Safety and Security Survey

AGENCY: Office of Postsecondary Education (OPE), 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 May 3, 2021.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2021-SCC-0031. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the www.regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at ICDocketMgr@ed.gov. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland

Ave. SW, LBJ, Room 6W208C, Washington, DC 20202-8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Sophia McArdle, 202-453-6318.

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: Campus Safety and Security Survey.

OMB Control Number: 1840-0833.

Type of Review: Extension without change of a currently approved collection.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 6,000.

Total Estimated Number of Annual Burden Hours: 2,499.

Abstract: The collection of information through the Campus Safety and Security Survey is necessary under section 485 of the Higher Education Act of 1965, as amended, with the goal of increasing transparency surrounding college safety and security information for students, prospective students, parents, employees and the general public. The survey is a collection tool to compile the annual data on campus crime and fire safety. The data collected from the individual institutions by ED is

made available to the public through the Campus Safety and Security Data Analysis and Cutting Tool as well as the College Navigator.

Dated: February 25, 2021.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021-04319 Filed 3-2-21; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2021-SCC-0173]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Evaluating the DC Opportunity Scholarship Program After the 2017 Reauthorization

AGENCY: Institute of Educational Sciences, Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before April 2, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection request by selecting "Department of Education" under "Currently Under Review," then check "Only Show ICR for Public Comment" checkbox. Comments may also be sent to ICDocketmgr@ed.gov.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Meredith Bachman, 202-245-7494.

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: Evaluating the DC Opportunity Scholarship Program After the 2017 Reauthorization.

OMB Control Number: 1850-NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments; Individuals and Households.

Total Estimated Number of Annual Responses: 842.

Total Estimated Number of Annual Burden Hours: 303.

Abstract: The U.S. Department of Education (ED)'s Institute of Education Sciences (IES) requests clearance for data collection activities to support a congressionally mandated study of the District of Columbia (DC) Opportunity Scholarship Program (OSP). Collecting information about the OSP is critical given ED's interest in private school choice as a way to improve students' educational outcomes and Congress's focus on the program. Proposed legislation supports both expanding the OSP to serve more students in DC and new tax credits that would make up to \$5 billion available to fund similar programs nationwide. The importance of the OSP to Congress is reflected in its requirement that IES conduct a third evaluation of the program, following those completed in 2011 and 2019. The study will result in a report on the implementation of the OSP, including identification of challenges encountered by OSP-eligible applicants, participating schools, and the program operator; and potential program or policy changes to help address these challenges. A subsequent issue brief will focus on challenges related to families' ongoing participation in the OSP, since about 20% of students stop using scholarships after one year of participation. The study will also use the collected data to disseminate up to three issue policy

briefs. This request covers administrative data as well as surveys of the OSP program operator, administrators of participating and non-participating OSP schools, OSP applicants, and OSP users. Also included is a request for classroom observations in OSP-participating schools.

Dated: February 25, 2021.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021-04306 Filed 3-2-21; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

[Case Number 2020-014; EERE-2020-BT-WAV-0028]

Energy Conservation Program: Notification of Petition for Waiver of KeepRite Refrigeration From the Department of Energy Walk-In Coolers and Walk-In Freezers Test Procedure and Notice of Grant of Interim Waiver

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

ACTION: Notification of petition for waiver and grant of an interim waiver; request for comments.

SUMMARY: This document announces receipt of and publishes a petition for waiver and interim waiver from KeepRite Refrigeration ("KeepRite"), which seeks a waiver for specified carbon dioxide ("CO₂") direct expansion unit cooler basic models from the U.S. Department of Energy ("DOE") test procedure used to determine the efficiency of walk-in cooler and walk-in freezer refrigeration systems. DOE also gives notice of an Interim Waiver Order that requires KeepRite to test and rate the specified CO₂ direct expansion unit cooler basic models in accordance with the alternate test procedure set forth in the Interim Waiver Order. DOE solicits comments, data, and information concerning KeepRite's petition and its suggested alternate test procedure so as to inform DOE's final decision on KeepRite's waiver request.

DATES: The Interim Waiver Order is effective on March 3, 2021. Written comments and information will be accepted on or before April 2, 2021.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at <http://www.regulations.gov>.

Alternatively, interested persons may submit comments, identified by case number “2020–014”, and Docket number “EERE–2020–BT–WAV–0028,” by any of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Email*: KeepRiteWICF2020WAV0028@ee.doe.gov. Include Case No. 2020–014 in the subject line of the message.

- *Postal Mail*: Appliance and Equipment Standards Program, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, Mail Stop EE–5B, Petition for Waiver Case No. 2020–014, 1000 Independence Avenue SW, Washington, DC 20585–0121. If possible, please submit all items on a compact disc (“CD”), in which case it is not necessary to include printed copies.

- *Hand Delivery/Courier*: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L’Enfant Plaza SW, 6th floor, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (“faxes”) will be accepted. For detailed instructions on submitting comments and additional information on this process, see the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: The docket, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at <http://www.regulations.gov>. All documents in the docket are listed in the <http://www.regulations.gov> index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at <http://www.regulations.gov/docket?D=EERE-2020-BT-WAV-0028>. The docket web page contains instruction on how to access all documents, including public comments, in the docket. See the **SUPPLEMENTARY INFORMATION** section for information on how to submit comments through <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, Mail Stop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Email: AS_Waiver_Request@ee.doe.gov.

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (202) 586–8145. Email: Michael.Kido@hq.doe.gov.

SUPPLEMENTARY INFORMATION: DOE is publishing KeepRite’s petition for waiver in its entirety in appendix 1 to this document, pursuant to 10 CFR 431.401(b)(1)(iv).¹ DOE invites all interested parties to submit in writing by April 2, 2021, comments and information on all aspects of the petition, including the alternate test procedure. Pursuant to 10 CFR 431.401(d), any person submitting written comments to DOE must also send a copy of such comments to the petitioner. The contact information for the petitioner is Vince Zolli, vzolli@k-rp.com, 159 Roy Blvd., Brantford, ON N3R 7K1, Canada.

Submitting comments via http://www.regulations.gov. The <http://www.regulations.gov> web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. If this instruction is followed, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to <http://www.regulations.gov> information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (“CBI”)). Comments submitted through [http://](http://www.regulations.gov)

www.regulations.gov cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through <http://www.regulations.gov> before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that <http://www.regulations.gov> provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or postal mail. Comments and documents submitted via email, hand delivery/courier, or postal mail also will be posted to <http://www.regulations.gov>. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. Faxes will not be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters’ names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and

¹ The petition did not identify any of the information contained therein as confidential business information.

exempt by law from public disclosure should submit via email, postal mail, or hand delivery/courier two well-marked copies: One copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked “non-confidential” with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE’s policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

Case Number 2020–014

Interim Waiver Order

I. Background and Authority

The Energy Policy and Conservation Act, as amended (“EPCA”),² authorizes the U.S. Department of Energy (“DOE”) to regulate the energy efficiency of a number of consumer products and certain industrial equipment (42 U.S.C. 6291–6317). Title III, Part C³ of EPCA (42 U.S.C. 6311–6316, as codified), added by the National Energy Conservation Policy Act, Public Law 95–619, sec. 441 (Nov. 9, 1978), established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve the energy efficiency for certain types of industrial equipment. Through amendments brought about by the Energy Independence and Security Act of 2007, Public Law 110–140, sec. 312 (Dec. 19, 2007), this equipment includes walk-in cooler and walk-in freezer (collectively, “walk-in”) refrigeration systems, the focus of this document (42 U.S.C. 6311(1)(G)).

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6311), energy conservation standards (42 U.S.C. 6313), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), and the authority to

require information and reports from manufacturers (42 U.S.C. 6316).

The Federal testing requirements consist of test procedures that manufacturers of covered equipment must use as the basis for: (1) Certifying to DOE that their equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6316(a); 42 U.S.C. 6295(s)), and (2) making representations about the efficiency of that equipment (42 U.S.C. 6314(d)). Similarly, DOE must use these test procedures to determine whether the covered equipment complies with relevant standards promulgated under EPCA. (42 U.S.C. 6316(a); 42 U.S.C. 6295(s))

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE is required to follow when prescribing or amending test procedures for covered equipment. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect the energy efficiency, energy use or estimated annual operating cost of covered equipment during a representative average use cycle and requires that test procedures not be unduly burdensome to conduct (42 U.S.C. 6314(a)(2)). The test procedure for walk-in refrigeration systems is contained in the Code of Federal Regulations (“CFR”) at 10 CFR part 431, subpart R, appendix C, *Uniform Test Method for the Measurement of Net Capacity and AWEF of Walk-In Cooler and Walk-In Freezer Refrigeration Systems* (“Appendix C”).

Under 10 CFR 431.401, any interested person may submit a petition for waiver from DOE’s test procedure requirements. DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model for which the waiver was requested contains a design characteristic that prevents testing of the basic model according to the prescribed test procedures, or that the prescribed test procedures evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 431.401(f)(2). A petitioner must include in its petition any alternate test procedures known to the petitioner to evaluate the performance of the equipment type in a manner representative of the energy consumption characteristics of the basic model. 10 CFR 431.401(b)(1)(iii). DOE may grant the waiver subject to conditions, including adherence to alternate test procedures specified by DOE. 10 CFR 431.401(f)(2).

As soon as practicable after the granting of any waiver, DOE will publish in the **Federal Register** a notice of proposed rulemaking to amend its regulations so as to eliminate any need for the continuation of such waiver. 10 CFR 431.401(l). As soon thereafter as practicable, DOE will publish in the **Federal Register** a final rule to that effect. *Id.*

The waiver process also provides that DOE may grant an interim waiver if it appears likely that the underlying petition for waiver will be granted and/or if DOE determines that it would be desirable for public policy reasons to grant immediate relief pending a determination on the underlying petition for waiver. 10 CFR 431.401(e)(2). Within one year of issuance of an interim waiver, DOE will either: (i) Publish in the **Federal Register** a determination on the petition for waiver; or (ii) publish in the **Federal Register** a new or amended test procedure that addresses the issues presented in the waiver. 10 CFR 431.401(h)(1).

When DOE amends the test procedure to address the issues presented in a waiver, the waiver will automatically terminate on the date on which use of that test procedure is required to demonstrate compliance. 10 CFR 431.401(h)(2).

II. KeepRite’s Petition for Waiver and Interim Waiver

DOE received a petition from KeepRite for waiver and interim waiver docketed on August 11, 2020 from the test procedure for walk-in refrigeration systems set forth at 10 CFR part 431, subpart R, appendix C (KeepRite, No. 1 at p. 1⁴). KeepRite claims that the test conditions described in Table 15 and Table 16 of the Air-Conditioning, Heating, and Refrigeration Institute (“AHRI”) Standard 1250–2009, *Standard for Performance Rating of Walk-In Coolers and Freezers* (“AHRI 1250–2009”) (for walk-in refrigerator unit coolers and freezer unit coolers tested alone, respectively), as incorporated by Appendix C with modification, cannot be achieved by the specified basic models and are not consistent with the operation of KeepRite’s CO₂ direct expansion unit coolers. These set conditions are based on the use of a refrigerant different from the CO₂-based refrigerant used by

² All references to EPCA in this document refer to the statute as amended through America’s Water Infrastructure Act of 2018, Public Law 115–270 (Oct. 23, 2018).

³ For editorial reasons, upon codification in the U.S. Code, Part C was redesignated as Part A–1.

⁴ A notation in the form “KeepRite, No.1” identifies a written submission: (1) Made by KeepRite; and (2) recorded in document number 1 that is filed in the docket of this petition for waiver (Docket No. EERE–2020–BT–WAV–0028) and available at <http://www.regulations.gov/docket?D=EERE-2020-BT-WAV-0028>.

KeepRite. As a result, KeepRite explained that because CO₂ has a critical temperature of 87.8 °F,⁵ the required liquid inlet saturation temperature of 105 °F and the required liquid inlet subcooling temperature of 9 °F required under the prescribed test procedure are not achievable. It stated that the test conditions should be more consistent with typical operating conditions for a transcritical CO₂ booster system (KeepRite, No. 1).

The statements made by KeepRite reference the difference in thermodynamic properties between CO₂ and other refrigerants. At modest pressures (*i.e.* below the critical point), many substances transition from a solid to a liquid to a gas as temperature increases. For example, a pure substance like water transitions from liquid to steam at a specific temperature, *e.g.* 212 °F, at atmospheric pressure. As heat is added during a liquid to gas transition, the temperature remains constant and the substance coexists as both liquid and vapor. Continuing to add heat converts more of the liquid to vapor at a constant temperature. The reverse occurs when heat is removed. However, the transition temperature depends on the pressure—the higher the pressure, the higher the transition temperature. This is a key principle in refrigeration systems, which operate at two pressure levels associated with two temperatures. A refrigerant absorbs heat when it is at a low temperature and pressure, converting to gas and cooling the surrounding space. At high temperature and pressure, the refrigerant transitions to a liquid while releasing heat to the environment. A compressor is used to raise the low-pressure gas to a high pressure, and a throttle (pressure reduction device) is used to reduce the pressure once the refrigerant has been fully liquefied (condensed) at high pressure.

All refrigerants have a “critical pressure” and an associated “critical temperature” above which liquid and vapor phases cannot coexist. Above this critical point, the refrigerant will be a gas and its temperature will increase or decrease as heat is added or removed. For all conventional refrigerants, the critical pressure is so high that it is

never exceeded in typical refrigeration cycles. For example, R404A is a common refrigerant used in refrigeration systems that has a critical pressure of 540.8 psia⁶ with an associated critical temperature of 161.7 °F. However, CO₂ behaves differently, with a critical pressure of 1,072 psia associated with a much lower critical temperature of 87.8 °F. The refrigerant temperature must be somewhat higher than the ambient temperature in order to reject refrigeration cycle heat to the ambient environment. Ambient temperatures greater than 87.8 °F are common and the performance of many refrigeration and air conditioning systems are tested using a 95 °F ambient temperature, as indicated by the A test condition in AHRI 1250–2009 Section 5. At temperatures greater than the critical temperature, the CO₂ refrigerant is in a supercritical state (*i.e.* a condition with pressure above the critical temperature) and heat is transferred to the environment. Since useful cooling is provided below the critical temperature, CO₂ cycles are said to be transcritical.

The transcritical nature of CO₂ generally requires more complex refrigeration cycle design to approach the efficiency of traditional refrigerants (*i.e.*, R404A, R407A, R448A, etc.) during operation in high temperature conditions. To increase efficiency and prevent overheating, transcritical booster systems introduce (or use) multiple stages of compression and intercooling. CO₂ is cooled in the gas cooler of a transcritical booster system, then expands through a high-pressure control valve and is delivered to a subcritical-pressure flash tank. In the flash tank, the refrigerant is in the subcritical phase and the liquid and vapor phases can be separated. A unit cooler in a CO₂ booster system would be supplied with liquid refrigerant from the flash tank via expansion valves where the refrigerant is evaporated. The evaporated refrigerant is subsequently compressed up to gas cooler pressure to complete the cycle (KeepRite, No. 3).

KeepRite also requests an interim waiver from the existing DOE test procedure. DOE will grant an interim waiver if it appears likely that the petition for waiver will be granted, and/or if DOE determines that it would be desirable for public policy reasons to grant immediate relief pending a determination of the petition for waiver. See 10 CFR 431.401(e)(2).

Based on the assertions in the petition, absent an interim waiver, the

prescribed test procedure is not appropriate for KeepRite's CO₂ direct expansion unit coolers and the test conditions are not achievable, since CO₂ refrigerant has a critical temperature of 87.8 °F and the current DOE test procedure calls for a liquid inlet saturation temperature of 105 °F. The inability to achieve test conditions for the stated basic models would result in economic hardship from loss of sales stemming from the inability of the DOE test procedure to address the operating conditions of KeepRite's equipment.

III. Requested Alternate Test Procedure

EPCA requires that manufacturers use the applicable DOE test procedures when making representations about the energy consumption and energy consumption costs of covered equipment (42 U.S.C. 6314(d)). Consistency is important when making representations about the energy efficiency of equipment, including when demonstrating compliance with applicable DOE energy conservation standards. Pursuant to 10 CFR 431.401, and after consideration of public comments on the petition, DOE may establish in a subsequent Decision and Order an alternate test procedure for the basic models addressed by the Interim Waiver Order.

KeepRite seeks to test and rate specific CO₂ direct expansion unit cooler basic models with modifications to the DOE test procedure. KeepRite's suggested approach specifies using modified liquid inlet saturation and liquid inlet subcooling temperatures of 38 °F and 5 °F, respectively, for both walk-in refrigerator unit coolers and walk-in freezer unit coolers. Additionally, KeepRite recommended that because the subject units are used in transcritical CO₂ booster systems the calculations in AHRI 1250–2009 section 7.9 should be used to determine the Annual Walk-in Efficiency Factor (“AWEF”) and net capacity for unit coolers matched to parallel rack systems as required under the DOE test procedure. This section of AHRI 1250–2009 is prescribed by the DOE test procedure for determining AWEF for all unit coolers tested alone (see 10 CFR part 431, subpart R, appendix C, section 3.3.1). Finally, KeepRite also recommended that AHRI 1250–2009 Table 17, EER [Energy Efficiency Ratio] for Remote Commercial Refrigerated Display Merchandisers and Storage Cabinets, should be used to determine power consumption of CO₂ direct expansion unit cooler systems as required under the DOE test procedure.

⁵ The test procedure specifies the unit cooler refrigerant inlet condition in terms of a saturation temperature (the temperature at which it completes the condensation process in a condenser) and the subcooling temperature (additional reduction in temperature lower than the specified saturation temperature). For CO₂, the critical temperature above which there cannot exist separate liquid and gas phases is below the saturation condition specified in the test procedure, hence the specified condition cannot be achieved.

⁶ Absolute pressure is the pressure measured relative to a complete vacuum; “psia” represents the absolute pressure in pounds per square inch.

IV. Interim Waiver Order

DOE has reviewed KeepRite's application, its suggested testing approach, industry materials regarding CO₂ transcritical booster systems, and KeepRite's consumer-facing materials, including websites and product specification sheets for the basic models listed in KeepRite's petition. Based on this review, the suggested testing approach appears to allow for the accurate measurement of energy efficiency of the specified basic models, while alleviating the testing issues associated with KeepRite's implementation of walk-in cooler and walk-in freezer testing for these basic models. Review of the CO₂ refrigeration market confirms that the test conditions of the testing approach suggested by KeepRite would be representative for operation of a unit cooler used in a transcritical CO₂ booster system (KeepRite, No. 3). CO₂ that is cooled in the gas cooler of a transcritical booster system expands through a high-pressure control valve that delivers CO₂ to a subcritical-pressure flash tank, where liquid and vapor phases of the refrigerant are separated. The liquid is then split and the unit coolers receive the refrigerant at the same condition, consistent with the use of the same liquid inlet saturation temperature for both the medium- and low-temperature systems in KeepRite's suggested test approach. Calculations on other external CO₂ refrigeration system designs in the market indicate that the 38 °F liquid unit cooler inlet saturation temperature suggested by KeepRite is representative of CO₂ booster systems (KeepRite, No.

4). Regarding use of the EER values in AHRI 1250–2009 Table 17 to determine the representative compressor power consumption for CO₂ unit cooler systems, research into the performance of different configurations of CO₂ booster systems shows that enhanced CO₂ cycles (like those used in transcritical booster systems) can match conventional refrigerants in average annual efficiency (KeepRite, No. 2). The findings from this research, along with the other collective factors previously noted, helps to justify the use of the EER values in AHRI 1250–2009 Table 17 for determining the power consumption for CO₂ booster system evaporators, despite these EER values being initially established for systems using conventional refrigerants. Consequently, DOE has determined that KeepRite's petition for waiver likely will be granted. Furthermore, DOE has determined that it is desirable for public policy reasons to grant KeepRite immediate relief pending a determination of the petition for waiver.

For the reasons stated, it is *ordered* that:

(1) KeepRite must test and rate the following CO₂ direct expansion unit cooler basic models with the alternate test procedure set forth in paragraph (2).

Basic Models on which the Waiver and Interim Waiver is being requested:

LP104C.*D*	*LP104D*.*D*	*LP103F*.*D*
LP106C.*D*	*LP105D*.*D*	*LP104F*.*D*
LP107C.*D*	*LP106D*.*D*	*LP106F*.*D*
LP209C.*D*	*LP207D*.*D*	*LP207F*.*D*
LP211C.*D*	*LP209P*.*D*	*LP208F*.*D*
LP214C.*D*	*LP211D*.*D*	*LP211F*.*D*
LP317C.*D*	*LP314D*.*D*	*LP313F*.*D*
LP320C.*D*	*LP316D*.*D*	*LP316F*.*D*
LP422C.*D*	*LP418D*.*D*	*LP418F*.*D*
LP427C.*D*	*LP421D*.*D*	*LP421F*.*D*

LP534C.*D*	*LP526D*.*D*	*LP524F*.*D*
LP640C.*D*	*LP631D*.*D*	*LP627F*.*D*
MP120C.*D*	*MP116L*.*D*	*MP113F*.*D*
MP124C.*D*	*MP120L*.*D*	*MP117F*.*D*
MP232C.*D*	*MP224L*.*D*	*MP221F*.*D*
MP240C.*D*	*MP233L*.*D*	*MP226F*.*D*
MP248C.*D*	*MP239L*.*D*	*MP234F*.*D*
MP360C.*D*	*MP347L*.*D*	*MP338F*.*D*
MP372C.*D*	*MP355L*.*D*	*MP349F*.*D*
MP486C.*D*	*MP470L*.*D*	*MP457F*.*D*
MP495C.*D*		
TM215C.*D*	*TM204D*.*D*	*LV106C*.*D*
TM318C.*D*	*TM206D*.*D*	*LV109C*.*D*
TM321C.*D*	*TM209D*.*D*	*LV212C*.*D*
TM426C.*D*	*TM212D*.*D*	*LV217C*.*D*
TM531C.*D*	*TM315D*.*D*	*LV325C*.*D*
TM215C.*D*	*TM318D*.*D*	*LV331C*.*D*
TM318C.*D*	*TM422D*.*D*	*LV437C*.*D*
TM321C.*D*	*TM526D*.*D*	*LV441C*.*D*
TM426C.*D*		*LV546C*.*D*
TM531C.*D*		

Brand Names for which the basic models will represent:

KeepRite/Trenton/Bally

(2) The KeepRite basic models identified in paragraph (1) of this Interim Waiver Order shall be tested according to the test procedure for walk-in cooler and walk-in freezer refrigeration systems prescribed by DOE at 10 CFR part 431, subpart R, appendix C ("Appendix C"), except that the liquid inlet saturation temperature test condition and liquid inlet subcooling temperature test condition shall be modified to 38 °F and 5 °F, respectively, for both walk-in refrigerator unit coolers and walk-in freezer unit coolers, as detailed below. All other requirements of Appendix C and DOE's regulations remain applicable.

In Appendix C, under section 3.1. *General modifications: Test Conditions and Tolerances*, revise section 3.1.5., to read as follows: 3.1.5. Tables 15 and 16 shall be modified to read as follows:

TABLE 15—REFRIGERATOR UNIT COOLER

Test description	Unit cooler air entering dry-bulb, °F	Unit cooler air entering relative humidity, %	Saturated suction temp, °F	Liquid inlet saturation temp, °F	Liquid inlet subcooling temp, °F	Compressor capacity	Test objective
Off Cycle Fan Power	35	<50	Compressor Off.	Measure fan input power during compressor off cycle.
Refrigeration Capacity Suction A	35	<50	25	38	5	Compressor On.	Determine Net Refrigeration Capacity of Unit Cooler.

Note: Superheat to be set according to equipment specification in equipment or installation manual. If no superheat specification is given, a default superheat value of 6.5 °F shall be used. The superheat setting used in the test shall be reported as part of the standard rating.

TABLE 16—FREEZER UNIT COOLER

Test description	Unit cooler air entering dry-bulb, °F	Unit cooler air entering relative humidity, %	Saturated suction temp, °F	Liquid inlet saturation temp, °F	Liquid inlet subcooling temp, °F	Compressor capacity	Test objective
Off Cycle Fan Power	–10	<50	Compressor Off.	Measure fan input power during compressor off cycle.
Refrigeration Capacity Suction A	–10	<50	–20	38	5	Compressor On.	Determine Net Refrigeration Capacity of Unit Cooler.
Defrost	–10	Various	Compressor Off.	Test according to Appendix C Section C11.

Note: Superheat to be set according to equipment specification in equipment or installation manual. If no superheat specification is given, a default superheat value of 6.5 °F shall be used. The superheat setting used in the test shall be reported as part of the standard rating.

(3) Representations. KeepRite may not make representations about the energy efficiency of a basic model listed in paragraph (1) of this Interim Waiver Order for compliance, marketing, or other purposes unless the basic model has been tested in accordance with the provisions set forth in this alternate test procedure and such representations fairly disclose the results of such testing.

(4) This Interim Waiver Order shall remain in effect according to the provisions of 10 CFR 431.401.

(5) This Interim Waiver Order is issued on the condition that the statements and representations provided by KeepRite are valid. If KeepRite makes any modifications to the controls or configurations of a basic model subject to this Interim Waiver Order, such modifications will render the waiver invalid with respect to that basic model, and KeepRite will either be required to use the current Federal test method or submit a new application for a test procedure waiver. DOE may rescind or modify this waiver at any time if it determines the factual basis underlying the petition for the Interim Waiver Order is incorrect, or the results from the alternate test procedure are unrepresentative of the basic model's true energy consumption characteristics. 10 CFR 431.401(k)(1). Likewise, KeepRite may request that DOE rescind

or modify the Interim Waiver Order if KeepRite discovers an error in the information provided to DOE as part of its petition, determines that the interim waiver is no longer needed, or for other appropriate reasons. 10 CFR 431.401(k)(2).

(6) Issuance of this Interim Waiver Order does not release KeepRite from the applicable requirements set forth at 10 CFR part 429.

DOE makes decisions on waivers and interim waivers for only those basic models specifically set out in the petition, not future models that may be manufactured by the petitioner. KeepRite may submit a new or amended petition for waiver and request for grant of interim waiver, as appropriate, for additional basic models of CO₂ direct expansion unit coolers. Alternatively, if appropriate, KeepRite may request that DOE extend the scope of a waiver or an interim waiver to include additional basic models employing the same technology as the basic model(s) set forth in the original petition consistent with 10 CFR 431.401(g).

Signing Authority

This document of the Department of Energy was signed on February 24, 2021, by Kelly Speakes-Backman, Principal Deputy Assistant Secretary and Acting Assistant Secretary for Energy Efficiency and Renewable

Energy, pursuant to delegated authority from the Acting 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 February 26, 2021.

Treena V. Garrett,

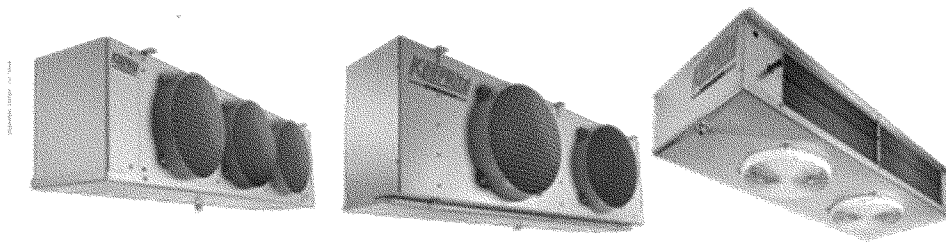
Federal Register Liaison Officer, U.S. Department of Energy.

Appendix 1

KeepRite Refrigeration Application for Waiver and Interim Waiver

Request for Waiver and Interim Waiver from a DOE test procedure pursuant to provisions described in 10 CFR 431.401 for the following product on the grounds that "the basic model contains one or more design characteristics that prevent testing of the basic model according to the prescribed test procedures."

CO₂ Direct Expansion Unit Coolers in Medium and Low Temperature



The design characteristics constituting the grounds for the Waiver and Interim Waiver Application:

- Appendix C to Subpart R of Part 431—Uniform Test Method for the

Measurement of Net Capacity and AWEF of Walk-in Cooler and Walk-in Freezer Refrigeration Systems specifies that unit coolers tested alone use the test procedures described in AHRI

1250–2009. Table 15 and Table 16 of AHRI 1250–2009 are as follows:

TABLE 15—REFRIGERATOR UNIT COOLER

Test description	Unit cooler air entering dry-bulb °F	Unit cooler air entering relative humidity, %	Saturated suction temp, °F	Liquid inlet saturation temp, °F	Liquid inlet subcooling temp, °F	Compressor capacity	Test objective
Off Cycle Fan Power	35	<50	Compressor Off.	Measure fan input power during compressor off cycle.
Refrigeration Capacity Suction A	35	<50	25	105	9	Compressor On.	Determine Net Refrigeration Capacity of Unit Cooler.

TABLE 15—REFRIGERATOR UNIT COOLER—Continued

Test description	Unit cooler air entering dry-bulb °F	Unit cooler air entering relative humidity, %	Saturated suction temp, °F	Liquid inlet saturation temp, °F	Liquid inlet subcooling temp, °F	Compressor capacity	Test objective
Refrigeration Capacity Suction B	35	<50	20	105	9	Compressor On.	Determine Net Refrigeration Capacity of Unit Cooler.

TABLE 16—FREEZER UNIT COOLER

Test description	Unit cooler air entering dry-bulb °F	Unit cooler air entering relative humidity, %	Saturated suction temp, °F	Liquid inlet saturation temp, °F	Liquid inlet subcooling temp, °F	Compressor capacity	Test objective
Off Cycle Fan Power	−0	<50	Compressor Off.	Measure fan input power during compressor off cycle.
Refrigeration Capacity Suction A	−10	<50	−20	105	9	Compressor On.	Determine Net Refrigeration Capacity of Unit Cooler.
Refrigeration Capacity Suction B	−10	<50	−26	105	9	Compressor On.	Determine Net Refrigeration Capacity of Unit Cooler.
Defrost	−10	Various	Compressor Off.	Test according to Appendix C Section C11

• CO₂ refrigerant has a critical temperature of 87.8 °F thus the liquid inlet saturation temperature of 105 °F and the liquid inlet subcooling temperature of 9 °F as specified in Table 15 and Table 16 are not achievable.

• The test condition values need to be more in line with typical operating conditions for a CO₂ refrigeration application.

Basic Models on which the Waiver and Interim Waiver is being requested:

LP104C***D*	*LP104D***D*	*LP103F***D*
LP106C***D*	*LP105D***D*	*LP104F***D*
LP107C***D*	*LP106D***D*	*LP106F***D*
LP209C***D*	*LP207D***D*	*LP207F***D*
LP211C***D*	*LP209D***D*	*LP208F***D*
LP214C***D*	*LP211D***D*	*LP211F***D*
LP317C***D*	*LP314D***D*	*LP313F***D*
LP320C***D*	*LP316D***D*	*LP316F***D*
LP422C***D*	*LP418D***D*	*LP418F***D*
LP427C***D*	*LP421D***D*	*LP421F***D*
LP534C***D*	*LP526D***D*	*LP524F***D*
LP640C***D*	*LP631D***D*	*LP627F***D*
MP120C***D*	*MP116L***D*	*MP113F***D*
MP124C***D*	*MP120L***D*	*MP117F***D*
MP232C***D*	*MP224L***D*	*MP221F***D*
MP240C***D*	*MP233L***D*	*MP226F***D*
MP248C***D*	*MP239L***D*	*MP234F***D*
MP360C***D*	*MP347L***D*	*MP338F***D*
MP372C***D*	*MP355L***D*	*MP349F***D*
MP486C***D*	*MP470L***D*	*MP457F***D*
MP495C***D*
TM215C***D*	*TM204D***D*	*LV106C***D*
TM318C***D*	*TM206D***D*	*LV109C***D*

TM321C***D*	*TM209D***D*	*LV212C***D*
TM426C***D*	*TM212D***D*	*LV217C***D*
TM531C***D*	*TM315D***D*	*LV325C***D*
TM215C***D*	*TM318D***D*	*LV331C***D*
TM318C***D*	*TM422D***D*	*LV437C***D*
TM321C***D*	*TM526D***D*	*LV441C***D*
TM426C***D*	*LV546C***D*
TM531C***D*

Brand Names for which the basic models will represent:

KeepRite/Trenton/Bally

Specific Requirements sought to be waived—Petitioning for a waiver and interim waiver to exempt CO₂ Direct Expansion Unit Coolers in Medium and Low Temperature application from being tested to the current test procedure. The prescribed test procedure is not appropriate for these products for the reasons stated previously (liquid inlet saturation temperature and liquid inlet subcooling temperature test condition values are not appropriate for a transcritical CO₂ booster system application).

List of manufacturers of all other basic models marketing in the United States and known to the petitioner to incorporate similar design characteristics—

Manufacturer: Heatcraft

Manufacturer: Heat Transfer Products Group (HTPG) Manufacturer: Hussmann Corp. (Krack)

Proposed Alternate Test Procedure

Utilize the test procedure as outlined in Appendix C to Subpart R of Part 431—Uniform Test Method for the Measurement of Net Capacity and AWEF of Walk-in Cooler and Walk-in Freezer Refrigeration Systems with reference to AHRI 1250–2009 with the exception of modifying the test conditions in Table 15 and 16 for liquid inlet saturation temperature and liquid inlet subcooling temperature as noted below. In addition, per Appendix C to Subpart R of 431 use the calculations in AHRI 1250 section 7.9 to determine AWEF and net capacity for unit coolers matched to parallel rack systems. Use AHRI 1250 Table 17, EER for Remote Commercial Refrigerated Display Merchandisers and Storage Cabinets to determine the power consumption of the system.

TABLE 15—REFRIGERATOR UNIT COOLER

Test description	Unit cooler air entering dry-bulb °F	Unit cooler air entering relative humidity, %	Saturated suction temp, °F	Liquid inlet saturation temp, °F	Liquid inlet subcooling temp, °F	Compressor capacity	Test objective
Off Cycle Fan Power	35	<50	Compressor Off.	Measure fan input power during compressor off cycle.
Refrigeration Capacity Suction A	35	<50	25	38	5	Compressor On.	Determine Net Refrigeration Capacity of Unit Cooler.
Refrigeration Capacity Suction B	35	<50	20	38	5	Compressor On.	Determine Net Refrigeration Capacity of Unit Cooler.

TABLE 16—FREEZER UNIT COOLER

Test description	Unit cooler air entering dry-bulb °F	Unit cooler air entering relative humidity, %	Saturated suction temp, °F	Liquid inlet saturation temp, °F	Liquid inlet subcooling temp, °F	Compressor capacity	Test objective
Off Cycle Fan Power	– 10	<50	Compressor Off.	Measure fan input power during compressor off cycle.
Refrigeration Capacity Suction A	– 10	<50	– 20	38	5	Compressor On.	Determine Net Refrigeration Capacity of Unit Cooler.
Refrigeration Capacity Suction B	– 10	<50	– 26	38	5	Compressor On.	Determine Net Refrigeration Capacity of Unit Cooler.
Defrost	– 10	Various	Compressor Off.	Test according to Appendix C Section C11.

Success of the application for Waiver and Interim Waiver will: Ensure that manufacturers of CO2 Direct Expansion Unit Coolers in Medium & Low Temperature application can continue to participate in the market.

What economic hardship and/or competitive disadvantage is likely to result absent a favorable determination on the Application for Interim Waiver—Economic hardship will be loss of sales due to not meeting the DOE requirements set forth.

Conclusion: KeepRite Refrigeration seeks a Waiver and Interim Waiver from DOE's current requirement to test CO2 direct expansion unit coolers.

Request submitted by:

/s/

Vince Zolli, P. Eng,

Vice President of Engineering, KeepRite Refrigeration.

[FR Doc. 2021–04357 Filed 3–2–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14799–002]

Lock 13 Partners, LLC; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for an original license for the Evelyn Hydroelectric Project No. 14799, and has prepared an Environmental Assessment (EA) for the project. The proposed project would be located on the Kentucky River in Lee County, Kentucky, at the existing Kentucky River Lock and Dam No. 13, which is owned by the Commonwealth of Kentucky and operated by the Kentucky River Authority. No federal land would be occupied by project

works or located within the project boundary.

The EA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The Commission provides all interested persons with an opportunity to view and/or print the EA 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), in a Presidential proclamation issued on March 13, 2020. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov, or toll-free at (866) 208–3676, or for TTY, (202) 502–8659.

You may also register online at <https://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at <https://ferconline.ferc.gov/eFiling.aspx>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://ferconline.ferc.gov/QuickComment.aspx>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions

sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–14799–002.

For further information, contact Sarah Salazar at (202) 502–6863, or by email at sarah.salazar@ferc.gov.

Dated: February 25, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–04385 Filed 3–2–21; 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 rate filings:

Docket Numbers: ER13–1508–006.
Applicants: Entergy Louisiana, LLC, Entergy New Orleans, LLC
Description: Informational Compliance Filing of Amended Power Purchase Agreement [Pro Forma Sheets] of Entergy Louisiana, LLC, et al.
Filed Date: 2/24/21.
Accession Number: 20210224–5196.
Comments Due: 5 p.m. ET 3/17/21.
Docket Numbers: ER21–1200–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Request for One-Time, Limited Waiver of Tariff Provisions of Midcontinent Independent System Operator, Inc.
Filed Date: 2/25/21.
Accession Number: 20210225–5084.
Comments Due: 5 p.m. ET 2/25/21.
Docket Numbers: ER21–1201–000.
Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original WMPA 5973; Queue No. AG1-044 to be effective 1/26/2021.

Filed Date: 2/25/21.

Accession Number: 20210225-5002.

Comments Due: 5 p.m. ET 3/18/21.

Docket Numbers: ER21-1202-000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Attachment A Section 2.5 of the WEIS Tariff to be effective 4/27/2021.

Filed Date: 2/25/21.

Accession Number: 20210225-5050.

Comments Due: 5 p.m. ET 3/18/21.

Docket Numbers: ER21-1203-000.

Applicants: Birchwood Power Partners, L.P.

Description: Tariff Cancellation: Cancellation entire tariff to be effective 3/1/2021.

Filed Date: 2/25/21.

Accession Number: 20210225-5066.

Comments Due: 5 p.m. ET 3/18/21.

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: February 25, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021-04381 Filed 3-2-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RM16-17-000 RM16-17-001]

Data Collection for Analytics and Surveillance and Market-Based Rate Purposes; Notice of Technical Workshop

Take notice that Federal Energy Regulatory Commission (Commission)

staff will convene a technical workshop to discuss the functionality and features of the relational database through which the Commission will begin collecting certain market-based rate (MBR) information in accordance with Order No. 860 (MBR Database).¹ This workshop provides a forum for dialogue between Commission staff and interested entities to discuss the general features of the MBR Database and the process for submitting information into this database. For reference, interested entities can access the relational database at <https://mbrweb.ferc.gov/>.

The technical workshop will be held on Thursday, March 25, 2021, from approximately 10:00 a.m. to 3:00 p.m. Eastern Time. The technical workshop will be held electronically. A supplemental notice will be issued prior to the technical workshop with further details regarding the agenda and if there are changes to the date or time of the technical workshop.

Individuals who are interested in registering for the conference can do so here: <https://ferc.webex.com/ferc/j.php?MTID=e6dd18def200b281ff165e57325102ee0>.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to accessibility@ferc.gov or call toll free 1-866-208-3372 (voice) or 202-208-8659 (TTY), or send a fax to 202-208-2106 with the required accommodations.

For more information about this technical workshop, please contact Ryan Stertz, 202-502-6473, mbrdatabase@ferc.gov for technical questions, or Sarah McKinley, 202-502-8368, sarah.mckinley@ferc.gov for logistical issues.

Dated: February 25, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021-04386 Filed 3-2-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21-1198-000]

Pay Less 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 Pay Less 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 March 17, 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

¹ Data Collection for Analytics and Surveillance and Market-Based Rate Purposes, Order No. 860, 168 FERC ¶ 61,039 (2019); Order No. 860-A, 170 FERC 61,129 (2020).

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 TTY, (202) 502-8659.

Dated: February 25, 2021.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2021-04384 Filed 3-2-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21-1197-000]

All Choice Energy MidAmerica 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 All Choice Energy MidAmerica 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 March 17, 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 TTY, (202) 502-8659.

Dated: February 25, 2021.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2021-04383 Filed 3-2-21; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER21-755-001.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits tariff filing per 35.17(b): 1875R4 Kansas Electric Power Cooperative, Inc. NITSA and NOA to be effective 12/1/2020.

Filed Date: 02/25/2021.

Accession Number: 20210225-5121.

Comment Date: 5 p.m. ET 3/18/21.

Docket Numbers: ER21-1204-000.

Applicants: Midcontinent Independent System Operator, Inc., ITC Midwest LLC.

Description: § 205(d) Rate Filing: 2021-02-25 SA 3639 ITC Midwest-Elk Creek Solar E&P (J1164) to be effective 2/22/2021.

Filed Date: 2/25/21.

Accession Number: 20210225-5107.

Comments Due: 5 p.m. ET 3/18/21.

Docket Numbers: ER21-1205-000.

Applicants: Basin Electric Power Cooperative.

Description: Basin Electric Power Cooperative submits tariff filing per 35.13(a)(2)(iii): Basin Electric Filing of Balancing Authority Services Agreement with WAPA-RMR to be effective 1/7/2021.

Filed Date: 02/25/2021.

Accession Number: 20210225-5115.

Comment Date: 5 p.m. ET 3/18/21.

Docket Numbers: ER21-1207-000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii): Rev. to PJM OATT and CTOA RE: update AEP affiliate company names (OATT) to be effective 4/27/2021.

Filed Date: 02/25/2021.

Accession Number: 20210225-5127.

Comment Date: 5 p.m. ET 3/18/21.

Docket Numbers: ER21-1208-000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii): Rev. to PJM OATT and CTOA RE: update AEP affiliate company names (CTOA) to be effective 4/27/2021.

Filed Date: 02/25/2021.

Accession Number: 20210225-5128.

Comment Date: 5 p.m. ET 3/18/21.

Docket Numbers: ER21-1209-000.

Applicants: Mid-Atlantic Interstate Transmission, LLC, PJM Interconnection, L.L.C.

Description: Mid-Atlantic Interstate Transmission, LLC submits tariff filing per 35.13(a)(2)(iii): MAIT submits Seven ECSAs, Nos. 5387, 5774, 5917, 5918, 5919, 5920 and 5921 to be effective 4/27/2021.

Filed Date: 02/25/2021.

Accession Number: 20210225-5143.

Comment Date: 5 p.m. ET 3/18/21.

Docket Numbers: ER21-1210-000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits tariff filing per 35.15: Notice of Cancellation of WMPA, SA No. 5153; Queue No. AD1-157 re: Withdrawal to be effective 3/27/2021.

Filed Date: 02/25/2021.

Accession Number: 20210225-5157.
Comment Date: 5 p.m. ET 3/18/21.

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: February 25, 2021.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2021-04382 Filed 3-2-21; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2021-0179; FRL-10021-06-OAR]

Clean Air Act Advisory Committee (CAAAC): Notice of Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), the Environmental Protection Agency (EPA) is announcing a public meeting of the Clean Air Act Advisory Committee (CAAAC) to be conducted via remote/virtual participation only. Due to unforeseen administrative circumstances, EPA is announcing this meeting with less than 15 calendar days' notice. The EPA renewed the CAAAC charter on November 19, 2020 to provide independent advice and counsel to EPA on policy issues associated with implementation of the Clean Air Act of 1990. The Committee advises EPA on economic, environmental, technical, scientific and enforcement policy issues.

DATES: The CAAAC will hold its next public meeting remote/virtually on Monday, March 15, 2021 from 2:00 p.m. to 3:00 p.m. (EST) to introduce current members to incoming Office of Air and

Radiation senior leadership. Members of the public may register to listen to the meeting or provide comments, by emailing caaac@epa.gov by 5:00 p.m. (EST) March 12, 2021.

FOR FURTHER INFORMATION CONTACT:

Shanika Whitehurst, Designated Federal Official, Clean Air Act Advisory Committee (6103A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202-564-8235; email address: whitehurst.shanika@epa.gov. Additional information about this meeting, the CAAAC, and its subcommittees and workgroups can be found on the CAAAC website: <http://www.epa.gov/oar/caaac/>.

SUPPLEMENTARY INFORMATION: Pursuant to 5 U.S.C. App. 2 section 10(a)(2), notice is hereby given that the Clean Air Act Advisory Committee will hold its next public meeting remote/virtually on Monday, March 15, 2021 from 2:00 p.m. to 3:00 p.m. (EST) to introduce current members to incoming Office of Air and Radiation senior leadership.

The committee agenda and any documents prepared for the meeting will be publicly available on the CAAAC website at <http://www.epa.gov/caaac/> prior to the meeting. Thereafter, these documents, together with CAAAC meeting minutes, will be available on the CAAAC website or by contacting the Office of Air and Radiation Docket and requesting information under docket EPA-HQ-OAR-2021-0179. The docket office can be reached by email at: a-and-r-Docket@epa.gov or FAX: 202-566-9744.

For information on access or services for individuals with disabilities, please contact Lorraine Reddick at [reddick.lorraine@epa.gov](mailto:redrick.lorraine@epa.gov), preferably at least 7 days prior to the meeting to give EPA as much time as possible to process your request.

Dated: February 25, 2021.

John Shoaff,
Director, Office of Air Policy and Program Support.

[FR Doc. 2021-04354 Filed 3-2-21; 8:45 am]

BILLING CODE 6560-50-P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Agency Information Collection Activity: Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice and request for comments.

SUMMARY: This notice announces that the U.S. Equal Employment Opportunity Commission (EEOC or Commission) is submitting a request for a three-year approval, under the Paperwork Reduction Act of 1995 (PRA), of a revision to the current Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery that the Office of Management and Budget (OMB) previously approved. This collection is part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery.

DATES: Written comments on this notice must be submitted on or before April 2, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

For EEOC Office of Field Programs: Michelle Crew, michelle.crew@eEOC.gov, (216) 306-1130;

For EEOC Office of Federal Operations: Patricia St. Clair, patricia.stclair@eEOC.gov, (202) 663-4922.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the government's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, course materials, course instructor, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are the only way to collect information; there are no alternative existing sources.
- The collections are noncontroversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used

as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential nonresponse bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Pursuant to the PRA and OMB regulation 5 CFR 1320.8(d)(1), the EEOC has solicited public comment on its intent to seek a three-year approval of this revised collection: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the EEOC's functions, including whether the information will have practical utility; (2) Evaluate the accuracy of the EEOC's estimate of the burden of the proposed collection of information, including the validity of

the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including 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.

One comment was received from the public in response to the 60-day notice published in the **Federal Register** of November 18, 2020 (85 FR 73479). The comment raised concerns regarding prospective employers requesting a transgender person's previous name(s) prior to their gender transition. Information regarding a person's previous name(s) is not requested as part of the EEOC's information collections of customer and stakeholder feedback on Agency service delivery. Accordingly, no changes have been made to the Generic Clearance based upon this comment.

In addition to clearance hours for the previously approved customer feedback forms, the EEOC requested an additional 39,716 clearance hours. Most of these requested hours—39,116—are for a randomly-generated, pop-up form that will solicit feedback from a sample of visitors to the EEOC website on the contents and performance of the web pages. The 39,116 hours burden estimate is based on the number of web page views in a year. The remaining 600 hours represent a reserve to cover any additional feedback forms that may be developed over the next three years for new trainings offered by the EEOC. The EEOC anticipates any new potential feedback forms will be similar in length and content to existing feedback forms. The EEOC is seeking clearance for the additional hours so the EEOC can use the existing clearance number if the need arises for additional training and feedback forms.

Type of survey	Respondent	Number of respondents	Number of responses/ respondent	Participation time	Response burden (in hours)
Questionnaire—FEPA Training Conference Feedback.	State and local government employees.	550	1	2 minutes per response.	18
Questionnaire—Technical Assistance Program Feedback.	Private employers, state and local government employees.	4,500	1	2 minutes per response.	150
Questionnaire—EXCEL Customer Feedback.	Private employers, state and local government employees.	250	1	10 minutes per response.	42
Questionnaire—Respectful Workplace Training Feedback.	Private employers, state and local government employees.	15,900	2 (survey delivered twice to same respondents).	10 minutes per response.	5,300
Questionnaire—Federal Course Evaluation Form.	Participants in federal courses and in customer specific trainings.	9,180	1	2 minutes per response.	306

Type of survey	Respondent	Number of respondents	Number of responses/ respondent	Participation time	Response burden (in hours)
Future Training Assessments	Training Center Attendees	7,200	1	5 minutes per response.	600
EEOC website feedback forms ...	Individuals or Households	1,173,472	1	2 minutes per response.	39,116

Overview of Information Collection

OMB Number: 3046-0048.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals and households; businesses and organizations; State, Local or Tribal Governments.

Average Expected Annual Number of Activities: 6 known, up to 2 more anticipated.

Respondents: 1,211,052.

Annual Responses: 1,226,952.

Frequency of Response: Twice per respondent for one activity, and once for all other activities.

Average Minutes per Response: 2.2.

Burden Hours: 45,532.

For the Commission.

Charlotte A. Burrows,
Chair.

[FR Doc. 2021-04305 Filed 3-2-21; 8:45 am]

BILLING CODE 6570-01-P

FARM CREDIT ADMINISTRATION

Sunshine Act Meetings

AGENCY: Farm Credit Administration Board, Farm Credit Administration.

ACTION: Notice, regular meeting.

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act, of the forthcoming regular meeting of the Farm Credit Administration Board.

DATES: The regular meeting of the Board will be held March 11, 2021, from 9:00 a.m. until such time as the Board may conclude its business. *Note: Because of the COVID-19 pandemic, we will conduct the board meeting virtually. If you would like to observe the open portion of the virtual meeting, see instructions below for board meeting visitors.*

ADDRESSES: To observe the virtual meeting, go to [FCA.gov](https://www.fca.gov), select "Newsroom," then "Events." There you will find a description of the meeting and a link to "Instructions for board meeting visitors." See **SUPPLEMENTARY INFORMATION** for further information about attendance requests.

FOR FURTHER INFORMATION CONTACT: Dale Aultman, Secretary to the Farm Credit

Administration Board (703) 883-4009. TTY is (703) 883-4056.

SUPPLEMENTARY INFORMATION: This meeting of the Board will be open to the public. If you wish to observe, follow the instructions above in the **ADDRESSES** section at least 24 hours before the meeting. If you need assistance for accessibility reasons or if you have any questions, contact Dale Aultman, Secretary to the Farm Credit Administration Board, at (703) 883-4009. The matters to be considered at the meeting are as follows:

Open Session

Approval of Minutes

- February 11, 2021

Report

- Funding Conditions for the Farm Credit System

New Business

- Repeal of certain FCA Regulations made obsolete by Section 5412 of the Agriculture Improvement Act of 2018
- Farm Credit East ACA's request to increase its capital contribution to FarmStart, LLP
- Spring 2021 Unified Agenda

Dated: March 1, 2021.

Dale Aultman,
Secretary, Farm Credit Administration Board.

[FR Doc. 2021-04459 Filed 3-1-21; 11:15 am]

BILLING CODE 6705-01-P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID: 17530]

Privacy Act of 1974; Matching Program

AGENCY: Federal Communications Commission.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended ("Privacy Act"), this document announces the establishment of a computer matching program the Federal Communications Commission ("FCC" or "Commission" or "Agency") and the Universal Service Administrative Company (USAC) will conduct with the

Pennsylvania's Department of Human Services (PDHS); ("Agency"). The purpose of this matching program is to verify the eligibility of applicants to and subscribers of the Emergency Broadband Benefit Program, which is administered by USAC under the direction of the FCC. More information about this program is provided in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Written comments are due on or before April 2, 2021. This computer matching program will commence on April 2, 2021, and will conclude 18 months after becoming effective.

ADDRESSES: Send comments to Margaret Drake, FCC, 45 L Street NE, Washington, DC 20554, or to Privacy@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Margaret Drake at 202-418-1707 or Privacy@fcc.gov.

SUPPLEMENTARY INFORMATION: The Emergency Broadband Benefit Program (EBBP) was established by Congress in the Consolidated Appropriations Act of 2021, Public Law 116-260, 134 Stat. 1182. EBBP is a program that will help low-income Americans obtain discounted broadband service and one-time co-pay for a connected device (laptop, desktop computer or tablet). This program was created specifically to assist American families' access to broadband, which has proven to be essential for work, school, and healthcare during the public health emergency that exists as a result of COVID-19. A household may qualify for the EBBP benefit under various criteria, including an individual qualifying for the FCC's Lifeline program.

In a Report and Order adopted on March 31, 2016 (81 FR 33026, May 24, 2016), the Commission ordered USAC to create a National Lifeline Eligibility Verifier ("National Verifier"), including the National Lifeline Eligibility Database (LED), that would match data about Lifeline applicants and subscribers with other data sources to verify the eligibility of an applicant or subscriber. The Commission found that the National Verifier would reduce compliance costs for Lifeline service providers, improve service for Lifeline subscribers, and reduce waste, fraud, and abuse in the program. The

Consolidated Appropriations Act of 2021 directs the FCC to leverage the National Verifier to verify applicants' eligibility for EBBP. The purpose of this matching program is to verify the eligibility of EBBP applicants and subscribers by determining whether they receive Medicaid or Supplemental Nutrition Assistance Program (SNAP) benefits administered by the Pennsylvania Department of Human Services. Under FCC rules, consumers receiving these benefits qualify for Lifeline discounts and also for EBBP benefits.

PARTICIPATING NON-FEDERAL AGENCIES:

Pennsylvania Department of Human Services (PDHS).

AUTHORITY FOR CONDUCTING THE MATCHING PROGRAM:

Consolidated Appropriations Act of 2021, Public Law 116–260, 134 Stat. 1182; 47 CFR part 54.

PURPOSE(S):

In the 2016 Lifeline Modernization Order (81 FR 33026, May 24, 2016), the FCC required USAC to develop and operate the National Verifier to improve efficiency and reduce waste, fraud, and abuse in the Lifeline program. The stated purpose of the National Verifier is “to increase the integrity and improve the performance of the Lifeline program for the benefit of a variety of Lifeline participants, including Lifeline providers, subscribers, states, community-based organizations, USAC, and the Commission.” 31 FCC Rcd 3962, 4006, para. 126. To help determine whether Lifeline applicants and subscribers are eligible for Lifeline benefits, the Order contemplates that the USAC-operated LED will communicate with information systems and databases operated by other Federal and State agencies. Id. at 4011–2, paras. 135–7.

The Consolidated Appropriations Act of 2021 directs the FCC to leverage the National Verifier to verify applicants' eligibility for EBBP. The purpose of this matching program is to verify the eligibility of EBBP applicants and subscribers by determining whether they receive Medicaid or SNAP benefits administered by the Pennsylvania Department of Human Services. Under FCC rules, consumers receiving these benefits qualify for Lifeline discounts and also for EBBP benefits.

CATEGORIES OF INDIVIDUALS:

The categories of individuals whose information is involved in the matching program include, but are not limited to, those individuals who have applied for EBBP benefits; are currently receiving

benefits; are individuals who enable another individual in their household to qualify for EBBP benefits; are minors whose status qualifies a parent or guardian for EBBP benefits; or are individuals who have received EBBP benefits.

CATEGORIES OF RECORDS:

The categories of records involved in the matching program include, but are not limited to, the last four digits of the applicant's Social Security Number, date of birth, and first name or last name. The National Verifier will transfer these data elements to the Pennsylvania DHS which will respond either “yes” or “no” that the individual is enrolled in a EBBP-qualifying assistance program: State of Pennsylvania's SNAP or Medicaid.

SYSTEM(S) OF RECORDS:

The USAC records shared as part of this matching program reside in the EBBP system of records, FCC/WCB–3, Emergency Broadband Benefit Program, which can be found on the FCC website at <https://www.fcc.gov/managing-director/privacy-transparency/privacy-act-information#systems>.

Federal Communications Commission.

Marlene Dortch,
Secretary.

[FR Doc. 2021–04397 Filed 3–2–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1030; FRS 17516]

Information Collection 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 April 2, 2021.

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: 3060–1030.

Title: Service Rules for Advanced Wireless Services (AWS) in the 1.7 GHz and 2.1 GHz Bands.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; state, local, or tribal government; Federal Government and not for profit institutions.

Number of Respondents: 223 Respondents; 3,463 responses.

Estimated Time per Response: 0.25 to 5 hours.

Frequency of Response: Annual, semi-annual, one time, and on occasion reporting requirements, recordkeeping requirement, third-party disclosure requirements, and every ten years reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in sections 1, 2, 4(i), 201, 301, 302, 303, 307, 308, 309, 310, 316, 319, 324, 332, and 333 of the Communications Act of 1934, as amended, and sections 6003, 6004, and 6401 of the Middle Class Tax Relief Act of 2012, Public Law 112–96, 126 Stat. 156, 47 U.S.C. 151, 152, 154(i), 201, 301, 302(a), 303, 307, 308, 309, 310, 316, 319, 324, 332, 333, 1403, 1404, and 1451.

Total Annual Burden: 10,351 hours.

Total Annual Cost: \$471,690.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The currently approved information collections under Control No. 3060–1030 relate to three groups of Advanced Wireless Service (“AWS”) spectrum, commonly referred to as AWS–1, AWS–3, and AWS–4. The FCC’s policies and rules apply to application, licensing, operating and technical rules for this spectrum. The respondents are AWS licensees, incumbent Fixed Microwave Service (FS) and Broadband Radio Service (BRS) licensees that relocate out of the AWS

bands. AWS licensees also have coordination requirements with certain Federal Government incumbents.

Recordkeeping, reporting, and third-party disclosure requirements associated with the FCC items listed in item 1 of the supporting statement will be used by incumbent licensees and new entrants to negotiate relocation agreements and to coordinate operations to avoid interference. The information also will be used by licensees to determine reimbursement obligations of other licensees pursuant to the Commission’s rules, and notify to notify such licensees of their reimbursement obligations. Additionally, the information will be used to facilitate dispute resolution and for FCC oversight of the cost-sharing plan.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–04396 Filed 3–2–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX; FRS 17513]

Information Collection 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 might “further reduce the information collection burden for small business concerns with fewer than 25 employees.” 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.

DATES: Written comments and recommendations for the proposed

information collection should be submitted on or before April 2, 2021.

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 Nicole Ongele, FCC, via email to PRA@fcc.gov and to Nicole.Ongele@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 Nicole Ongele at (202) 418–2991. 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: 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–XXXX.

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

Form Number: N/A.

Type of Review: New information collection.

Respondents: Business or other for-profit entities.

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

Estimated Time per Response: 0.5 hours (30 minutes)–3 hours.

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

Obligation to Respond: Mandatory and required to obtain or retain benefits. Statutory authority for these collections are contained in 47 U.S.C. 227b, 251(e), and 227(e) of the Communications Act of 1934.

Total Annual Burden: 15,520 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

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

Needs and Uses: The Pallone-Thune Telephone Robocall Abuse Criminal Enforcement and Deterrence (TRACED) Act directs the Commission to require, no later than 18 months from enactment, all voice service providers to implement STIR/SHAKEN caller ID authentication technology in the internet protocol (IP) portions of their networks and implement an effective caller ID authentication framework in the non-IP portions of their networks. Among other provisions, the TRACED Act also directs the Commission to create extension and exemption mechanisms for voice service providers. On September 29, 2020, the Commission adopted its *Call Authentication Trust Anchor Second*

Report and Order. See Call Authentication Trust Anchor, WC Docket No. 17–97, Second Report and Order, FCC 20–136 (adopted Sept. 29, 2020). The Second Report and Order implemented section 4(b)(1)(B) of the TRACED Act, in part, by requiring a voice service provider maintain and be ready to provide the Commission upon request with documented proof that it is participating, either on its own or through a representative, including third party representatives, as a member of a working group, industry standards group, or consortium that is working to develop a non-Internet Protocol caller identification authentication solution, or actively testing such a solution. The Second Report and Order also implemented the extension mechanisms in section 4(b)(5) by, in part, requiring voice service providers to certify that they have either implemented STIR/SHAKEN or a robocall mitigation program. And finally, the Second Report and Order completed the implementation of the exemption process of 4(b)(2) by requiring voice service providers file a second certification after June 30, 2021 to verify that they met the criteria to receive their exemption.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–04399 Filed 3–2–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL HOUSING FINANCE AGENCY

[No. 2021–N–3]

Proposed Collection; Comment Request

AGENCY: Federal Housing Finance Agency.

ACTION: Federal Home Loan Bank Director—60-day notice of submission of information collection for approval from Office of Management and Budget.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Housing Finance Agency (FHFA or the Agency) is seeking public comments concerning an information collection known as “Federal Home Loan Bank Directors,” which has been assigned control number 2590–0006 by the Office of Management and Budget (OMB). FHFA intends to submit the information collection to OMB for review and approval of a three-year extension of the control number, which is due to expire on February 28, 2021.

DATES: Interested persons may submit comments on or before May 3, 2021.

ADDRESSES: Submit comments to FHFA, identified by “Proposed Collection; Comment Request: ‘Federal Home Loan Bank Directors, (No. 2021–N–3)’” by any of the following methods:

- *Agency Website:* www.fhfa.gov/open-for-comment-or-input.
- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. If you submit your comment to the *Federal eRulemaking Portal*, please also send it by email to FHFA at RegComments@fhfa.gov to ensure timely receipt by the agency.
- *Mail/Hand Delivery:* Federal Housing Finance Agency, Eighth Floor, 400 Seventh Street SW, Washington, DC 20219, ATTENTION: Proposed Collection; Comment Request: “Federal Home Loan Bank Directors, (No. 2021–N–3).”

We will post all public comments we receive without change, including any personal information you provide, such as your name and address, email address, and telephone number, on the FHFA website at <http://www.fhfa.gov>. In addition, copies of all comments received will be available for examination by the public through the electronic comment docket for this PRA Notice also located on the FHFA website.

FOR FURTHER INFORMATION CONTACT:

Vickie Olafson, Assistant General Counsel, Vickie.Olafson@fhfa.gov, (202) 649–3025; or Angela Supervielle, Counsel, Angela.Supervielle@fhfa.gov, (202) 649–3973 (these are not toll-free numbers); Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. The Telecommunications Device for the Deaf is (800) 877–8339.

SUPPLEMENTARY INFORMATION:

A. Need for and Use of the Information Collection

Section 7 of the Federal Home Loan Bank Act (Bank Act) vests the management of each Federal Home Loan Bank (Bank) in its board of directors.¹ As required by section 7, each Bank’s board comprises two types of directors: (1) Member directors, who are drawn from the officers and directors of member institutions located in the Bank’s district and who are elected to represent members in a particular state in that district; and (2) independent directors, who are unaffiliated with any of the Bank’s member institutions, but who reside in the Bank’s district and are

¹ See 12 U.S.C. 1427(a)(1).

elected on an at-large basis.² Both types of directors serve four-year terms, which are staggered so that approximately one-quarter of a Bank's total directorships are up for election every year.³ Section 7 and FHFA's implementing regulation, codified at 12 CFR part 1261, establish the eligibility requirements for both types of Bank directors and the professional qualifications for independent directors, and set forth the procedures for their election.

Part 1261 of the regulations requires that each Bank administer its own annual director election process. As part of this process, a Bank must require each nominee for both types of directorship, including any incumbent that may be a candidate for re-election, to complete and return to the Bank a form that solicits information about the candidate's statutory eligibility to serve and, in the case of independent director candidates, about his or her professional qualifications for the directorship being sought.⁴ Specifically, member director candidates are required to complete the *Federal Home Loan Bank Member Director Eligibility Certification Form* (*Member Director Eligibility Certification Form*), while independent director candidates must complete the *Federal Home Loan Bank Independent Director Application Form* (*Independent Director Application Form*). Each Bank must also require all of its incumbent directors to certify annually that they continue to meet all eligibility requirements.⁵ Member directors do this by completing the *Member Director Eligibility Certification Form* again every year, while independent directors complete the abbreviated *Federal Home Loan Bank Independent Director Annual Certification Form* (*Independent Director Annual Certification Form*) to certify their ongoing eligibility.

The Banks use the information collection contained in the *Independent Director Application Form* and part 1261 to determine whether individuals who wish to stand for election or re-election as independent directors satisfy the statutory eligibility requirements and possess the professional qualifications required under the statute and regulations. Only individuals meeting those requirements and qualifications may serve as an independent director.⁶ On an annual basis, the Banks use the information collection contained in the *Independent Director Annual Certification Form* and

part 1261 to determine whether its incumbent independent directors continue to meet the statutory eligibility requirements. The Banks use the information collection contained in the *Member Director Eligibility Certification Form* and part 1261 to determine whether individuals who wish to stand for election or re-election as member directors satisfy the statutory eligibility requirements. Only individuals meeting these requirements may serve as a member director.⁷ On an annual basis, the Banks also use the information collection contained in the *Member Director Eligibility Certification Form* and part 1261 to determine whether its incumbent member directors continue to meet the statutory eligibility requirements.

The OMB control number for this information collection is 2590-0006. The current clearance for the information collection expired on February 28, 2021. The likely respondents are individuals who are prospective and incumbent Bank directors.

B. Revisions to the Existing Bank Director Forms

In advance of the 2021 Bank director election cycle, FHFA is revising each of the three Bank Director Application and Certification forms, all of which have existed in substantially their current form since the current statutory requirements for Bank directors were adopted in 2008.

The *Independent Director Application Form*, by far the longest of the three forms at eight pages and requiring a number of essay-type answers, is completed by all independent directorship nominees, including incumbents seeking re-nomination. The information requested on the form is intended to confirm that the nominee is legally eligible to serve as an independent director, has the required professional qualifications for the type of independent directorship being sought, and is of high personal integrity and to identify any potential conflicts of interest of which the Bank should be aware. The proposed revisions would tie the questions more closely to statutory and regulatory requirements, provide more structured answer choices so as to ensure responses are relevant, solicit more comprehensive information on issues about which the Bank must weigh facts to make a legal judgment about the nominee's eligibility, and move most instructions to a separate sheet and otherwise streamline the questions. The revisions should allow

nominees to complete the form more quickly by providing preset answer choices for many questions, permitting attachments in answer to certain questions, and eliminating some superfluous questions. FHFA estimates that, in addition to encouraging more accurate and complete answers, the revisions will reduce the amount of time it takes a nominee to complete the form from three to two hours.

The *Independent Director Annual Certification Form*, which runs two pages including instruction, is completed by incumbent independent directors annually to certify that they remain legally eligible to serve. The existing form provides independent directors with the option merely to check a box stating that "no changes have occurred" with respect to the director's compliance with the statutory eligibility requirements. In the Agency's view, providing this option has resulted in some independent directors overlooking changes in residence or employment that might render them ineligible to continue to serve. As revised, the form would require independent directors to provide current information on residence and employment to allow the Bank to determine whether there may be new information leading to eligibility concerns.

The *Member Director Eligibility Certification Form*, which includes one-and-a-half pages of questions and two pages of instructions (reflecting the fact that the form is used for multiple purposes), is completed both by nominees running for a member directorship and annually by incumbent member directors to certify their continuing eligibility. The form is designed to confirm that member directors and member directorship nominees are legally eligible to serve in the directorship positions they occupy or are seeking. Although some questions on the form will be revised to provide preset answers, the substance of questions on the revised form will remain essentially the same as those on the existing form. The *Member Director Eligibility Certification Form* was most recently revised in August 2020 to remove a notarization requirement (neither of the other two Bank director forms had such a requirement).

The revised questions, including preset answer selections, and instructions for each of the Bank director forms appear at the end of this notice. The final formatting of the revised forms has yet to be determined.

² See 12 U.S.C. 1427(b) and (d).

³ See 12 U.S.C. 1427(d).

⁴ See 12 CFR 1261.7(c) and (f); 12 CFR 1261.14(b).

⁵ See 12 CFR 1261.12.

⁶ See 12 U.S.C. 1427(a)(3).

⁷ See 12 U.S.C. 1427(a)(3) and (b)(1).

C. Burden Estimate

FHFA estimates the total annual hour burden imposed upon respondents by the three Bank director forms comprising this information collection to be 119 hours (39 hours + 50 hours + 30 hours = 119 hours, as detailed below).

The Agency estimates the total annual hour burden on all member director candidates and incumbent member directors associated with review and completion of the *Member Director Eligibility Certification Form* to be 39 hours. This includes a total annual average of 72 member director nominees (24 open seats per year with three nominees for each) completing the form as an application, with 1 response per nominee taking an average of 15 minutes (.25 hours) (72 respondents \times .25 hours = 18 hours). It also includes a total annual average of 84 incumbent member directors not up for election completing the form as an annual

certification, with 1 response per individual taking an average of 15 minutes (.25 hours) (84 individuals \times .25 hours = 21 hours).

The Agency estimates the total annual hour burden on all independent director candidates associated with review and completion of the *Independent Director Application Form* to be 50 hours. This includes a total annual average of 25 independent director candidates (22 open seats per year, plus three vacancies, with one nominee for each), with 1 response per individual taking an average of 2.0 hours (25 individuals \times 2.0 hours = 50 hours).

The Agency estimates the total annual hour burden on all incumbent independent directors associated with review and completion of the *Independent Director Annual Certification Form* to be 30 hours. This includes a total annual average of 60 incumbent independent directors not up for election, with 1 response per

individual taking an average of 30 minutes (.5 hours) (60 individuals \times .5 hours = 30 hours).

D. Comments Request

FHFA requests written comments on the following: (1) Whether the collection of information is necessary for the proper performance of FHFA functions, including whether the information has practical utility; (2) the accuracy of FHFA's estimates of the burdens of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Kevin Smith,

Chief Information Officer, Federal Housing Finance Agency.

BILLING CODE 8070-01-P

FEDERAL HOME LOAN BANK MEMBER DIRECTOR ELIGIBILITY CERTIFICATION FORM (REVISED)**INSTRUCTIONS**

This Federal Home Loan Bank Member Director Eligibility Certification Form must be completed by individuals wishing to accept a nomination to stand for election as a member director of the Federal Home Loan Bank of [TO BE COMPLETED BY EACH BANK] (Bank) or to be considered for appointment by the Bank's board to fill a member directorship that has become vacant. It must also be completed annually by each incumbent member director. Your responses to the questions on this Form will assist the Bank in verifying that you meet the eligibility requirements to serve as a member director.

You are eligible to serve as a member director of the Bank only if you meet all of the following requirements:

- You are a citizen of the United States;
- You are an officer or director of a member institution of the Bank:
 - That was a member of the Bank as of December 31, [PRIOR YEAR]; and
 - Whose voting state for purposes of Bank directorship elections is the state that is represented by the directorship for which you have been nominated; and
- Each member of the Bank for which you are an officer or director is in compliance with all of its applicable minimum capital requirements established by its primary regulator.

These eligibility requirements may be found in sections 7(a) and (b) of the Federal Home Loan Bank Act, 12 U.S.C. §§ 1427(a), (b), and in FHFA's regulations at 12 CFR 1261.5(a) and (b).

Please follow the instructions below appropriate for the purpose for which you are completing this form.

NOMINEES IN THE ANNUAL ELECTION CYCLE

If you have been nominated to stand for election as a member director of the Bank you must complete and execute this Form and submit it to the Bank on or before the date specified by the Bank to accept the nomination. If you do not submit a completed and executed Form by that date, you will be deemed to have declined the nomination. By law, the Bank may not permit a directorship nominee to stand for election unless it has verified that the nominee is legally eligible to serve in the directorship for which he or she has been nominated. Further, the Bank may neither declare elected any nominee nor seat any director-elect whom it has reason to know is ineligible to serve.

CANDIDATES TO FILL A VACANT MEMBER DIRECTORSHIP

If the Bank's board of directors is considering you as a candidate to fill the unexpired term of office of a vacant member directorship on the Bank's board, you must complete and execute this Form and return it to the Bank on or before the date specified by the Bank. If you fail to submit a completed and executed form by that date, or if you submit a form that does not adequately demonstrate that you meet all applicable eligibility requirements, the Bank may determine that you are ineligible to serve, in which case the Bank's board would be prohibited by law from electing you to fill the vacant directorship. By law, the Bank's board may not elect any person to fill a vacant directorship unless it has verified that the individual is legally eligible to serve in that directorship.

FEDERAL HOME LOAN BANK MEMBER DIRECTOR ELIGIBILITY CERTIFICATION FORM (REVISED)***ANNUAL ELIGIBILITY CERTIFICATIONS BY INCUMBENT DIRECTORS***

The Bank is required by law to solicit information from its incumbent directors annually to verify that each director remains in compliance with the applicable statutory and regulatory eligibility requirements. During each calendar year that you are an incumbent member director, you must complete and execute this Form and return it to the Bank on or before the date specified by the Bank. If you fail to submit a completed and executed form by that date, or if you submit a form that does not adequately demonstrate that you continue to meet all applicable eligibility requirements, the Bank may determine that you are ineligible to serve, in which case it would be required by law to declare your directorship vacant.

YOUR PERSONAL INFORMATION

Please provide your personal information as indicated in Questions 1 – 2.

1. **Full name:**
2. **Contact information:**
 - Phone number (leave room for multiple; indicate home, office, or cell); E-mail address
 - Mailing address: Number/Street (or PO Box), City, State, Zip Code

ELIGIBILITY REQUIREMENTS

Please answer in full Questions 3 – 5, which pertain to your compliance with the statutory and regulatory eligibility requirements for member directors.

3. **Citizenship.** Are you a citizen of the United States? ☐ Yes ☐ No
4. **Primary Member Affiliation.** Please provide the following information about the institution you serve as an officer or director that is a member of the Bank on whose board you serve or have been nominated to serve:
 - Name of the institution:
 - Your title or position:
 - Address of the member's principal place of business for Bank membership purposes:
 - Does this institution comply with all applicable minimum capital requirements established by its primary regulator? ☐ Yes ☐ No
5. **Other Member Affiliations.**
 - A. Other than the institution you listed in response to Question 4, do you serve as an officer or director of any other institution that is a member of this Federal Home Loan Bank? ☐ Yes ☐ No
 - B. If you answered Yes to Question 5A, please provide the following information for each member of the Federal Home Loan Bank that you serve as an officer or director:
 - Name of the institution:
 - Your title or position:

FEDERAL HOME LOAN BANK MEMBER DIRECTOR ELIGIBILITY CERTIFICATION FORM (REVISED)

- Address of the member's principal place of business for Bank membership purposes:
- Does this institution comply with all applicable minimum capital requirements established by its primary regulator? ____ Yes ____ No

By executing this form, you are certifying that the information you have provided is true, correct, and complete to the best of your knowledge and that you understand that you have a continuing obligation to inform the Bank of any facts that may call into question your eligibility or ability to serve as a Bank director.

Signature:

Dated:

FEDERAL HOME LOAN BANK INDEPENDENT DIRECTOR APPLICATION FORM (REVISED)

INSTRUCTIONS

You either have expressed interest in, or have been recommended for, nomination to stand for election as an independent director of the Federal Home Loan Bank of [TO BE COMPLETED BY EACH BANK] (Bank). **If you would like the Bank's board of directors to consider you as a possible nominee for an independent directorship, you must complete and execute this Federal Home Loan Bank Independent Director Application Form and submit it to the Bank on or before [DATE AT LEAST 30 DAYS AFTER BANKS PROVIDES ACCESS TO THE FORM].** If you do not submit a completed and executed Form by that date, you will be deemed to have declined to be considered for nomination.

By law, the Bank's board of directors may nominate you for an independent directorship only if it has verified that you meet the legal eligibility requirements applying to independent directors and possess the professional qualifications that are specified by law for the type of independent directorship for which you are being considered. Your responses to the questions on this Form will assist the Bank in verifying that you are legally eligible, and possess the required professional qualifications, to serve as an independent director of the Bank if elected.

You are eligible to serve as an independent director of the Bank only if you meet all of the following requirements:

- You are a citizen of the United States.
- You are a *bona fide* resident of the Bank District, as determined by meeting either one of the following two sets of criteria:
 - Your principal residence is located in the Bank District; or
 - You both:
 - Own or lease in your own name a residence in the Bank District; and
 - Are employed in a voting state in the Bank District.
- Neither you nor your spouse are:
 - An officer of any Federal Home Loan Bank; or
 - An officer, employee, or director of any member of, or recipient of advances from, the Bank. For purposes of this prohibition:
 - "Advances" includes any form of lending, regardless of whether it is denominated as an "advance"; and
 - "Member" and "recipient of advances" include the institution itself and the institution's holding company, except where the assets of all members or all recipients of advances constitute less than 35 percent of the assets of the holding company, on a consolidated basis.

These eligibility requirements may be found in sections 7(a) and (b) of the Federal Home Loan Bank Act (Bank Act), 12 U.S.C. §§ 1427(a), (b), and in FHFA's regulations at 12 CFR 1261.5(c) and 1261.10.

In addition, you must demonstrate that you possess certain professional qualifications, which differ depending on whether you are seeking nomination for a "regular" or a "public interest" independent directorship. By law, the Bank must designate at least two of the independent directorships on its board as "public interest" directorships. These may be filled only by individuals having, at the time of nomination, more than four (4) years of experience representing consumer or community interests in banking services, credit needs, housing, or consumer financial protections.

FEDERAL HOME LOAN BANK INDEPENDENT DIRECTOR APPLICATION FORM (REVISED)

Regular independent directorships—that is, those that are not public interest directorships—must be filled by individuals having, at the time of nomination, experience in or knowledge of one or more of the following areas: auditing and accounting, derivatives, financial management, organizational management, project development, risk management practices, and the law. Such knowledge or experience must be commensurate with that needed to oversee a financial institution with a size and complexity comparable to that of the Bank. The requirements regarding professional qualifications may be found in section 7(a)(3)(B) of the Bank Act, 12 U.S.C. § 1427(a)(3)(B), and in FHFA's regulations at 12 CFR 1261.7(e).

Please answer all applicable questions in full and do not answer any question by referring to another document, except where expressly permitted to do so.

YOUR PERSONAL INFORMATION

Please provide your personal information as indicated in Questions 1 – 3.

1. **Full name:**
2. **Contact information:**
 - Phone number (leave room for multiple; indicate home, office, or cell); E-mail address
 - Mailing address: Number/Street (or PO Box), City, State, Zip Code
3. **Current employment, if applicable:**
 - Name of your current employer; Your title or position
 - Your contact information at your place of employment:
 - Phone number; E-mail address
 - Number/Street, City, State, Zip Code

ELIGIBILITY REQUIREMENTS

Please answer Questions 4 – 8, regarding your eligibility to serve as an independent director in full.

CITIZENSHIP AND RESIDENCY

You must meet the legal requirements as to U.S. citizenship and Bank District residency to be eligible for nomination for an independent directorship.

4. **Citizenship.** Are you a citizen of the United States? ____ Yes ____ No
5. **Residency.**
 - A. Do you own or lease a residence within the Bank District? ____ Yes ____ No
If you answered No to Question 5A, you do not meet the residency requirement.
 - B. If you answered Yes to Question 5A, please provide the street address of your residence within the Bank District: (Number/Street, City, State, Zip Code)
 - C. Is the address provided in response to Question 5B your principal residence?
____ Yes ____ No

FEDERAL HOME LOAN BANK INDEPENDENT DIRECTOR APPLICATION FORM (REVISED)

If you answered Yes to Question 5C, you meet the residency requirement.

If you answered No to Question 5C, you may still meet the residency requirement if you are employed within the Bank District. Please continue with Question 5D to indicate your in-District employment status.

D. Are you employed within the Bank District? ☐ Yes ☐ No

E. If you answered Yes to Question 5D, please identify your in-District employer:

- ☐ ☐ Check if your in-District employment information is the same as that entered in response to Question 3.
- ☐ ☐ Check if your in-District employment information is different from that entered in response to Question 3, then provide the following information:
 - Name of your in-district employer; Your title or position
 - Number/Street, City, State, Zip Code

INDEPENDENCE

The information you provide below will enable the Bank to determine whether you meet the independence requirements. You may be nominated if you do not currently meet the independence requirements, but you must agree as part of the certification at the end of this form that you and your spouse will relinquish any positions that the Bank determines to be prohibited under those requirements. If elected, you may not be seated as an independent director so long as you or your spouse hold any such prohibited positions and, once seated, would become ineligible to continue to serve as an independent director if you or your spouse were to take any such prohibited positions.

6. Employment by a Federal Home Loan Bank.

- A. Are you or your spouse an employee of any Federal Home Loan Bank? ☐ Yes ☐ No
- B. If you answered Yes to Question 6A, please provide the following information for each such position held by you or your spouse:
- ☐ Name of the person holding the position:
 - ☐ Federal Home Loan Bank of:
 - ☐ Position or Title:
 - ☐ Dates held:

7. Employment by a Bank Member, Housing Associate, or Holding Company.

- A. Are you or your spouse an officer, director, or employee of a member of the Bank, an entity certified as a housing associate of the Bank, or a holding company that controls one or more members or housing associates of the Bank? ☐ Yes ☐ No
- B. If you answered Yes to Question 7A, please provide the following information for each such position held by you or your spouse:
- ☐ Name of the person holding the position:
 - ☐ Name of the employer:
 - ☐ Check the appropriate response below to indicate whether the employer is:
 - ☐ a member
 - ☐ a holding company of a member
 - ☐ a housing associate
 - ☐ a holding company of a housing associate

FEDERAL HOME LOAN BANK INDEPENDENT DIRECTOR APPLICATION FORM (REVISED)

- Position or Title:
- Dates held:
- If the employer is a holding company:
 - Indicate the total assets of the holding company;
 - Indicate the total assets of each member or housing associate of the Bank controlled by the holding company; and
 - Provide, or direct the Bank to, documentation to support those amounts.

ACADEMIC AND EMPLOYMENT HISTORY

Please answer in full Questions 8 - 10, regarding your academic and employment background. If you wish, you may answer any or all of these questions by attaching a resume or CV, so long as you provide all of the information requested.

- ☐ Check if you have attached a resume or CV in response to Questions 8 - 10.
8. **Academic degrees.** Please list any college or advanced academic degrees that you have been awarded, specifying for each: the type of degree, the name and location of the academic institution that awarded your degree, and the date awarded.
9. **Employment History.** Please list, from most to least recent, the positions you have held during your professional career, specifying for each: the name and location of your employer, your position, and the date range during which you served in that position. Please explain any major gaps in your employment chronology.
10. **Other Relevant Experience and Achievements.** Please list any other significant positions you have held, or currently hold, (such as other directorships or volunteer positions) that you believe are relevant to your qualifications to serve as an independent director of the Bank, specifying for each: the name and location of the organization with which you served, your position, and the date range during which you served in that position.

PROFESSIONAL QUALIFICATIONS

Please indicate below whether you are seeking nomination for a public interest independent directorship or a regular independent directorship and then complete the appropriate questions regarding your qualifications for that type of independent directorship.

11. **Type of Independent Directorship Being Sought.** Please check one of the boxes below to indicate the type of independent directorship you are seeking.
- ☐ Check if you are seeking a public interest independent directorship.
 - ☐ Check if you are seeking a regular independent directorship.

FEDERAL HOME LOAN BANK INDEPENDENT DIRECTOR APPLICATION FORM (REVISED)***PUBLIC INTEREST INDEPENDENT DIRECTORSHIP***

If you are seeking a public interest independent directorship, please answer in full Question 12, which pertains to your professional qualifications to serve in that capacity. Although you are not required to do so, you may also answer Questions 13 – 14, regarding professional qualifications requirements for regular independent directors, if you wish to highlight relevant knowledge or experience in the areas addressed in those questions. If you are seeking a regular independent directorship, you may skip to Question 13, although you may choose to answer Question 12, regarding professional qualifications requirements for public interest independent directors, if you wish to highlight relevant knowledge or experience in the areas addressed in that question.

By statute, a nominee for a public interest independent directorship must have “more than 4 years of experience in representing consumer or community interests on banking services, credit needs, housing, or consumer financial protections.” Qualifying experience in one of the four enumerated areas may have been acquired in professional, public service, or volunteer positions, so long as the work done was substantial in terms of time commitment and responsibility. Further, the experience must accrue from activities personally undertaken by the individual seeking nomination as a public interest independent director, as opposed to being attributed based merely on the activities of an organization with which the person was associated. As indicated by the statute’s use of the word “representing,” the experience must have involved advocating for, or otherwise acting primarily for the direct benefit of, consumer or community interests in one of the four enumerated areas. Thus, industry-side experience, even if the activities undertaken may have benefitted consumer or community interests, is generally not qualifying because it does not involve “representing” those interests.

12. *Representation of Consumer and Community Interests.* Please explain in detail how you have represented consumer or community interests in banking services, credit needs, housing, or consumer financial protections for more than four years. At a minimum:

- Identify the positions through which you obtained your qualifying experience and specify the dates during which you served in those positions.
- Specify whether those positions involved banking services, credit needs, housing, or consumer financial protections.
- To the extent that your experience was obtained with an organization or agency, describe generally the mission of each such organization or agency and the manner in which its mission is typically fulfilled.
- Describe your responsibilities in those positions and, if any were not full-time paid employment, indicate the amount of time you spent fulfilling those responsibilities annually.
- Describe your major accomplishments in those positions that relate to the experience needed to qualify as a public interest independent director.

FEDERAL HOME LOAN BANK INDEPENDENT DIRECTOR APPLICATION FORM (REVISED)**REGULAR INDEPENDENT DIRECTORSHIP**

If you are seeking a regular independent directorship, please answer in full Questions 13 – 14, which pertain to your professional qualifications to serve in that capacity. If you are seeking a public interest independent directorship, you are not required to answer these questions, but may choose to do so if you possess relevant knowledge and experience that you wish to highlight.

13. **Primary Areas of Knowledge and Experience.** Please indicate below, by checking the appropriate boxes, the professional areas in which you have significant knowledge or experience that is commensurate with that needed to oversee a financial institution with a size and complexity comparable to that of the Bank.

- ☐ Auditing and accounting
- ☐ Derivatives
- ☐ Financial management
- ☐ Organizational management
- ☐ Project development
- ☐ Risk management practices
- ☐ The law

14. **Description of Knowledge and Experience.** For each of your primary areas of professional knowledge and experience indicated in response to Question 13, please describe in detail the nature of that knowledge and experience and the circumstances under which you obtained it. At a minimum, for each area:

- Identify the entities with which you were employed or otherwise associated when you gained the knowledge or experience and describe briefly the business or mission of those entities (e.g., “investment bank,” “law firm,” etc.).
- Identify the positions you have held with those entities and describe your major accomplishments in those positions with respect to the relevant areas.

OTHER MATTERS

15. **Personal Integrity.** Is there anything in your background that might cause a reasonable person to question your personal integrity, your ability to fulfill the fiduciary duties of a board director, or your competence to supervise the management of the Bank (issues of concern could include, but are not limited to: past felony convictions or pending felony charges; any findings by a court or administrative body that you have violated federal or state civil laws relating to securities, banking, housing, or real estate; suspension or revocation of a professional license; a personal or business bankruptcy filing; or having been the subject of a tax lien)? ☐ Yes ☐ No

If you answered Yes, please fully describe the incidents, the timeframes in which they occurred, and their ultimate disposition and provide supporting documentation where appropriate.

16. **Conflicts of Interest.** Other than any relationships described in response to Questions 6 – 7, do you or, to your knowledge, do any of your immediate family members (i.e., a parent, sibling, spouse, child, other dependent, or any relative sharing your residence) or close business associates (i.e., a corporation or organization of which you are an officer or a partner, or in which you own more than ten percent of any class of equity security (including subordinated

FEDERAL HOME LOAN BANK INDEPENDENT DIRECTOR APPLICATION FORM (REVISED)

debt); an individual that is an officer or a partner of, or who owns more than ten percent of any class of equity security (including subordinated debt) in, such a corporation or organization; or a trust in which you have a substantial interest or serve in a fiduciary capacity) have any financial interests or other relationships that might create actual or apparent conflicts of interest or might otherwise lead a reasonable person to question your ability to administer the affairs of the Bank fairly and impartially? ____ Yes ____ No

If you answered Yes, please fully describe the nature of those interests or relationships, the individuals or entities involved, and their relationship to you.

By executing this form, you are certifying that:

- The information you have provided is true, correct, and complete to the best of your knowledge;
- You understand that you have a continuing obligation to inform the Bank of any facts that may call into question your eligibility or ability to serve as a Bank director; and
- If you are nominated and elected to serve as a director:
 - You and your spouse will relinquish any positions that the Bank determines to be prohibited by the statutory and regulatory independence requirements for independent directors; and
 - You will regularly attend the meetings of the board of directors and the board committees to which you are assigned and will devote the time necessary to adequately prepare for those meetings and execute your other responsibilities as an independent director.

Signature:**Dated:**

FEDERAL HOME LOAN BANK INDEPENDENT DIRECTOR ANNUAL CERTIFICATION FORM (REVISED)**INSTRUCTIONS**

The Federal Home Loan Bank of [TO BE COMPLETED BY EACH BANK] (Bank) is required by law to solicit information from its incumbent directors annually to verify that each director remains in compliance with the applicable statutory and regulatory eligibility requirements. Your responses to the questions on this **Federal Home Loan Bank Independent Director Annual Certification Form** will assist the Bank in verifying that you continue to meet the eligibility requirements that apply to the independent directorship in which you are currently serving.

Please complete and execute this Form and return it to the Bank on or before [MARCH 1, {CURRENT YEAR} (or, if 3/1 is not a business day, THE NEXT BUSINESS DAY FOLLOWING 3/1)]. If you fail to submit a completed and executed form by that date, or if you submit a form that does not adequately demonstrate that you continue to meet all applicable eligibility requirements, the Bank may determine that you are ineligible to serve, in which case the Bank would be required by law to declare your directorship vacant.

You are eligible to serve as an independent director of the Bank only if you meet all of the following requirements:

- You are a citizen of the United States.
- You are a *bona fide* resident of the Bank District, as determined by meeting either one of the following two sets of criteria:
 - Your principal residence is located in the Bank District; or
 - You both:
 - Own or lease in your own name a residence in the Bank District; and
 - Are employed in a voting state in the Bank District.
- Neither you nor your spouse are:
 - An officer of any Federal Home Loan Bank; or
 - An officer, employee, or director of any member of, or recipient of advances from, the Bank. For purposes of this prohibition:
 - “Advances” includes any form of lending, regardless of whether it is denominated as an “advance”; and
 - “Member” and “recipient of advances” include the institution itself and the institution’s holding company, except where the assets of all members or all recipients of advances constitute less than 35 percent of the assets of the holding company, on a consolidated basis.

These eligibility requirements may be found in sections 7(a) and (b) of the Federal Home Loan Bank Act (Bank Act), 12 U.S.C. §§ 1427(a), (b), and in FHFA’s regulations at 12 CFR 1261.5(c) and 1261.10.

FEDERAL HOME LOAN BANK INDEPENDENT DIRECTOR ANNUAL CERTIFICATION FORM (REVISED)**YOUR PERSONAL INFORMATION**

Please provide your personal information as indicated in Questions 1 – 3.

1. **Full name:**
2. **Contact information:**
 - Phone number (leave room for multiple; indicate home, office, or cell); E-mail address
 - Mailing address: Number/Street (or PO Box), City, State, Zip Code
3. **Current employment, if applicable:**
 - Name of your current employer; Your title or position
 - Your contact information at your place of employment:
 - Phone number; E-mail address
 - Number/Street, City, State, Zip Code

ELIGIBILITY REQUIREMENTS

Please answer Questions 4 – 8, regarding your eligibility to serve as an independent director in full.

CITIZENSHIP AND RESIDENCY

You must meet the legal requirements as to U.S. citizenship and Bank District residency to be eligible for nomination for an independent directorship.

4. **Citizenship.** Are you a citizen of the United States? ☐ Yes ☐ No
5. **Residency.**
 - A. Do you own or lease a residence within the Bank District? ☐ Yes ☐ No
If you answered No to Question 5A, you do not meet the residency requirement.
 - B. If you answered Yes to Question 5A, please provide the street address of your residence within the Bank District: (Number/Street, City, State, Zip Code)
 - C. Is the address provided in response to Question 5B your principal residence?
☐ Yes ☐ No
If you answered Yes to Question 5C, you meet the residency requirement.
If you answered No to Question 5C, you may still meet the residency requirement if you are employed within the Bank District. Please continue with Question 5D to indicate your in-District employment status.
 - D. Are you employed within the Bank District? ☐ Yes ☐ No
 - E. If you answered Yes to Question 5D, please identify your in-District employer:
 - ☐ Check if your in-District employment information is the same as that entered in response to Question 3.
 - ☐ Check if your in-District employment information is different from that entered in response to Question 3, then provide the following information:
 - Name of your in-district employer; Your title or position
 - Number/Street, City, State, Zip Code

FEDERAL HOME LOAN BANK INDEPENDENT DIRECTOR ANNUAL CERTIFICATION FORM (REVISED)**INDEPENDENCE**

The information you provide below will enable the Bank to determine whether you meet the independence requirements. You may be nominated if you do not currently meet the independence requirements, but you must agree as part of the certification at the end of this form that you and your spouse will relinquish any positions that the Bank determines to be prohibited under those requirements. If elected, you may not be seated as an independent director so long as you or your spouse hold any such prohibited positions and, once seated, would become ineligible to continue to serve as an independent director if you or your spouse were to take any such prohibited positions.

6. Employment by a Federal Home Loan Bank.

- A. Are you or your spouse an employee of any Federal Home Loan Bank? ☐ Yes ☐ No
- B. If you answered Yes to Question 6A, please provide the following information for each such position held by you or your spouse:
- ☐ Name of the person holding the position:
 - ☐ Federal Home Loan Bank of:
 - ☐ Position or Title:
 - ☐ Dates held:

7. Employment by a Bank Member, Housing Associate, or Holding Company.

- A. Are you or your spouse an officer, director, or employee of a member of the Bank, an entity certified as a housing associate of the Bank, or a holding company that controls one or more members or housing associates of the Bank? ☐ Yes ☐ No
- B. If you answered Yes to Question 7A, please provide the following information for each such position held by you or your spouse:
- ☐ Name of the person holding the position:
 - ☐ Name of the employer:
 - ☐ Check the appropriate response below to indicate whether the employer is:
 - ☐ a member
 - ☐ a holding company of a member
 - ☐ a housing associate
 - ☐ a holding company of a housing associate
 - ☐ Position or Title:
 - ☐ Dates held:
 - ☐ If the employer is a holding company:
 - ☐ Indicate the total assets of the holding company;
 - ☐ Indicate the total assets of each member or housing associate of the Bank controlled by the holding company; and
 - ☐ Provide, or direct the Bank to, documentation to support those amounts.

By executing this form, you are certifying that the information you have provided is true, correct, and complete to the best of your knowledge and that you understand that you have a continuing obligation to inform the Bank of any facts that may call into question your eligibility or ability to serve as a Bank director.

Signature:**Dated:**

[FR Doc. 2021-04316 Filed 3-2-21; 8:45 am]

BILLING CODE 8070-01-C

FEDERAL MARITIME COMMISSION

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Maritime Commission.

ACTION: Notice.

SUMMARY: The Federal Maritime Commission (Commission) is giving public notice that the agency has submitted to the Office of Management and Budget (OMB) for approval the continuing information collections described in this notice. The public is invited to comment on the proposed information collections pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted at the addresses below on or before April 2, 2021.

ADDRESSES: Comments should be addressed to:

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Shannon Joyce, Desk Officer for Federal Maritime Commission, *OIRA_Submission@OMB.EOP.GOV*

and to:

Karen V. Gregory, Managing Director, Office of the Managing Director, Federal Maritime Commission, *OMD@fmc.gov*

Please send separate comments for each specific information collection listed below, and reference the information collection's title and OMB number in your comments.

FOR FURTHER INFORMATION CONTACT:

Copies of the submission(s) may be obtained by contacting Donna Lee at *OMD@fmc.gov*.

SUPPLEMENTARY INFORMATION:

Request for Comments

Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13), the Commission invites the general public and other Federal agencies to comment on proposed information collections. On October 13, 2020, the Commission published a notice and request for comments in the **Federal Register** (85 FR 64467) regarding the agency's request for continued approval from OMB for information collections as required by the Paperwork Reduction Act of 1995. The Commission received no comments on any of the requests for extensions of OMB clearance. The Commission has submitted the described information collections to OMB for approval.

In response to this notice, comments and suggestions should address one or more of the following points: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collections Open for Comment

I. Title: 46 CFR part 525—Marine Terminal Operator Schedules and Related Form FMC-1.

OMB Approval Number: 3072-0061 (Expires January 31, 2021).

Abstract: Section 8(f) of the Shipping Act, 46 U.S.C. 40501(f), provides that a marine terminal operator (MTO) may make available to the public a schedule of its rates, regulations, and practices, including limitations of liability for cargo loss or damage, pertaining to receiving, delivering, handling, or storing property at its marine terminal. The Commission's rules governing MTO schedules are set forth at 46 CFR part 525.

Current Actions: There are no changes to this information collection, and it is being submitted for extension purposes only.

Type of Review: Reinstatement.

Needs and Uses: The Commission uses information obtained from Form FMC-1 to determine the organization name, organization number, home office address, name and telephone number of the firm's representatives and the location of MTO schedules of rates, regulations and practices, and publisher, should the MTOs determine to make their schedules available to the public, as set forth in section 8(f) of the Shipping Act.

Frequency: This information is collected prior to an MTO's commencement of its marine terminal operations.

Type of Respondents: Persons operating as MTOs.

Number of Annual Respondents: The Commission estimates the respondent universe at 20, of which 10 opt to make their schedules available to the public.

Estimated Time per Response: The time per response for completing Form FMC-1 averages 0.5 person-hours, and approximately 5 person-hours for related MTO schedules.

Total Annual Burden: The Commission estimates the total annual person-hour burden at 60 person-hours.

II. Title: 46 CFR part 520—Carrier Automated Tariffs and Related Form FMC-1.

OMB Approval Number: 3072-0064 (Expires February 28, 2021).

Abstract: Except with respect to certain specified commodities, section 8(a) of the Shipping Act, 46 U.S.C. 40501(a)–(c), requires that each common carrier and conference keep open to public inspection, in an automated tariff system, tariffs showing its rates, charges, classifications, rules, and practices between all ports and points on its own route and on any through transportation route that has been established. The Commission is responsible for reviewing the accessibility and accuracy of automated tariff systems, in accordance with its regulations set forth at 46 CFR part 520.

Current Actions: There are no changes to this information collection, and it is being submitted for extension purposes only.

Type of Review: Extension.

Needs and Uses: The Commission uses information obtained from Form FMC-1 to ascertain the location of common carrier and conference tariff publications, and to access their provisions regarding rules, rates, charges, and practices.

Frequency: This information is collected when common carriers or conferences publish tariffs.

Type of Respondents: Persons operating or desiring to operate as common carriers or conferences.

Number of Annual Respondents: The Commission estimates there are 6,042 Carrier Automated Tariffs. It is estimated that the number of annual respondents will be 1,500.

Estimated Time per Response: The time per response ranges from 0.1 to 2 person-hours for reporting and recordkeeping requirements contained in the rules, and 0.5 person-hours for completing Form FMC-1.

Total Annual Burden: The Commission estimates the total annual person-hour burden at 2,295 person-hours.

Rachel Dickon,

Secretary.

[FR Doc. 2021-04378 Filed 3-2-21; 8:45 am]

BILLING CODE 6730-02-P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or

documents regarding the agreements to the Secretary by email at Secretary@fmc.gov, or by mail, Federal Maritime Commission, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**. Copies of agreements are available through the Commission's website (www.fmc.gov) or by contacting the Office of Agreements at (202)–523–5793 or tradeanalysis@fmc.gov.

Agreement No.: 201357.

Agreement Name: Sallaum Lines/Liberty Global Logistics LLC Space Charter Agreement.

Parties: Sallaum Lines Switzerland SA and Liberty Global Logistics LLC.
Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The agreement authorizes the parties to charter space to/from one another on an "as needed/as available" basis in the trade between the U.S. Atlantic and Gulf Coasts on the one hand and ports in Ghana, Togo, Benin, Nigeria, Jordan, Saudi Arabia, the United Arab Emirates, Qatar, Kuwait, and Pakistan on the other hand.

Proposed Effective Date: 2/22/2021.

Location: <https://www2.fmc.gov/FMC/Agreements.Web/Public/AgreementHistory/39512>.

Dated: February 26, 2021.

Rachel E. Dickon,
Secretary.

[FR Doc. 2021–04379 Filed 3–2–21; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Temporary Approval by the Board Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Temporary approval of information collection, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) has temporarily revised the Reporting and Disclosure Requirements Associated with Emergency Lending, pursuant to the authority delegated to the Board by the Office of Management and Budget (OMB).

DATES: Comments must be submitted on or before May 3, 2021.

ADDRESSES: You may submit comments, identified by *FR A*, by any of the following methods:

- *Agency Website:* <https://www.federalreserve.gov/>. Follow the

instructions for submitting comments at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx>.

- *Email:* regs.comments@federalreserve.gov. Include the OMB number in the subject line of the message.

- *Fax:* (202) 452–3819 or (202) 452–3102.

- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx> as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghribi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies. Pursuant to its delegated authority, the Board may temporarily approve a revision to a collection of

information, without providing opportunity for public comment, if the Board determines that a change in an existing collection must be instituted quickly and that public participation in the approval process would defeat the purpose of the collection or substantially interfere with the Board's ability to perform its statutory obligation.

As discussed below, the Board has made certain temporary revisions to the *FR A* information collection. The Board's delegated authority requires that the Board, after temporarily approving a collection, publish a notice soliciting public comment. Therefore, the Board is also inviting comment on a proposal to extend the *FR A* information collection for three years, with these revisions.

A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be available at <https://www.reginfo.gov/public/do/PRAMain>. These documents will also be made available on the Board's public website at <https://www.federalreserve.gov/apps/reportforms/review.aspx> or may be requested from the agency clearance officer, whose name appears above.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Approval Under OMB Delegated Authority of the Temporary Revision of the Following Information Collection

Report title: Reporting and Disclosure Requirements Associated with Emergency Lending Under Section 13(3).

Agency form number: FR A.

OMB control number: 7100-0373.

Frequency: Event-generated.

Respondents: Entities or persons borrowing under an emergency lending program or facility established pursuant to section 13(3) of the Federal Reserve Act.

Estimated number of respondents: FR A-1: 4,914; FR A-2: 3,073; FR A-3: 12,150; FR A-4: 5.

Estimated average hours per response: FR A-1: 8; FR A-2: 40; FR A-3, Lender per-loan certifications: 2; FR A-3, Borrower certifications: 8; FR A-4: 1.

Estimated annual burden hours: 257,305.

General description of report: The Board's Regulation A (12 CFR part 201) establishes policies and procedures with respect to emergency lending under section 13(3) of the Federal Reserve Act, as required by sections 1101 and 1103 of the Dodd-Frank Wall Street Reform and Consumer Protection Act. Regulation A requires that borrowers make two certifications in order to participate in any emergency lending authorized under section 13(3). These certifications, designated in this information collection as FR A-1, include that the borrowers are not insolvent and that they cannot obtain adequate credit accommodation.

In addition to these certifications, the Board may establish additional certification requirements for an individual emergency lending facility. The second part of the FR A information collection, the FR A-2, pertains to reporting requirements associated with individual facilities that are related to requirements of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The third part of FR A, designated as the FR A-3, pertains to reporting requirements specific to the Main Street Expanded Loan Facility, the Main Street New Loan Facility, the Main Street Priority Loan Facility, the Nonprofit Organization Expanded Loan Facility, and the Nonprofit Organization New Loan Facility (collectively, the "Main Street Lending Program"). The fourth part of FR A, designated as the FR A-4, pertains to a disclosure requirement for Paycheck Protection Program (PPP) borrowers seeking to reduce the calculation of existing outstanding and undrawn available debt to participate in the Main Street Lending Program.

Legal authorization and confidentiality: The FR A is authorized pursuant to section 13(3) of the Federal Reserve Act, which sets out requirements for emergency lending. The obligation to respond is required to obtain a benefit.

The information collected under the FR A may be kept confidential under exemption 4 of the Freedom of Information Act, which protects commercial or financial information obtained from a person that is privileged or confidential.

Current actions: The Board is revising the FR A information collection to address information collection requirements related to borrowers under the Main Street Lending Program, who participate in the PPP. Participating borrowers seeking to reduce the calculation of "existing outstanding and undrawn available debt" for purposes of determining the maximum allowable loan amount under the Main Street Lending Program must provide its eligible lender either with the Small Business Administration form it has already completed and submitted to its PPP lender (which may be the same lender), or must complete and submit a Board form to its Main Street lender during the Main Street loan underwriting process, as applicable. The FR A respondent counts for all parts of the information collection are being revised to reflect updated estimates of lender participation in the Main Street Lending Program.

Detailed Discussion of Public Comments: On March 2, 2020, the Board published a notice in the **Federal Register** (85 FR 12295) requesting public comment for 60 days on the extension, without revision, of the FR A. One comment was received; it did not address aspects of the information collection as described in 5 CFR 1320.8(d). On May 15, 2020, following the temporary approval of a first set of revisions to the FR A, the Board published a **Federal Register** notice (85 FR 29447) requesting public comment for 60 days on those temporary revisions. On June 4, 2020, following the temporary approval of a second set of revisions to the FR A, the Board published a **Federal Register** notice (85 FR 34448) requesting public comment for 60 days on those temporary revisions. On August 21, 2020, following the temporary approval of a third set of revisions to the FR A, the Board published a **Federal Register** notice (85 FR 51715) requesting public comment for 60 days on those temporary revisions. Comments in response to all of those requests for comment are expected to be considered,

along with any comments received in response to this request for comment.

Board of Governors of the Federal Reserve System, February 26, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021-04362 Filed 3-2-21; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0362]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice for Manufacturing, Processing, Packing, and Holding of Finished Pharmaceuticals, Including Medical Gases, and Active Pharmaceutical Ingredients

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 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 associated with current good manufacturing practice (CGMP) for drugs, finished pharmaceuticals, including medical gases, and active pharmaceutical ingredients (APIs).

DATES: Submit either electronic or written comments on the collection of information by May 3, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 3, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 3, 2021. 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-2011-N-0362 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Manufacturing, Processing, Packing, and Holding of Finished Pharmaceuticals, Including Medical Gases, and Active Pharmaceutical Ingredients." 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:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@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.

Current Good Manufacturing Practice for Finished Pharmaceuticals, Including Medical Gases, and Active Pharmaceutical Ingredients—21 CFR parts 210 and 211 and 21 U.S.C 351(a)(2)(B).

OMB Control Number 0910-0139—Extension

This information collection supports FDA regulations that govern the manufacture, processing, packing, or holding of finished pharmaceuticals, including medical gases, and APIs. Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMP regulations. FDA is responsible for enforcing the FD&C Act as well as related statutes, including the Public Health Service Act. Congress enacted these laws to ensure that covered products meet applicable requirements regarding the safety, identity and strength, and the quality and purity characteristics they purport or are represented to possess, and are labeled with adequate warnings and instructions for use.

The pharmaceutical or drug quality-related regulations appear in several parts of Title 21 Code of Federal Regulations (CFR) (Food and Drugs), including sections in parts 1 through 99, 200 through 299, 300 through 499, 600 through 799, and 800 through 1299. The

regulations enable a common understanding of the regulatory process by describing requirements to be followed by drug manufacturers, applicants, and FDA. Under part 211 (21 CFR part 211; see 21 CFR 211.94(e)(1)), specific requirements for medical gas containers and closures are also found in the regulations. Finally, the information collection also supports regulations codified under parts 610 and 680 (21 CFR parts 610 and 680), which reference certain CGMP regulations in part 211 (see §§ 610.12(g), 610.13(a)(2), 610.18(d), 680.2(f), and 680.3(f)).

These regulations set forth information collection requirements that allow FDA to meet its public health protection responsibilities. Products

that fail to comply with CGMP requirements may be rendered adulterated under section 501(a)(2)(B) of the FD&C Act. To demonstrate that their products comply with the requirements of section 501(a)(2)(B), API manufacturers must maintain CGMP records; therefore, we have counted them among respondents who incur burden for the information collection. In the table below, we have included an additional 1,260 respondents to reflect API manufacturers not included in our previous submission for renewal.

To assist respondents with the information collection requirements for medical gases, we developed a draft guidance for industry entitled “Current Good Manufacturing Practice for

Medical Gases.” This guidance, when finalized will discuss our recommendations regarding compliance with applicable requirements found in the regulations as they apply to these products. The guidance is available for download from our internet site at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/current-good-manufacturing-practice-medical-gases>. We believe the recommendations, if followed, will help respondents focus their information collection activities most efficiently with regard to demonstrating regulatory compliance.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN—APIs, FINISHED PHARMACEUTICALS, AND MEDICAL GASES^{1 2}

Section 501(a)(2)(B) of the FD&C Act; parts 210 and 211	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
CGMP API Manufacturers	1,260	256	322,560	0.82 (49.2 minutes)	264,499
CGMP Finished Pharmaceuticals Manufacturers (excludes medical gases).	3,270	299	977,730	0.64 (38 minutes)	625,747
CGMP Medical Gases Manufacturers.	2,284	280	639,520	0.62 (37 minutes)	396,502
Total			1,939,810		1,286,748

¹ There are no capital or operating and maintenance costs associated with the information collection.

² Records and burden per activity have been averaged and rounded.

Our estimated burden for the information collection reflects an overall decrease of 29,073 hours and 1,762 records annually for CGMP for finished pharmaceutical manufacturers, excluding those manufacturers of medical gases. Our estimated burden for the information collection also reflects an overall decrease of 486 hours and 1,574 records annually for medical gas manufacturers. Our inclusion of API manufacturers in this collection represents an addition of 264,499 hours and 322,560 records prepared.

Dated: February 25, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-04380 Filed 3-2-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0132]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration's Study of How Consumers Use Flavors To Make Inferences About Electronic Nicotine Delivery System Product Qualities and Intentions To Use (Phase 2)

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's

investigation of how consumers use flavors to make inferences about Electronic Nicotine Delivery System (ENDS) product qualities and intentions to use.

DATES: Submit either electronic or written comments on the collection of information by May 3, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 3, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 3, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://>

www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-0132 for "Food and Drug Administration's Investigation of How Consumers Use Flavors to Make Inferences About Electronic Nicotine Delivery System (ENDS) Product Qualities and Intentions to Use (Phase 2)." 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:

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, 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 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 and Drug Administration's Study of How Consumers Use Flavors To Make Inferences About Electronic Nicotine Delivery System (ENDS) Product Qualities and Intentions To Use (Phase 2)

OMB Control Number 0910-NEW

ENDS, also called electronic cigarettes, e-cigarettes, and vaporizers, are deemed tobacco products and fall under FDA's regulatory scope. FDA has the authority under the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31, H.R. 1256) to regulate and restrict the marketing of tobacco products. However, given the recency of ENDS products to the market, limited research exists to inform the regulation of certain aspects of their marketing. Research to understand "marketing influences on youth experimentation, initiation, use and cessation of tobacco products" is a regulatory priority for the FDA Center for Tobacco Products (CTP).¹

Flavors are a unique and important aspect of ENDS. ENDS use a liquid ("e-liquid" or "e-juice") that can span a diverse range of flavors, from tobacco flavor, menthol, mint, fruit flavors, non-fruit sweet flavors (e.g., cr me br lee, gummi bears), spices (e.g., cinnamon, vanilla), alcohol (e.g., strawberry daiquiri, bourbon, Irish cream), and "concept" flavors (e.g., "Heliomilk", "Sungazer"). Flavors are a regulatory area of interest, and FDA has issued an advance notice of proposed rulemaking (Docket No. FDA-2017-N-6565) "to obtain information related to the role that flavors play in tobacco products," with a specific interest in how flavors may spur youth product initiation.

This study of "How Consumers Make Inferences about ENDS" is voluntary research. The primary goal of the study is to understand whether flavor-related imagery, descriptors, and flavor name modifiers affect product appeal, curiosity about the product, interest in

¹ <https://www.fda.gov/tobacco-products/research/research-priorities>.

using the product, and product perceptions among youth and young adults. The project will examine three features identified in the research team's prior work: the use of flavor-related imagery, the use of flavor descriptors (e.g., "cool", "fresh"), and the use of flavor name modifiers (e.g., Cherry Crush).

The study will collect data from two groups of consumers: 2,500 youth (aged 13 to 17 years old) and 2,500 young adults (aged 18 to 24 years old). The sample will be stratified by ENDS and cigarette use, so that 625 participants in each age group will be (a) non-cigarette and non-ENDS users (N=625), (b) cigarette users only (N=625), (c) ENDS users only (N=625), and (d) dual ENDS and cigarette users (N=625). Participants will participate in a repeated measure experiment in which they will be asked to view five ads and report their liking of the ad, curiosity about using the product (an important precursor to use), and interest in using the product. Participants will also report additional perceptions of product qualities. Findings from this study will inform FDA rulemaking regarding the

marketing and presence of flavor features in ENDS and be used to guide other public health agencies' policies and messaging regarding the role of flavors in ENDS.

Study Overview: In this study, youth non-cigarette and non-ENDS users, current cigarette smokers, ENDS only users, and dual users of ENDS and cigarettes, as well as young adult non-cigarette and non-ENDS users, current cigarette smokers, ENDS only users, and dual users of ENDS and cigarettes will be recruited from two existing internet online panels and screened for inclusion into the study. All recruited participants must complete a double opt-in procedure, and parents of youth participants must consent for their child to be on the panel. Youth will provide assent and young adults will provide consent to participate in the surveys. Per institutional review board approval, parental consent has been waived and will not be required for youth to participate in this study. The survey platform can detect and prevent duplicate responses by scanning for duplicate cookies and internet protocol (IP) addresses. Participants will receive

a small incentive as a token of appreciation in exchange for their survey participation.

Participants who meet the inclusion criteria will be randomized to view five ads across five conditions to report their liking of the ad, curiosity about using the product (an important precursor to use), and interest in using the product. The order of ad presentation will be randomized. These procedures will minimize order effects as well as the likelihood of a demand characteristic in which a participant guesses the purpose of the experiment and intentionally or unintentionally alters their response.

Study outcomes include comparisons to assess the extent to which presence or absence of a flavor-representing image, name modifier, or descriptor will be associated with increased or decreased (a) product appeal, (b) curiosity about the product, (c) interest in using the product, and (d) increased positive product perceptions compared to a control condition ad (without or with flavor features).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Participant subgroup	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Number to read the survey invitation					
Youth (aged 13–17)	125,000	1	125,000	0.016 (1 minute)	2,084
Young adults (aged 18–24)	125,000	1	125,000	0.016 (1 minute)	2,084
Total	250,000	4,168
Number to complete the consent and screener					
Youth (aged 13–17)	3,750	1	3,750	0.116 (7 minutes)	438
Young adults (aged 18–24)	3,750	1	3,750	0.116 (7 minutes)	438
Total	7,500	876
Number to complete main study					
Youth (aged 13–17)	2,500	1	2,500	0.333 (20 minutes)	834
Young adults (aged 18–24)	2,500	1	2,500	0.333 (20 minutes)	834
Total	5,000	1,668
Total	6,712

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's burden estimate is based on prior experience with research that is similar to this proposed study (OMB control number 0910–0848). Applying assumptions from previous experience in conducting similar studies, approximately 250,000 respondents from an internet panel will be recruited via an email invitation, which is estimated to take 1 minute to read and respond. An estimated 7,500 (3,750 youth and 3,750 young adults)

respondents will provide assent and consent and be screened to yield the desired sample size of 5,000 total (2,500 youth and 2,500 young adults) participants. The consent/screening process is estimated to take an average of 7 minutes per respondent. Participants that qualify for the study will be automatically directed to begin the online survey, which is estimated to take an average of 20 minutes per respondent.

The total estimated burden for the data collection is 6,712 hours.

Dated: February 25, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–04372 Filed 3–2–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0208]

Proposal To Refuse To Approve a New Drug Application for Sotagliflozin Oral Tablets, 200 Milligrams and 400 Milligrams; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Director of the Center for Drug Evaluation and Research (Center Director) of the Food and Drug Administration (FDA or Agency) is proposing to refuse to approve a new drug application (NDA) submitted by Lexicon Pharmaceuticals, Inc. (Lexicon) for sotagliflozin oral tablets, 200 milligrams (mg) and 400 mg, in its present form. This notice summarizes the grounds for the Center Director's proposal and offers Lexicon an opportunity to request a hearing on the matter.

DATES: Submit either electronic or written requests for a hearing by April 2, 2021; submit data, information, and analyses in support of the hearing and any other comments by May 3, 2021.

ADDRESSES: You may submit hearing requests, documents in support of the hearing, and any other comments as follows. Please note that late, untimely filed requests and documents will not be considered. Electronic requests for a hearing must be submitted on or before April 2, 2021; electronic documents in support of the hearing and any other comments must be submitted on or before May 3, 2021. The <https://www.regulations.gov> electronic filing system will accept hearing requests until 11:59 p.m. Eastern Time at the end of April 2, 2021, and will accept documents in support of the hearing and any other comments until 11:59 p.m. Eastern Time at the end of May 3, 2021. Documents 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 these dates.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-0208 for "Proposal to Refuse to Approve a New Drug Application for Sotagliflozin Oral Tablets, 200 Milligrams and 400 Milligrams; Opportunity for a Hearing." 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: Kevin Fain, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6419, Silver Spring, MD 20993, 301-796-5842, Kevin.Fain@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Proposal To Refuse To Approve NDA 210934

Sanofi-aventis U.S. LLC (Sanofi), Lexicon's predecessor-in-interest, submitted NDA 210934 for sotagliflozin oral tablets in 200 and 400 mg strengths on March 22, 2018, pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)(1)). Sanofi proposed that sotagliflozin tablets be indicated as an adjunct to insulin therapy to improve glycemic control in adults with type 1 diabetes mellitus (T1DM).

On March 22, 2019, the Office of Drug Evaluation II (ODE II) in the Office of New Drugs (OND) in FDA's Center for Drug Evaluation and Research (CDER) issued a complete response letter to Sanofi under § 314.110(a) (21 CFR 314.110(a)) stating that NDA 210934 could not be approved in its present form, describing the specific deficiencies, and, where possible, recommending ways that Sanofi might remedy these deficiencies. The application in its present form is not approvable because the data submitted

do not show that the drug is safe under the proposed conditions of use. The deficiencies, which are summarized below, include the following:

(1) The data demonstrated that the addition of sotagliflozin to insulin is associated with an increased risk of diabetic ketoacidosis (DKA), a serious and often life-threatening consequence of insulin insufficiency.

a. In particular, the submitted clinical trial data showed a nearly 8-fold excess risk of DKA associated with sotagliflozin. Based on an FDA analysis of all three trials, an overall estimated hazard ratio (95 percent confidence interval) for DKA associated with sotagliflozin was 7.9 (3.2, 19.9).

b. The majority of these cases required hospitalization and treatment in the intensive care unit, which underscores the seriousness of this risk.

c. Although DKA is an inherent risk in T1DM, the magnitude of excess risk, severity of the cases, and characteristics of DKA (e.g., euglycemic DKA) associated with sotagliflozin treatment raised significant safety concerns, particularly because they occurred in a clinical trial setting, where patients are carefully selected for enrollment and receive more intensive safety monitoring than in clinical practice.

d. Time-to-event analyses of the clinical trial data showed earlier development of DKA in sotagliflozin-treated patients than in patients assigned to placebo, without evidence that the risk stopped increasing over time.

e. The clinical trial data did not identify a patient group at lower risk of DKA, but instead showed the DKA risk was associated with sotagliflozin regardless of sex, age, duration of diabetes, method of insulin delivery, or body mass index.

f. Overall, risk mitigation strategies used in the clinical trials were not sufficient to address the excess DKA risk observed in the clinical trials, as evidenced by the nearly 8-fold excess risk.

g. Data analyses assessing the impact of risk mitigation strategies implemented during the course of the trials were inadequate to provide reassurance that these strategies would be successful in reducing DKA risk post-approval.

(2) The data demonstrated the significant DKA risk resulting from the addition of sotagliflozin to insulin was not justified by the drug's modest clinical benefits.

a. The data showed that sotagliflozin reduced HbA1c, a validated surrogate endpoint for clinical benefits expected due to improved glycemic control in the

treatment of diabetes mellitus, including T1DM. However, the effect on HbA1c in the sotagliflozin clinical trials was modest.

b. In the three pivotal trials, addition of sotagliflozin to insulin resulted in statistically significant reductions in HbA1c at Week 24. The treatment difference relative to placebo was approximately –0.3 percent with sotagliflozin 200 mg and –0.4 percent with sotagliflozin 400 mg.

c. In the extension of two pivotal trials to 52 weeks, the effect of sotagliflozin on HbA1c was smaller (–0.23 percent and –0.33 percent HbA1c reductions with the 200 mg and 400 mg doses, respectively), and there are no longer term data to evaluate persistence of effect. The decrease in treatment effect from Week 24 to Week 52 is clinically relevant, as the major benefits to consider with sotagliflozin treatment are related to improved long-term glycemic control reducing the risk of microvascular complications.

d. The improved HbA1c associated with sotagliflozin was not accompanied by an increased rate of hypoglycemia (defined as glucose \leq 55 mg/dL) in the clinical trials, an adverse clinical effect that occurs with insulin therapy; however, this observation does not outweigh the increased rate of DKA. The data did not show sotagliflozin was associated with an overall decrease in the rate of severe hypoglycemia.

e. In addition to improved glycemic control, other clinical benefits associated with sotagliflozin, small reductions in body weight and blood pressure, were not sufficient to outweigh the serious risk of DKA.

f. The data did not show that sotagliflozin was associated with an effect on glycemic variability and time-in-range that provided benefits distinct from reduced HbA1c.

g. Patient reported outcome measures were not adequate in directly reflecting important aspects of the patient's experience with T1DM and how sotagliflozin treatment affected these important aspects.

The complete response letter stated that Sanofi is required either to resubmit the application, fully addressing all deficiencies listed in the letter, or take other actions available under § 314.110 (i.e., withdraw the application or request an opportunity for a hearing). Applicable regulations, including 21 CFR 10.75, also provide a mechanism for applicants to obtain formal review of one or more decisions reflected in a complete response letter (see FDA's guidance for industry and review staff "Formal Dispute Resolution: Sponsor

Appeals Above the Division Level" (May 2019)).¹

Sanofi submitted a formal dispute resolution request (FDRR) on September 3, 2019, concerning the complete response letter issued by ODE II. Peter Stein, Director of CDER's OND, denied the FDRR by correspondence dated November 29, 2019, based on his determination that the drug's immediate, sustained, and substantial increase in DKA risk outweighed the modest benefit on glycemic control and any potential additional benefits (e.g., reductions in body weight and blood pressure). Sanofi submitted another FDRR on December 19, 2019, for review of the OND denial. On January 30, 2020, FDA was notified that NDA 210934 had been transferred from Sanofi to Lexicon. Robert Temple, Deputy Director for Clinical Science, CDER, denied the second FDRR on behalf of CDER by correspondence dated March 11, 2020, based on his determination that the drug's DKA risk outweighed its benefits, reaffirming the reasoning in OND's denial of the prior FDRR.

On November 10, 2020, Lexicon submitted a request for an opportunity for a hearing under § 314.110(b)(3) on whether there are grounds under section 505(d) of the FD&C Act for denying approval of NDA 210934.

II. Notice of Opportunity for a Hearing

For the reasons stated above and as explained in further detail in the complete response letter and the November 29, 2019, and March 11, 2020, FDRR denials, notice is given to Lexicon and all other interested persons that the Center Director proposes to issue an order refusing to approve NDA 210934 on the grounds that the application fails to meet the criteria for approval under section 505(d)(2) of the FD&C Act because data submitted in the application do not show that the product would be safe under the proposed conditions of use.²

Lexicon may request a hearing before the Commissioner of Food and Drugs

¹ Available at <https://www.fda.gov/media/126910/download>. FDA updates guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance web page at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>.

² Section 505(d)(2) of the FD&C Act provides that FDA shall refuse to approve an NDA if "the results of . . . tests show that such drug is unsafe for use under [the] conditions [prescribed, recommended, or suggested in the proposed labeling] or do not show that such drug is safe for use under such conditions[.]" For the reasons explained in this notice, CDER has concluded that the data and information submitted in the NDA do not show that the drug is safe for use under the proposed conditions of use.

(the Commissioner) on the Center Director's proposal to refuse to approve NDA 210934. If Lexicon decides to seek a hearing, it must file: (1) A written notice of participation and request for a hearing (see the **DATES** section) and (2) the studies, data, information, and analyses relied upon to justify a hearing (see the **DATES** section), as specified in § 314.200 (21 CFR 314.200).

As stated in § 314.200(g), a request for a hearing may not rest upon allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing to resolve. We note in this regard that because CDER proposes to refuse to approve NDA 210934 based on the multiple deficiencies summarized above, any hearing request from Lexicon must address all of those deficiencies. Failure to request a hearing within the time provided and in the manner required by § 314.200 constitutes a waiver of the opportunity to request a hearing. If a hearing request is not properly submitted, FDA will issue a notice refusing to approve NDA 210934.

The Commissioner will grant a hearing if there exists a genuine and substantial issue of fact or if the Commissioner concludes that a hearing would otherwise be in the public interest (§ 314.200(g)(6)). If a hearing is granted, it will be conducted according to the procedures provided in 21 CFR parts 10 through 16 (21 CFR 314.201).

Paper submissions under this notice of opportunity for a hearing should be filed in one copy. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, submissions may be seen in the Dockets Management Staff Office between 9 a.m. and 4 p.m., Monday through Friday, and on the internet at <https://www.regulations.gov>. This notice is issued under section 505(c)(1)(B) of the FD&C Act and §§ 314.110(b)(3) and 314.200.

Dated: February 25, 2021.

Patrizia Cavazzoni,
Acting Director, Center for Drug Evaluation
and Research.

[FR Doc. 2021-04342 Filed 3-2-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1413]

Michael Gurry: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarbing Michael Gurry from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Gurry was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Gurry was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred. As of October 22, 2020 (30 days after receipt of the notice), Mr. Gurry had not responded. Mr. Gurry's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable March 8, 2021.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM-4029) Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Drive, Rockville, MD 20857, 240-402-8743, debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On January 13, 2020, Mr. Gurry was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against him in the U.S. District Court for the District of Massachusetts, after a jury verdict, on one count of racketeering conspiracy in violation of 18 U.S.C. 1962(d). The pattern of racketeering activity he was convicted of included engaging in multiple acts of mail fraud (18 U.S.C. 1341) and wire fraud (18 U.S.C. 1343).

The factual basis for this conviction is as follows: Mr. Gurry held executive

management positions, to include Vice President of Managed Markets, of Insys Therapeutics Inc. (Insys), a Delaware Corporation, with headquarters in Chandler, Arizona. Insys developed and owned a drug called SUBSYS, a liquid formulation of fentanyl to be applied under the tongue. FDA approved SUBSYS for the management of breakthrough pain in adult cancer patients who are already receiving and are already tolerant to opioid therapy for their underlying persistent cancer pain. From early 2012 and continuing through 2015, Mr. Gurry participated in a conspiracy whereby employees of Insys bribed medical practitioners in various states to get those practitioners to increase prescribing SUBSYS to their patients, many of whom did not have cancer. Mr. Gurry, along with his coconspirators, measured the effect of these bribes on each practitioner's prescribing habits and on the revenue that each bribed practitioner generated for Insys. Mr. Gurry, along with his coconspirators, reduced or eliminated bribes paid to those practitioners who failed to meet the minimum prescription requirements or failed to generate enough revenue to justify additional bribes. To further this conspiracy, Mr. Gurry and his coconspirators misled and defrauded health insurance providers to ensure those providers approved payment for SUBSYS. Insys achieved this goal by establishing the "Insys Reimbursement Center", which was designed to shift the burden of seeking prior authorization for SUBSYS from practitioners to Insys. This allowed Insys to determine what medical information was presented to insurers. Mr. Gurry and his coconspirators directed Insys employees to mislead insurers to obtain payment authorization.

As a result of this conviction, FDA sent Mr. Gurry, by United Parcel Service, on September 21, 2020, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Gurry was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Gurry an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this

action. Mr. Gurry received the proposal on September 22, 2020. He did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Gurry has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Gurry is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and (c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Gurry in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Gurry provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Gurry during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of section 306 of the FD&C Act, a “drug product” is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Gurry for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2020-N-1413 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see

ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: February 25, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-04374 Filed 3-2-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0104]

PolyMedica Industries Inc., et al.; Proposal To Withdraw Approval of Three New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration’s (FDA or Agency) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of three new drug applications (NDAs) and is announcing an opportunity for the NDA holders to request a hearing on this proposal. The basis for the proposal is that the NDA holders have repeatedly failed to file required annual reports for those NDAs.

DATES: The NDA holders may submit a request for a hearing by April 2, 2021. Submit all data, information, and analyses upon which the request for a hearing relies by May 3, 2021. Submit electronic or written comments by May 3, 2021.

ADDRESSES: The request for a hearing may be submitted by the NDA holders by either of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to <https://www.regulations.gov>, including any attachments to the request for a hearing, will be posted to the docket unchanged.

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.

- Because your request for a hearing will be made public, you are solely responsible for ensuring that your request 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. The request for a hearing must include the Docket No. FDA-2021-N-0104 for “PolyMedica Industries Inc. et al.; Proposal to Withdraw Approval of Three New Drug Applications; Opportunity for a Hearing.” The request for a hearing will be placed in the docket and 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.

The NDA holders may submit all data and analyses upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- **Confidential Submissions**—To submit any data analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analyses. 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 any decisions on this matter. 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> or available at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Submit both copies to the Dockets Management Staff. Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law.

Comments Submitted by Other Interested Parties: For all comments submitted by other interested parties, submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to [https://](https://www.regulations.gov)

www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-

2021-N-0104 for "PolyMedica Industries Inc. *et al.*; Proposal to Withdraw Approval of Three New Drug Applications; Opportunity for a Hearing." Received comments, those filed in a timely manner (see **DATES**), 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: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holder of an approved NDA to market a new drug for human use is required to submit annual reports to FDA concerning its approved NDA under §§ 314.81 and 314.98 (21 CFR 314.81 and 314.98). The holders of the approved NDAs listed in table 1 have repeatedly failed to submit the required annual reports and have not responded to the Agency's request for submission of the reports.

TABLE 1—APPROVED NDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED

Application No.	Drug	NDA holder
NDA 016401	NEOPAP (acetaminophen) Suppositories, 120 milligrams (mg).	PolyMedica Industries Inc., 2 Constitution Way, Woburn, MA 01801.
NDA 050266	ACHROMYCIN (tetracycline hydrochloride (HCl)) Ophthalmic Ointment, 10 mg/gram.	Storz Ophthalmics Inc. (subsidiary of American Cyanamid Co.), 401 North Middletown Rd., Pearl River, NY 10965.
NDA 050268	ACHROMYCIN (tetracycline HCl) Ophthalmic Suspension, 1%.	Do.

Therefore, notice is given to the holders of the approved NDAs listed in table 1 and to all other interested persons that the Director of CDER proposes to issue an order, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)), withdrawing approval of the NDAs and all amendments and supplements thereto on the grounds that the NDA holders have failed to submit reports required under § 314.81.

In accordance with section 505 of the FD&C Act and 21 CFR part 314, the NDA holders are hereby provided an

opportunity for a hearing to show why the approval of the NDAs listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these NDAs.

An NDA holder who decides to seek a hearing must file the following: (1) A written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a

hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 (21 CFR 314.200) and in 21 CFR part 12.

The failure of an NDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that

NDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the NDAs and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the NDAs, and the drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All paper submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>.

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: February 25, 2021.

Patrizia Cavazzoni,

Acting Director, Center for Drug Evaluation and Research.

[FR Doc. 2021-04344 Filed 3-2-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 054

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing

modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 054" (Recognition List Number: 054), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments on the notice at any time. These modifications to the list of recognized standards are applicable March 3, 2021.

ADDRESSES: You may submit comments on the current list of FDA Recognized Consensus Standards at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://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-2004-N-0451 for "Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 054." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 054.

- **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.

An electronic copy of Recognition List Number: 054 is available on the internet at <https://www.fda.gov/MedicalDevices/>

DeviceRegulationandGuidance/Standards/ucm123792.htm. See section IV for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 054 modifications and other standards related information. Submit written requests for a single hard copy of the document entitled “Modifications to the List of Recognized Standards, Recognition List Number: 054” to Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5606, Silver Spring, MD 20993, 301-796-6287. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8144.

FOR FURTHER INFORMATION CONTACT:

Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5606, Silver Spring, MD 20993, 301-796-6287, CDRHStandardsStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards

developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In the **Federal Register** of September 14, 2018 (83 FR 46738), FDA announced the availability of a guidance entitled “Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.” The guidance describes how FDA has implemented its standards recognition program and is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>. Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents>.

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains on its website hypertext markup language (HTML) and portable document format (PDF) versions of the list of FDA Recognized Consensus Standards, available at <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents>. Additional information on the Agency’s Standards and Conformity Assessment Program is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program>.

www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program.

II. Modifications to the List of Recognized Standards, Recognition List Number: 054

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency is recognizing for use in premarket submissions and other requirements for devices. FDA is incorporating these modifications to the list of FDA Recognized Consensus Standards in the Agency’s searchable database. FDA is using the term “Recognition List Number: 054” to identify the current modifications.

In table 1, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, if applicable; (2) the correction of errors made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III, FDA lists modifications the Agency is making that involve new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 054.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard ¹	Change
A. Anesthesiology			
1-98	1-146	ISO 80601-2-12 Second edition 2020-02 Medical electrical equipment—Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators.	Withdrawn and replaced with newer version.
B. Biocompatibility			
2-168	2-273	ISO 10993-9 Third edition 2019-11 Biological evaluation of medical devices—Part 9: Framework for identification and quantification of potential degradation products.	Withdrawn and replaced with newer version. Extent of recognition.
2-197	2-274	ASTM F749-20 Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit.	Withdrawn and replaced with newer version.
2-238	ANSI/AAMI BE83:2006/(R)2011 Biological evaluation of medical devices—Part 18: Chemical characterization of materials.	Withdrawn.
C. Cardiovascular			
3-55	3-164	ASTM F1830-19 Standard Practice for Collection and Preparation of Blood for Dynamic In Vitro Evaluation of Blood Pumps.	Withdrawn and replaced with newer version.
3-56	3-165	ASTM 1841-19 Standard Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps.	Withdrawn and replaced with newer version.
3-127	3-155	ANSI/AAMI/IEC 60601-2-47:2012/(R)2016 Medical electrical equipment—Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.	Transferred.
3-142	8-525	ISO/TS 17137 Second edition 2019-09 Cardiovascular implants and extracorporeal systems—Cardiovascular absorbable implants.	Withdrawn and replaced with newer version. Transferred.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard ¹	Change
3-152	3-123	IEC 80601-2-30: Edition 2.0 2018-03 Medical electrical equipment Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers.	Withdrawn and replaced with newer version.
3-160	3-166	ISO 81060-2 Third edition 2018-11 Non-invasive sphygmomanometers—Part 2: Clinical investigation of intermittent automated measurement type [Including AMENDMENT1 (2020)].	Withdrawn and replaced with newer version.
D. Dental/Ear, Nose, and Throat (ENT)			
4-201	4-263	ISO 9693 Third edition 2019-10 Dentistry—Compatibility testing for metal-ceramic and ceramic-ceramic systems.	Withdrawn and replaced with newer version.
E. General I (Quality Systems/Risk Management) (QS/RM)			
5-110	5-126	ISTA 3A 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less.	Withdrawn and replaced with newer version.
5-111	5-127	ISTA 3B 2017 Packaged-Products for Less-Than-Truckload (LTL) Shipment.	Withdrawn and replaced with newer version.
5-112	5-128	ISTA 3E 2017 Similar Packaged-Products in Unitized Loads of Truckload Shipment.	Withdrawn and replaced with newer version.
5-114	5-129	IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices—Part 1: Application of usability engineering to medical devices.	Withdrawn and replaced with newer version.
5-116	5-130	ISO 7010 Third edition 2019-07 Graphical symbols—Safety colours and safety signs—Registered safety signs.	Withdrawn and replaced with newer version.
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
No new entries at this time.			
G. General Hospital/General Plastic Surgery (GH/GPS)			
6-68	6-439	ISO 7886-2 Second edition 2020-04 Sterile hypodermic syringes for single use—Part 2: Syringes for use with power-driven syringe pumps.	Withdrawn and replaced with newer version.
6-145	6-440	ASTM D3578—19 Standard Specification for Rubber Examination Gloves.	Withdrawn and replaced with newer version.
6-148	6-441	ISO 7886-3 Second edition 2020-05 Sterile hypodermic syringes for single use—Part 3: Auto-disabled syringes for fixed-dose immunization.	Withdrawn and replaced with newer version.
6-165	6-442	ASTM D6977—19 Standard Specification for Polychloroprene Examination Gloves for Medical Application.	Withdrawn and replaced with newer version.
6-168	6-443	ASTM D3577—19 Standard Specification for Rubber Surgical Gloves.	Withdrawn and replaced with newer version.
6-176	6-444	ASTM D7103—19 Standard Guide for Assessment of Medical Gloves.	Withdrawn and replaced with newer version.
6-178	ASTM D6124—06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves.	Extent of recognition.
6-183	6-445	ASTM D5250—19 Standard Specification for Poly(vinyl chloride) Gloves for Medical Application.	Withdrawn and replaced with newer version.
6-244	6-446	ASTM D6319—19 Standard Specification for Nitrile Examination Gloves for Medical Application.	Withdrawn and replaced with newer version.
6-318	6-447	ISO 8536-4 Sixth edition 2019-09 Infusion equipment for medical use—Part 4: Infusion sets for single use, gravity feed.	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
No new entries at this time.			
I. Materials			
8-227	8-526	ASTM F2182—19e2 Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging.	Withdrawn and replaced with newer version.
8-343	8-527	ASTM F899—20 Standard Specification for Wrought Stainless Steels for Surgical Instruments.	Withdrawn and replaced with newer version.
8-349	8-528	ASTM F2503—20 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.	Withdrawn and replaced with newer version.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard ¹	Change
8-374	8-529	ASTM F2633—19 Standard Specification for Wrought Seamless Nickel-Titanium Shape Memory Alloy Tube for Medical Devices and Surgical Implants.	Withdrawn and replaced with newer version.
8-461	8-530	ASTM F3208—19 Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices.	Withdrawn and replaced with newer version.
J. Nanotechnology			
No new entries at this time.			
K. Neurology			
No new entries at this time.			
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
No new entries at this time.			
M. Ophthalmic			
No new entries at this time.			
N. Orthopedic			
11-215	11-363	ASTM F897—19 Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws.	Withdrawn and replaced with newer version.
11-222	11-364	ISO 14243-1 Second edition 2009-11-15 Implants for surgery—Wear of total knee-joint prostheses—Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test [Including AMENDMENT1 (2020)].	Withdrawn and replaced with newer version.
11-253	11-365	ASTM F1800—19e1 Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements.	Withdrawn and replaced with newer version.
11-275	11-366	ASTM F2381—19 Standard Test Method for Evaluating Trans-Vinylene Yield in Irradiated Ultra-High Molecular Weight Polyethylene Fabricated Forms Intended for Surgical Implants by Infrared Spectroscopy.	Withdrawn and replaced with newer version.
11-292	11-367	ISO 14243-3 Second edition 2014-11-01 Implants for surgery—Wear of total knee-joint prostheses—Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test [Including AMENDMENT 1 (2020)].	Withdrawn and replaced with newer version.
O. Physical Medicine			
16-170	ANSI RESNA WC-1:2009 Section 3 American National Standard for Wheelchairs—Volume 1: Additional Requirements for Wheelchairs (including Scooters) Section 3: Determination of effectiveness of brakes.	Title change.
P. Radiology			
12-287	12-330	NEMA Standards Publication XR 28-2018 Supplemental Requirements for User Information and System Function Related to Dose in CT.	Withdrawn and replaced with newer version.
12-325	NEMA Standards Publication XR 25-2019 Computed Tomography Dose Check.	Transition period extended.
Q. Software/Informatics			
13-80	13-113	IEEE Std 11073-20601-2019 Health informatics—Personal health device communication—Part 20601: Application profile—Optimized exchange protocol.	Withdrawn and replaced with newer version.
13-110	13-114	IEEE Std 11073-10101-2019 Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.	Withdrawn and replaced with newer version.
R. Sterility			
14-313	14-539	ASTM F2475—20 Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials.	Withdrawn and replaced with newer version.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard ¹	Change
14-327	14-540	ISO 11737-2 Third edition 2019-12 Sterilization of health care products—Microbiological methods—Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.	Withdrawn and replaced with newer version.
14-360	14-541	ANSI/AAMI ST72:2019 Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing.	Withdrawn and replaced with newer version.
14-408	2-275	ISO 10993-7 Second edition 2008-10-15 Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals [Including Corrigendum 1 (2009) and AMENDMENT 1 (2020)].	Withdrawn and replaced with newer version. Transferred.
14-436	14-542	ISO/ASTM 52628 Second edition 2020-04 Standard practice for dosimetry in radiation processing.	Withdrawn and replaced with newer version.
14-515	ISO 17664 Second edition 2017-10 Processing of health care products—Information to be provided by the medical device manufacturer for the processing of medical devices.	Extent of recognition.
14-528	14-543	ISO 11139 First edition 2018-08 Sterilization of health care products—Vocabulary of terms used in sterilization and related equipment and process standards.	New recognition number.
14-529	14-544	ISO 18472 Second edition 2018-08 Sterilization of health care products—Biological and chemical indicators—Test equipment.	New recognition number.
14-530	14-545	ISO/ASTM 51276 Fourth edition 2019-08 Practice for use of a polymethylmethacrylate dosimetry system.	New recognition number.
14-531	14-546	USP 42-NF37:2019 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.	New recognition number.
14-532	14-547	USP 42-NF37:2019 <71> Sterility Tests	New recognition number.
14-533	14-548	USP 42-NF37:2019 <85> Bacterial Endotoxins Test	New recognition number.

S. Tissue Engineering

15-19	15-59	ASTM F2450—18 Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue-Engineered Medical Products.	Withdrawn and replaced with newer version.
15-30	15-60	ASTM F2212—19 Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs).	Withdrawn and replaced with newer version.
15-39	15-61	ASTM F2150 19 Standard Guide for Characterization and Testing of Biomaterial Scaffolds Used in Regenerative Medicine and Tissue-Engineered Medical Products.	Withdrawn and replaced with newer version.
15-41	15-62	ASTM F2602—18 Standard Test Method for Determining the Molar Mass of Chitosan and Chitosan Salts by Size Exclusion Chromatography with Multi-angle Light Scattering Detection (SEC-MALS).	Withdrawn and replaced with newer version.
15-50	15-63	ASTM F2739—19 Standard Guide for Quantifying Cell Viability and Related Attributes within Biomaterial Scaffolds.	Withdrawn and replaced with newer version.

¹ All standard titles in this table conform to the style requirements of the respective organizations.

III. Listing of New Entries

In Table 2, FDA provides the listing of new entries and consensus standards

added as modifications to the list of standards not previously recognized by FDA.
List Number: 054. These entries are of

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard ¹	Reference No. and date
A. Anesthesiology		
No new entries at this time.		
B. Biocompatibility		
2-276	Biological evaluation of medical devices—Part 18: Chemical characterization of medical device materials within a risk management process.	ISO 10993-18 Second edition 2020-01.
C. Cardiovascular		
3-167	Non-invasive sphygmomanometers—Part 5: Requirements for the repeatability and reproducibility of NIBP simulators for testing of automated non-invasive sphygmomanometers.	ISO/TS 81060-5 First edition 2020-02.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard ¹	Reference No. and date
3-168	Standard for Wearable, Cuffless Blood Pressure Measuring Devices [Including Amendment 1 (2019)].	IEEE Std 1708-2014.
D. Dental/Ear, Nose, and Throat (ENT)		
No new entries at this time.		
E. General I (Quality Systems/Risk Management) (QS/RM)		
No new entries at this time.		
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)		
No new entries at this time.		
G. General Hospital/General Plastic Surgery (GH/GPS)		
No new entries at this time.		
H. In Vitro Diagnostics (IVD)		
7-296	Measurement Procedure Comparison and Bias Estimation Using Patient Samples.	CLSI EP09c 3rd Edition.
7-297	Medical laboratories—Practical guidance for the estimation of measurement uncertainty.	ISO/TS 20914 First edition 2019-07.
7-298	Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures.	CLSI EP35 1st Edition.
I. Materials		
8-531	Standard Guide for Methods of Extraction of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices.	ASTM F3321—19.
8-532	Standard Guide for Assessing the Removal of Additive Manufacturing Residues in Medical Devices Fabricated by Powder Bed Fusion.	ASTM F3335—20.
8-533	Additive Manufacturing—Feedstock materials—Methods to characterize metal powders.	ISO/ASTM 52907: First Edition 2019-11.
8-534	Additive Manufacturing—Design—Part 1: Laser-based powder bed fusion of metals.	ISO/ASTM 52911-1: First Edition 2019-07.
8-535	Additive Manufacturing—Design—Part 2: Laser-based powder bed fusion of polymers.	ISO/ASTM 52911-2: First Edition 2019-09.
8-536	Additive Manufacturing—Test Artifacts—Geometric capability assessment of additive manufacturing systems.	ISO/ASTM 52902: First Edition 2019-07.
J. Nanotechnology		
18-15	Standard Guide for Tiered Approach to Detection and Characterization of Silver Nanomaterials in Textiles..	ASTM E3025—16.
18-16	Nanotechnologies—Analysis of nano-objects using asymmetrical-flow and centrifugal field-flow fractionation.	ISO/TS 21362 First edition 2018-06.
K. Neurology		
No new entries at this time.		
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)		
9-124	Colorimetry—Part 1: CIE standard colorimetric observers	ISO/CIE 11664-1 First edition 2019-06.
9-125	Colorimetry—Part 2: CIE standard illuminants	ISO 11664-2 CIE S 014-2/E First edition 2007-10-15 Corrected version 2008-11-01.
9-126	Colorimetry—Part 3: CIE tristimulus values	ISO/CIE 11664-3 First edition 2019-06.
9-127	Colorimetry—Part 4: CIE 1976 L*a*b* colour space	ISO/CIE 11664-4 First edition 2019-06.
9-128	Colorimetry—Part 6: CIEDE2000 colour-difference formula	ISO/CIE 11664-6 First edition 2014-02-01.
9-129	Multimedia systems and equipment—Colour measurement and management—Part 2-1: Colour management—Default RGB colour space—sRGB [Including Amendment 1 (2003) and Corrigendum 1 (2014)].	IEC 61966-2-1 First edition 1999-10.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard ¹	Reference No. and date
M. Ophthalmic		
No new entries at this time.		
N. Orthopedic		
11-368	Standard Practice for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Tibial Components.	ASTM F3334—19.
11-369	Standard Practice for Inspection of Spinal Implants Undergoing Testing	ASTM F3292—19.
O. Physical Medicine		
No new entries at this time.		
P. Radiology		
12-331	Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems.	NEMA Standards Publication MS 14–2019.
12-332	Magnetic resonance equipment for medical imaging—Part 1: Determination of essential image quality parameters.	IEC 62464–1 Edition 2.0 2018–12.
12-333	Guidance on error and warning messages for software used in radiotherapy	IEC TR 63183 Edition 1.0 2019–12.
12-334	Radiation therapy machine characterization	AAMI RT3:2020.
Q. Software/Informatics		
13-115	Software and systems engineering—Software testing—Part 1: Concepts and definitions.	ISO/IEC/IEEE 29119–1 First edition 2013–09–01.
R. Sterility		
14-549	Standard Test Method for Evaluation of Seal Quality and Integrity Using Airborne Ultrasound.	ASTM F3004—13e1.
S. Tissue Engineering		
No new entries at this time.		

¹ All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. Such standards are those that FDA has recognized by notice published in the **Federal Register** or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the **Federal Register**). FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to CDRHStandardsStaff@fda.hhs.gov. To

be considered, such recommendations should contain, at a minimum, the information listed on FDA's website, which is specifically available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process>.

Dated: February 26, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-04376 Filed 3-2-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1638]

Lawrence B. Ryan: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debaring Lawrence B. Ryan from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Ryan was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Ryan was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred. As of October 18, 2020 (30 days after receipt of the notice), Mr. Ryan had not responded. Mr. Ryan's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable March 3, 2021.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Jaime Espinosa, (ELEM-4029) Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On June 18, 2020, Mr. Ryan was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against him in the U.S. District Court for the Eastern District of Virginia, Norfolk Division, after his plea of guilty to one count of conspiracy to defraud the United States in violation of 18 U.S.C. 371.

The factual basis for this conviction is as follows: As contained in the Statement of Facts in Mr. Ryan's case, filed on January 8, 2020, from October 2007, and continuing through September 2010, Mr. Ryan, a physician, authorized drug orders for RX Limited (also known as RX Partners), an internet pharmacy organization that facilitated the unlawful distribution of prescription drugs to consumers throughout the United States. RX Limited had a business model whereby it allowed consumers to fill out a brief medical questionnaire, select the type of drugs the consumer desired, the desired drug strength, and the desired drug quantity and pay by credit card. RX Limited then forwarded the order to a participating physician for "approval." The drugs sold by RX Limited were dispensed without a valid prescription because there was no valid doctor-patient relationship established between the authorizing physicians and the customers. Customers had no face-to-face contact with the participating physician and were not subject to any mental or physical examinations.

The physicians authorizing the orders for prescription drugs sold by RX Limited did not take patient histories or perform any diagnostic or laboratory testing, did not check the accuracy of the information customers provided

(including their identities, ages, and qualifying medical conditions), and did not monitor, or provide any means to monitor, medication response. After the participating physician authorized the prescription, RX Limited sent the order to a fulfillment pharmacy, which fulfilled the order and mailed the drugs to the customer.

As a participating physician, Mr. Ryan authorized more than 158,000 drug orders for well over 10 individual RX Limited customers. Prescription drugs distributed pursuant to these orders included, FIORICET (and its generic equivalents), Carisoprodol (SOMA), Tramadol (ULTRAM), VIAGRA, CIALIS, and XENICAL. RX Limited paid Mr. Ryan \$2.00 per drug order he authorized. From October 2007 through September 2010, RX Limited paid Mr. Ryan at least \$316,153 for the orders he authorized.

As a result of this conviction, FDA sent Mr. Ryan by certified mail on September 11, 2020, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Ryan was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Ryan an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Ryan received the proposal on September 18, 2020. Mr. Ryan did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Ryan, has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Ryan, is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and

(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of, Mr. Ryan, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Ryan provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Ryan during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B)). Note that, for purposes of section 306 of the FD&C Act, a "drug product" is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (see section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Ryan for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2020-N-1638 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: February 25, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-04375 Filed 3-2-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0008]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a

forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on April 6, 2021, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions including information regarding special accommodations due to a disability may be accessed at: <https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings>.

FOR FURTHER INFORMATION CONTACT:

Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993-0002, aden.asefa@fda.hhs.gov, 301-796-0400, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On April 6, 2021, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application for the TransMedics Organ Care System (OCS) Heart, by TransMedics, Inc. The proposed Indication for Use for the TransMedics OCS Heart, is as follows: The TransMedics Organ Care System (OCS) Heart System is a portable extracorporeal heart perfusion and monitoring system indicated for the resuscitation, preservation, and assessment of donor hearts in a near-physiologic, normothermic, and beating

state intended for a potential transplant recipient.

OCS Heart is indicated for donor hearts with one or more of the following characteristics:

- Expected cross-clamp or ischemic time ≥ 4 hours due to donor or recipient characteristics (e.g., donor-recipient geographical distance, expected recipient surgical time); or
- Expected total cross-clamp time of ≥ 2 hours PLUS one of the following risk factors:
 - Donor Age ≥ 55 years; or
 - Donors with history of cardiac arrest and downtime ≥ 20 minutes; or
 - Donor history of alcoholism; or
 - Donor history of diabetes; or
 - Donor Left Ventricular Ejection Fraction ≤ 50 percent but ≥ 40 percent; or
 - Donor history of Left Ventricular Hypertrophy (septal or posterior wall thickness of >12 and ≤ 16 mm); or
 - Donor angiogram with luminal irregularities but no significant coronary artery disease.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/advisory-committees/circulatory-system-devices-panel/2021-meeting-materials-circulatory-system-devices-panel>. Select the link for the 2021 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 30, 2021. Oral presentations from the public will be scheduled on April 6, 2021, between approximately 1 p.m. Eastern Time and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and

an indication of the approximate time requested to make their presentation on or before March 22, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 23, 2021.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallet at Artair.Mallet@fda.hhs.gov or 301-796-9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 25, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-04371 Filed 3-2-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1411]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for Data To Support Cross-Center Collaboration for Social Behavioral Sciences Associated With Disease Prevention, Treatment, and the Safety, Efficacy, and Usage of Food and Drug Administration Regulated Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a proposed collection

of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by April 2, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The title of this information collection is “Generic Clearance for Data to Support Cross-Center Collaboration for Social Behavioral Sciences Associated with Disease Prevention, Treatment, and the Safety, Efficacy, and Usage of FDA Regulated Products.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for Data To Support Cross-Center Collaboration for Social Behavioral Sciences Associated With Disease Prevention, Treatment, and the Safety, Efficacy, and Usage of FDA Regulated Products

OMB Control Number 0910–NEW

FDA is seeking to conduct qualitative and quantitative research studies to better understand consumers’, patients’, caregivers’, academic/scientific experts’, and public health professionals’ perceptions and behaviors regarding various issues and outcomes associated with disease prevention, treatment, and the safety and efficacy of all FDA-regulated products. These studies may consist of small groups, focus groups/town halls, individual in-depth interviews, and surveys relating to the evaluation of disease prevention and treatment and the safety, efficacy, and usage of FDA-regulated products; the studies may also include communication messages and strategies, and other materials directed to consumers, patients, caregivers, and

public health professionals (e.g., evaluate the effectiveness of communication messages, educational materials, and interventions directed toward promoting and protecting human and animal health).

Among the general provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is charged with promoting the public health through regulatory oversight as well as clinical research. Specifically, section 1003(d)(2)(C) and (D) of the FD&C Act (21 U.S.C. 393(d)(2)(C) and (D)) provides that the Commissioner of Food and Drugs shall be responsible for research. Accordingly, FDA is seeking to conduct qualitative and quantitative research studies.

The information collection is intended to support research conducted by, or on behalf of, FDA. Understanding consumers’, patients’, caregivers’, academic/scientific experts’, and public health professionals’ perceptions and behaviors plays an important role in improving FDA’s decision-making processes and communications impacting various stakeholders. To better understand consumers’, patients’, caregivers’, academic/scientific experts’, and public health professionals’ perceptions and behaviors regarding various issues and outcomes associated with disease prevention, treatment, and the safety, efficacy, and usage of products overseen by the Agency, FDA is requesting approval of this generic information collection request.

The qualitative and quantitative research anticipated by FDA aligns with Agency objectives. For example, among eight scientific priorities is the goal to support social and behavioral sciences. Such research helps the Agency meet this goal by:

- Identifying gaps in the target audiences’ knowledge regarding FDA-regulated products, and outcomes associated the disease prevention and treatment;
- reaching diverse audiences;
- assessing target audiences’ knowledge, perceptions, and behaviors about FDA-regulated products;
- evaluating the effectiveness of FDA’s communications;
- exploring ways to incorporate patient input into decision making;
- leveraging real-world data;
- evaluating outcomes; and
- integrating the knowledge gained from the research into Agency communications, activities, interventions, and programs.

FDA will only submit a collection for approval under this generic clearance if it meets the following condition: Information provided by respondents

will be kept private and anonymous, except as otherwise required by law. This will be communicated to respondents by means of introductory letters, explanatory texts on the cover pages of questionnaires, scripts read prior to focus groups or telephone interviews, and consent forms as appropriate. Respondents also will be advised of the following: (1) The nature of the activity; (2) the intended purpose and use of the data collected; (3) FDA sponsorship (when appropriate); and (4) the fact that participation is voluntary at all times. Because responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the information collection as a whole or to any individual questions.

Only Agency or Agency-sponsored personnel will have access to individual-level surveys, interviews, or focus group data. All project staff from a contractor or cooperative agreement grantee conducting the information collection must take required measures to ensure respondent privacy and confidentiality of data. Personally identifiable information (PII) shall be limited to data that may be required in the process of respondent enrollment. PII will be accessible to only those contractors or cooperative agreement grantees who need it and will not be linked to interview data. Neither FDA employees nor any Federal employee of any other Agency will have access to PII. All PII will be destroyed by contractors as soon as feasible following data collected during interviews.

All electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, all data will be reported to FDA in aggregate form, with no links to individuals preserved. Reports generated by this information collection will be used only for research purposes and for the development of communication messages.

Social and behavioral testing efforts described in this proposal are typically considered exempt from the “Regulations for the Protection of Human Subjects” in accordance with 45 CFR 46.101(b)(3). Before data are collected, FDA researchers must obtain either an exemption or an expedited or full approval for all research from FDA’s institutional review board (IRB).

When FDA’s IRB determines that minors are capable of giving assent, the

IRB shall determine whether adequate provisions are made for soliciting assent. Generally, assent requires securing the signature of a minor potentially participating in the research on a separate assent form, in addition to the consent form the parent or legal guardian signs. An assent document should: (1) Contain an explanation of the study; (2) a description of what is required of the subject (e.g., what he or she will experience (whether the minor will be in the hospital, whether the minor's parents will be with him or her, etc.)); (3) an explanation of any risks and pain associated with the study; (4) an explanation of any anticipated change in the minor's appearance; and (5) an explanation of the benefits to the minor or others.

FDA plans to use the data collected under the generic clearance to inform the following information for education, interventions, outcomes, regulatory science programs, materials and resources, and disease prevention and treatment. FDA expects the data to guide the formulation of the Agency's

educational and public health objectives on FDA-regulated products and support development of subsequent research efforts. The data will not be used to make policy or regulatory decisions. Rather, these data will: (1) Inform FDA's public education campaigns and other educational/interventional materials directed to informing consumers, patients, caregivers, and public health professionals about human and animal health issues; and (2) provide information on the safety, efficacy, and usage of FDA-regulated products.

If these conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process.

To obtain approval for a collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB, along with supporting documentation (e.g., a copy of the interview or moderator guide, screening questionnaire).

FDA will submit individual qualitative and quantitative collections

under this generic clearance to the OMB. Individual collections will also undergo review by FDA's IRB, senior leadership for the primary investigator's respective offices, and PRA specialists.

Description of Respondents: The respondents to this collection of information are all FDA stakeholders, including general population individuals, as well as consumers of certain products, patients and their caregivers, academic/scientific experts, individuals from specific target labor groups, such as physicians, medical specialists, pharmacists, dentists, nurses, veterinarians, dietitians, and other public health professionals.

In the **Federal Register** of July 7, 2020 (85 FR 40655), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although five comments were received, they were not responsive to the four collection of information topics solicited and, therefore, will not be discussed in this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews/Surveys/Focus Groups	2,520	14.6	36,792	0.25 (15 minutes)	9,198

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

This is a new collection of information whose total estimated annual reporting burden is 9,198 hours. The number of participants to be included in each individual generic submission under this collection of information will vary, depending on the nature of the compliance efforts and the target audience.

Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-04407 Filed 3-2-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a

meeting of the Board of Scientific Counselors, NIAMS.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIAMS.

Date: April 27–28, 2021.

Time: April 27, 2021, 12:30 p.m. to 4:45 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 10 Center Drive, Bethesda, MD 20892, (Virtual Meeting).

Time: April 28, 2021, 12:00 p.m. to 4:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 10 Center Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: John J. O'Shea, MD, Ph.D., Scientific Director, National Institute of Arthritis & Musculoskeletal and Skin Diseases, Building 10, Room 6N204, Bethesda, MD 20892, (301) 496-2612, oshea.j@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: February 25, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-04366 Filed 3-2-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Urology RC2 applications.

Date: April 2, 2021.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, 6707 Democracy Boulevard, Room 7015, Bethesda, MD 20892-2542, 301-594-4721, ryan.morris@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 25, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-04365 Filed 3-2-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Fellowship Review.

Date: March 9, 2021.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Eliane Lazar-Wesley, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, 6001 Executive Boulevard, Room 8339, MSC 9670, Bethesda, MD 20892-8401, (301) 496-8683, el6r@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: February 26, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-04363 Filed 3-2-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Deafness and Other Communication Disorders Special Emphasis Panel, which was published in the **Federal Register** on January 26, 2021, 86FR7101.

This meeting is being amended to change the SRO to Eliane Lazar-Wesley. The meeting is closed to the public.

Dated: February 26, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-04364 Filed 3-2-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning a Transceiver

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

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (CBP) has issued a final determination concerning the country of origin of a transceiver, identified as the Barrett 4050 HF SDR Transceiver. Based upon the facts presented, CBP has concluded in the final determination that the transceiver, which is assembled in the United States of various imported components, including three Australian-origin printed circuit board assemblies, is not a product of a foreign country or instrumentality designated for purposes of U.S. Government procurement.

DATES: The final determination was issued on February 25, 2021. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within April 2, 2021.

FOR FURTHER INFORMATION CONTACT: Cynthia Reese, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade (202-325-0046).

SUPPLEMENTARY INFORMATION: Notice is hereby given that on February 25, 2021, CBP issued a final determination concerning the country of origin of the Barrett 4050 HF SDR Transceiver for purposes of Title III of the Trade Agreements Act of 1979. This final determination, HQ H314982, was issued at the request of Barrett Communications USA Corporation, under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511-18). In the final determination, CBP has concluded that, based upon the facts presented, as a result of the assembly of various imported components, including three Australian-origin

printed circuit board assemblies, in the United States, the finished transceiver is not a product of a foreign country or instrumentality designated pursuant to 19 U.S.C. 2511(b) for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that notice of final determinations shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: February 25, 2021.

Joanne R. Stump,

Acting Executive Director, Regulations and Rulings, Office of Trade.

HQ H314982

February 25, 2021

OT:RR:CTF:VS H314982 CMR

CATEGORY: Origin

Jon P. Yormick, Esq. Flannery Georgalis LLC
1375 East Ninth Street One Cleveland Center,
Floor 30 Cleveland, Ohio 44114

RE: U.S. Government Procurement; Title III,
Trade Agreements Act of 1979 (19 U.S.C.
2511); subpart B, Part 177, CBP Regulations;
Country of Origin of a Transceiver

Dear Mr. Yormick:

This is in response to your request of October 22, 2020, on behalf of your client, Barrett Communications USA Corporation, for a final determination concerning the country of origin of a device referred to as a Barrett 4050 HF SDR Transceiver pursuant to Title III of the Trade Agreements Act of 1979 (TAA), as amended (19 U.S.C. 2511 *et seq.*). As the importer of merchandise entered into the United States and further processed in the United States, your client may request a final determination pursuant to 19 CFR 177.23(a).

Facts

The item at issue, the Barrett 4050 HF SDR Transceiver (hereinafter, “transceiver”), is a software-defined based, single-sideband (“SSB”) transceiver with a frequency range of 1.6 to 30 MHz (transmit) and 250 kHz to 30 MHz (receive). You describe the transceiver as “a commercial product that supports features such as Selective Call (Selcall), direct dial telephone connection to base stations fitted with telephone interconnect systems (Telcall), GPS location, 2G and 3G ALE (Automatic Link Establishment), frequency hopping, digital voice, data transmission and remote diagnostics.” You indicate that the transceiver provides “a comprehensive data modem interface port, high speed transmit-to-receive switching, a high stability frequency standard and an efficient cooling system option.”

You indicate that the transceiver’s control head “features a GUI [graphical user

interface] on a high definition 24-bit LCD color touchscreen.” You state that “[t]he [c]ontrol [h]ead can be detached from the main body of the [t]ransceiver for remote control. The [t]ransceiver can also be controlled remotely from most mobile and desktop platforms, including iOS, Android, and Windows devices.”

You specify that there are three main assemblies for each transceiver—(1) the control head assembly; (2) the power amplifier (PA) assembly and chassis; and, (3) the microprocessor board and interface board assembly and chassis. Within these three main assemblies are five printed circuit board assemblies (PCBAs). The five PCBAs and the countries in which each PCBA is produced are as follows: the control head board (United States); the interface board (United States); the micro board (Australia); the PA board (Australia); and the volume control board (Australia). You indicate that prior to export to the United States, the only software installed on the boards produced in Australia is for the limited purpose of testing and diagnostics. The Australian produced boards are non-functional at the time of importation into the United States.

In addition to the PCBAs described above, “each transceiver includes, a radio chassis, a speaker, an LCD screen, looms, various molded plastic parts including dials and buttons, and various seals and fasteners.”

The transceiver is assembled in the United States from imported and domestically produced components. You state the transceiver is assembled as a “clamshell.” You state:

The Micro and Interface Boards are mounted on one half of the “clamshell;” the PA Board is on the other half of the “clamshell.” When the “clamshell” is assembled there are cables between the two (2) halves to allow signaling and RF to pass between them. An HD15 pin connector interface on one half of the “clamshell” provides signaling to the Control Head. The Control Head has a color, touch screen display, volume knob, and buttons.

The Control Head Board is mounted to the chassis of the Control Head, using screws and a loom. The loom takes the signaling from the screen and buttons to the Control Head Board, while another loom takes the signaling from the Control Head Board out to the interfacing HD connector. The Volume Control Board fits directly to the Control Head Board, as a daughter board.

With regard to the functions of the boards, you state that the transceiver cannot function without the control head board. In addition, the interface board “allows the [t]ransceiver to connect to antennae and auxiliaries such as modems and audio devices.” Further, you indicate that the interface board enables the micro board to function. You state that the interface board allows the micro board “to interface with all external items.”

With regard to the control head, an integrated circuit (IC) and firmware programming process must be performed prior to assembly. After the IC is provided with its base programming, the control head is partially assembled and the control head board is loaded with base firmware programming. Once the programming is

completed, the assembly of the control head (which entails cleaning and inspecting parts, installing the LCD screen and control head board, and assembling the remaining twenty-two control head components) is completed and the control head board is modified to function as part of the main assembly.

After the transceiver is fully assembled, base operating firmware and software, which will control and enable functionality, is installed on the interface board and micro board. This software is developed by a combination of efforts. Source code is written for the transceiver by software developers in Australia. Technicians in the United States convert the source code into executable object code, load it onto the interface board and micro board and test the downloaded object code. Software for optional features, which is obtained from a foreign third-party, may also be installed if required according to a customer’s purchase order specifications. Personnel in the U.S. “install the software and firmware, which takes approximately forty-five (45) minutes, including programming the 2G ALE modem and the [t]ransceiver.”

After the transceivers are assembled and programmed, they are tested. The software and the transceiver operation are tested. The testing occurs at the U.S. facility where the transceivers are assembled and programmed. Testing may also occur at customer sites within and outside the United States. After assembling, programming and testing, the transceivers are packed and shipped to customers located in the United States and throughout the Americas.

Issue

Whether the transceivers at issue, which are assembled and programmed in the United States of domestic and foreign inputs, are eligible under Title III of the TAA, as amended (19 U.S.C. 2511–2518), as products of a foreign country or instrumentality designated pursuant to section 2511(b).

Law and Analysis

U.S. Customs and Border Protection (CBP) issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purpose of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 CFR 177.21 *et seq.*, which implements Title III, Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–2518).

The rule of origin set forth in 19 U.S.C. 2518(4)(B) states:

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 CFR 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S.

Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with the Federal Procurement Regulations. See 19 CFR 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. See 48 CFR 25.403(c)(1). The Federal Acquisition Regulations define "U.S.-made end product" as:

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

The regulations define a "designated country end product" as:

WTO GPA [World Trade Organization Government Procurement Agreement] country end product, an FTA [Free Trade Agreement] country end product, a least developed country end product, or a Caribbean Basin country end product.

A "Free Trade Agreement country end product" means an article that—

(1) Is wholly the growth, product, or manufacture of a Free Trade Agreement (FTA) country; or

(2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in an FTA country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product, includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

"Free Trade Agreement country" means Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Oman, Panama, Peru, or Singapore. See 48 CFR 25.003. Thus, Australia is an FTA country for purposes of the Federal Acquisition Regulations.

CBP's authority to issue advisory rulings and final determinations is set forth in 19 U.S.C. 2515(b)(1), which states:

For the purposes of this subchapter, the Secretary of the Treasury shall provide for the prompt issuance of advisory rulings and final determinations on whether, under section 2518(4)(B) of this title, *an article is or would be a product of a foreign country or instrumentality designated pursuant to section 2511(b) of this title.*

Emphasis added.

In this case, the transceiver contains five separate PCBAs. We are told that three of these are produced by the assembly of the various components onto the PCB in Australia, and two are similarly produced in the United States. CBP has consistently held that the assembly of various components onto a blank printed circuit board to produce a PCBA is a substantial transformation. See Headquarters Ruling Letter (HQ) H311447,

dated September 10, 2020, citing HQ 735306, dated December 21, 1993 (" . . . Customs has ruled that the complete assembly of all the components onto a printed circuit board was a substantial transformation of the printed circuit board . . . "), and HQ H302801, dated October 3, 2019 ("The SMT [surface-mount technology] operations result in a new and different product with an overall use and function different than any one function of the individual components."). In this case, the three Australian-produced PCBAs and numerous other components from various countries are imported into the United States for assembly into the finished transceiver. The PCBAs for the control head board and the interface board, PCBAs which CBP considers to be dominant as they are within components which are essential to the functioning of the transceiver, are assembled in the United States. You state that the transceiver cannot function without the control head board. Further, the interface board allows the transceiver to connect to antennae and items such as, modems and audio devices. The interface board enables the micro board to function and interface with external items.

We note the production includes the assembly in the United States of the dominant PCBAs related to the transceiver's function, along with the assembly of all the remaining components of the transceiver to produce the finished good. While CBP does not recognize downloading of firmware or software to constitute a substantial transformation, we note that the conversion of the Australian software into executable code, which occurs in the United States, and programming of the transceiver boards is additional work to be considered in assessing the proper origin of the finished transceiver. See HQ H306349, dated November 26, 2019, (" . . . CBP has consistently held that the downloading of software or firmware is not a substantial transformation.").

Noting that CBP is limited by the language of 19 U.S.C. 2515(b)(1) to a determination of whether a good is a product of a foreign country or instrumentality designated pursuant to section 2511(b) of this title, based upon the information presented, the transceiver is not a product of Australia or any other foreign country or instrumentality designated pursuant to section 2511(b) of Title 19. As to whether the transceiver which is assembled in the United States qualifies as a "U.S.-made end product," we encourage you to review the recent court decision in *Acetris Health, LLC v. United States*, 949 F.3d 719 (Fed. Cir. 2020), and to consult with the relevant government procuring agency.

Holding

The transceiver at issue, the Barrett 4050 HF SDR Transceiver, is not a product of Australia or any other foreign country or instrumentality designated pursuant to section 2511(b) of Title 19.

You should consult with the relevant government procuring agency to determine whether the transceiver qualifies as a "U.S.-made end product" for purposes of the Federal Acquisition Regulations implementing the TAA.

Notice of this final determination will be given in the **Federal Register**, as required by

19 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request pursuant to 19 CFR 177.31 that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days of publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Joanne R. Stump

Acting Executive Director Regulations and Rulings Office of Trade

[FR Doc. 2021-04334 Filed 3-2-21; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

[Docket Number DHS-2021-0004]

Agency Information Collection Activities: COVID-19 Contact Tracing, COVID-19 Contact Tracing Scripts, COVID-19 Contact Tracing Form

AGENCY: Department of Homeland Security (DHS).

ACTION: 30-Day notice and request for comments; extension without change of a currently approved Collection, DHS-2021-0004.

SUMMARY: The Department of Homeland Security, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. DHS previously published this information collection request (ICR) in the **Federal Register** on Friday, January 15, 2021 for a 30-day public comment period. No comment was received by DHS. The purpose of this notice is to allow additional 30-days for public comments.

DATES: The comment period for the information collection request published on January 15, 2021 at 86 FR 4107 is extended. Comments are encouraged and will be accepted until April 2, 2021. This process is conducted in accordance with 5 CFR 1320.1

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

SUPPLEMENTARY INFORMATION: COVID-19 Contact Tracing information is necessary to support the President's

National Guidelines for all phases of *Opening Up America Again*. The Office of Management and Budget (OMB) M–20–23 Memorandum for Heads of Executive Department requires employers to develop and implement policies and procedures for workforce contact tracing following an employee's COVID–19 positive test. The M–20–23 Memorandum requires symptomatic Federal employees and contractors to follow their Agency's process if they are symptomatic or test positive for COVID–19. It specifies that the agency processes should protect the anonymity and privacy of Federal employees and contractors, to the extent possible, while disclosing only the information necessary for agencies to take appropriate actions of notifying potentially affected employees and cleaning the facility. Additionally, per the Centers for Disease Control and Prevention guidance entitled *Get and Keep America Open*, COVID–19 Contact Tracing is essential to reduce the spread of COVID–19. Furthermore, in response to the Coronavirus Pandemic, public health leaders are calling for communities around the country to ramp up capacity and implement a massive contact tracing effort to control spread of the Coronavirus. The response and recovery from the effect of COVID–19 will continue to present Federal agencies with unprecedented challenges, as well as opportunities for improvement, that require new processes and practices such as COVID–19 Contact Tracing to keep the workforce and the public safe. As DHS plans to reconstitute the workforce, it is essential to have an internal DHS Contact Tracing Program that protects the workforce and our families by preventing further spread of COVID–19.

Note: In the following responses the term employee is used to include federal employee, contractor, detailee, volunteer, and intern.

Authority

DHS is authorized to collect the information pursuant to Section 319 of the Public Health Service (PHS) Act (42 U.S.C. 274d); DHS Chief Medical Officer's authorities pursuant to 6 U.S.C. 350 and 6 U.S.C. 597; 6 U.S.C. 464; 21 U.S.C. 360bbb–3; 40 U.S.C. 1315; 42 U.S.C. 97; American with Disabilities Act, including 42 U.S.C. 12112(d)(3), 29 CFR 1630.2(r), 1630.14(b), (c) Workforce safety federal requirements, including the Occupational Safety and Health Act of 1970, Executive Order 12196, 5 U.S.C. 7902; 29 U.S.C. Chapter 15 (e.g., 29 U.S.C. 668), 29 CFR part 1904, 29 CFR 1910.1020, and 29 CFR 1960.66.

This is a new collection for the agency. The contract tracing process is triggered when an employee voluntarily self-reports to their supervisor that they are COVID–19 positive. The supervisor will provide the employee's name and contact information to a DHS Supervisory Contact Tracer. The Supervisory Contact tracer will assign a Contact Tracer to contact and interview the COVID–19 positive employee and obtain a list of employees the COVID–19 positive employee was in close contact with, as well as locations in the DHS worksite that the COVID–19 positive employee visited for 15 minutes or more. The Contact Tracer will call the exposed employees to inform them that were exposed by a DHS COVID–19 positive employee so they can take appropriate precautions in minimizing exposure to other DHS personnel and speak with their supervisor to discuss their work status. The contact tracer will not disclose the name or any other personally identifiable information regarding the COVID–19 positive employee to the exposed employees. The contact tracer will inform the exposed employee to notify their supervisor, contracting company (contractors only), medical provider, and local public health authorities to get instructions. The purpose of contact tracing is to control the spread of COVID–19 in the workforce.

The following information will be collected from the respondent:

- Name (first and last)
- COVID–19 lab test result
- Component Name
- Office address
- Personal phone number (Mobile or Home)
- Work phone number
- Work email address
- Where is your primary site of work (e.g., department, floor, field desk location)
- Supervisor Name (First and Last)
- Supervisor's Phone Number
- Supervisor's Email
- All activities, floors visited in the DHS work site, meeting attended (including lunches, etc.) that the COVID–19 symptoms began
- Last date worked in a DHS worksite
- Names (first and last) of federal employees, contractors, detailees, interns, volunteers who the COVID–19 positive employee was in close contact with, along with the close contacts' work email addresses, work phone numbers, and the last dates of contact.

The collection of information will be automated using Service Now, the

existing DHS Information Technology Help desk ticketing platform. Service Now will be modified to be used as the COVID–19 reporting tool. The COVID–19 positive employee will voluntarily inform their supervisor that they are COVID–19 positive. The COVID–19 positive employee or their supervisor will create a new ticket in the COVID–19 reporting tool and include locations in the office that they were in for 15 minutes or more (to initiate facility cleaning) and names of employees they were in close contact with for 15 minutes or more (to identify exposed individuals to notify). The COVID–19 reporting tool will create a ticket and route this to the employee's supervisor and the supervisory contract tracer. The supervisory contact tracer will assign the case (ticket) to the contact tracer. The contact tracer will call the COVID–19 positive employee to verify information submitted by the employee. The Contact Tracer will call the exposed employees to inform them that were exposed to a DHS COVID–19 positive employee so they can take appropriate precautions in minimizing exposure to other DHS personnel and speak with their supervisor to discuss their work status as detailed in response #2.

The basis of the decision for adopting Service Now as a contact tracing reporting/collection tool are: Service now is an existing operating system with an approved Authority to Operate and is in accordance with DHS IT policies, procedures, and controls. Using information technology helps to streamline the process, adds uniformity, and reduces the burden on the contact tracer. The system includes an active directory for all DHS personnel, and contains the data collection, routing, reporting, and tracking capability required to automate contact tracing reporting, case (ticket) assignment and disposition.

This information collection request will not impact small businesses or other small entities.

In response to the Coronavirus Pandemic, public health leaders are calling for communities around the country to ramp up capacity and implement a massive contact tracing effort to control spread of the Coronavirus. The response and recovery from the effect of COVID–19 will continue to present Federal agencies with unprecedented challenges, as well as opportunities for improvement, that require new processes and practices such as COVID–19 Contact Tracing to keep the workforce and the public safe. As DHS plans to reconstitute the workforce, it is essential to have an internal DHS Contact Tracing Program

that protects the workforce and our families. It is also essential to comply with requirements in the President's National Guidelines for all phases of *Opening Up America Again*, the Office of Management and Budget (OMB) M–20–23 Memorandum for Heads of Executive Department, the Centers for Disease Control and Prevention guidance entitled *Get and Keep America Open*, and for DHS to fulfill its overall mission. If DHS does not establish an internal COVID–19 Contact Tracing program capable of quickly identifying, isolating, tracking, and being aware of potential office outbreaks and workforce exposures, COVID–19 can unknowingly spread throughout the DHS workspace and negatively impact mission readiness and National Security.

As required by the COVID–19 Contact Tracing Script, the Contact Tracer is required to read the following statement at the beginning of the call with each respondent: *“Before we begin, I would like to provide you with the following privacy notice: DHS is requesting information as part of this call for the purpose of maintaining and ensuring a healthy workforce and a safe DHS workspace. Further, this information will help the Department in slowing down the spread of COVID–19 by notifying those individuals who may have been exposed to the disease so that they can take appropriate precautions in minimizing exposure to other DHS personnel and DHS-affiliated personnel. As such, DHS may use the information I collect from you to provide notifications to other potentially exposed personnel. No personally identifiable information will be shared on you to those personnel in an identifiable format. However, information contained from this call may be shared with my supervisory contact tracer to ensure data is appropriately collected. In addition, if you report symptoms of COVID–19, this information may be shared with your supervisor so that he or she may work with you on your work status. Further, no personally identifiable information collected from this call will be shared outside of DHS. This collection is voluntary. However, your participation is requested because contact tracing is a key strategy for preventing further spread of COVID–19.”*

The following privacy notice is imprinted on the COVID–19 Contact Tracing script and form:

Warning: This document is FOR OFFICIAL USE ONLY (FOUO). It contains information that may be exempt from public release under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a).

It is to be controlled, stored, handled, transmitted, distributed, and disposed of in accordance with DHS policy relating to FOUO information and is not to be released to the public or other personnel who do not have a valid “need-to-know” without prior approval of an authorized DHS official.

The following Privacy Act Statement is for the Service Now COVID–19 Contact Tracing Reporting Tool

Contact Tracing Privacy Act Statement

Pursuant to 5 U.S.C. 552a(e)(3), this Privacy Act Statement serves to inform you of why DHS is requesting the information that will be collected by this information system.

Authority

DHS is authorized to collect the information pursuant to Section 319 of the Public Health Service (PHS) Act (42 U.S.C. 274d); DHS Chief Medical Officer's authorities pursuant to 6 U.S.C. 350 and 6 U.S.C. 597; 6 U.S.C. 464; 21 U.S.C. 360bbb–3; 40 U.S.C. 1315; 42 U.S.C. 97; American with Disabilities Act, including 42 U.S.C. 12112(d)(3)(B), 29 CFR 602.14, 1630.2(r), 1630.14(b)(1), (c)(1), (d)(4); Medical Examinations for Fitness for Duty Requirements, including 5 CFR part 339; Genetic Information Nondiscrimination Act (GINA), including 42 U.S.C. Chapter 21f, 29 CFR part 1635; Workforce safety federal requirements, including the Occupational Safety and Health Act of 1970, Executive Order 12196, 5 U.S.C. 7902; 29 U.S.C. Chapter 15 (e.g., 29 U.S.C. 668), 29 CFR part 1904, 29 CFR 1910.1020, and 29 CFR 1960.66.

Purpose

DHS will be collecting the information for the purpose of maintaining and ensuring a healthy workforce and a safe DHS workspace. This information will help the Department to prevent the spread of infectious disease by notifying those individuals who may have been exposed so they can take appropriate precautions in minimizing exposure to other DHS personnel and DHS-affiliated personnel.

Routine Uses

The information will not be shared externally or with any third parties. It will only be used by the DHS Component or Office who employs the individual about whom the information will be collected. Further, no personally identifiable information will be shared with anyone other than the individual's supervisor and the assigned contact tracer. A complete list of routine uses for the information this system will

collect can be found in the system of records notice associated with the system “Office of Personnel Management/GOVT–10—Employee Medical File System Records.” The Department's full list of system of records notices can be found on the Department's website at <http://www.dhs.gov/system-records-notices-sorns>.

Consequences of Failure To Provide Information

Providing information via this system is completely voluntary and no adverse action will be taken against individuals who refuse to participate. However, participation is requested because contact tracing is a key strategy in preventing further spread of infectious disease among the DHS workforce.

The Contact Tracer is required to sign a DHS non-Disclosure Agreement and take the following DHS Training—Privacy and Protecting Personal Information, IT Security Awareness and Rules of Behavior, Cybersecurity Awareness and one of the following Contact Tracer Trainings offered by the Michigan Department of Public Health Michigan Department of Public Health <https://www.train.org/wv/course/1091008/>. Additional contact tracing will be available from the Association of State and Territorial Health Officials <https://learn.astho.org/p/ContactTracer> and Johns Hopkins University <https://www.coursera.org/learn/covid-19-contact-tracing?action=enroll&edocomorp=covid-19-contact-tracing>.

The Supervisory Contact Tracer is required to review a minimum of 10% of interview calls with Contact Tracers to ensure comprehensive and high-quality interviews and compliance with privacy and confidentiality.

Explain the reasons for any program changes or adjustments reporting in Items 13 or 14 of the OMB Form 83–I.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who

are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

Analysis

Agency: Department of Homeland Security (DHS).

Title: COVID-19 Contact Tracing.

OMB Number: 1601-0027.

Frequency: Annually.

Affected Public: Affected Public.

Number of Respondents: 500.

Estimated Time per Respondent: 1.

Total Burden Hours: 167.

Robert Dorr,

Executive Director, Business Management Directorate.

[FR Doc. 2021-04320 Filed 3-2-21; 8:45 am]

BILLING CODE 9112-FL-P

DEPARTMENT OF HOMELAND SECURITY

[Docket Number DHS-2020-0047]

Agency Information Collection Activities: DHS Civil Rights Evaluation Tool 1601-0024, DHS Form 3095

AGENCY: Department of Homeland Security, (DHS)

ACTION: 30-Day notice and request for comments; extension without change of a currently approved collection, 1601-0024.

SUMMARY: The Department of Homeland Security, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. DHS previously published this information collection request (ICR) in the **Federal Register** on Thursday, November 19, 2020 at 85 FR 73731 for a 60-day public comment period. No comment was received by DHS. The purpose of this notice is to allow additional 30-days for public comments.

DATES: Comments are encouraged and will be accepted until April 2, 2021. This process is conducted in accordance with 5 CFR 1320.1.

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.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

SUPPLEMENTARY INFORMATION: Recipients of federal financial assistance from the Department of Homeland Security (DHS) are required to meet certain legal requirements relating to nondiscrimination and nondiscriminatory use of federal funds. Those requirements include ensuring that entities receiving Federal financial assistance from the Department of Homeland Security do not deny benefits or services, or otherwise discriminate on the basis of race, color, national origin, disability, age, sex, or religion, in accordance with the following authorities:

- Title VI of the Civil Rights Act of 1964 (Title VI) Public Law 88-352, 42 U.S.C. 2000d-1 *et seq.*, and the Department's implementing regulation, 6 CFR part 21 and 44 CFR part 7, which prohibit discrimination on the grounds of race, color, or national origin by recipients of Federal financial assistance. Title VI, through its prohibition against discrimination on the basis of national origin, requires recipients to take reasonable steps to provide meaningful access to persons who are limited English proficient (LEP). See *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, 76 FR 21755-21768 (April 18, 2011).

- Section 504 of the Rehabilitation Act of 1973 (Section 504), Public Law 93-112, as amended by Public Law 93-

516, 29 U.S.C. 794, which prohibits discrimination on the basis of disability by recipients of Federal financial assistance.

- Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. 1681 *et seq.*, and the Department's implementing regulations, 6 CFR part 17, and 44 CFR part 19, which prohibits discrimination on the basis of sex in education program and activities received Federal financial assistance.

- Age Discrimination Act of 1975, Public Law 94-135, 42 U.S.C. Section 6101 *et seq.*, and the Department implementing regulation at 44 CFR part 7, which prohibits discrimination on the basis of age by recipients of Federal financial assistance.

- U.S. Department of Homeland Security regulation 6 CFR part 19, which prohibits organizations that receive financial assistance from DHS for a social service program from discriminating against beneficiaries on the basis of religion or religious belief, a refusal to hold a religious belief, or a refusal to attend or participate in a religious practice.

The aforementioned civil rights authorities also prohibit retaliatory acts against individuals for participating or opposing discrimination in a complaint, investigation, or other proceeding related to prohibited discrimination.

DHS has an obligation to enforce nondiscrimination requirements to ensure that its federally assisted programs and activities are administered in a nondiscriminatory manner. In order to carry out its enforcement responsibilities, DHS must obtain a signed assurance of compliance and collect and review information from recipients to ascertain their compliance with applicable requirements. DHS implementing regulations and the Department of Justice (DOJ) regulation *Coordination of Non-discrimination in Federally Assisted Program*, 28 CFR part 42, provide for the collection of data and information from recipients (see 28 CFR 42.406).

DHS uses DHS Form 3095: DHS Civil Rights Evaluation Tool as the primary tool to implement this information collection. DHS is seeking an extension of the form for another three-year period. DHS is not proposing any changes to the information collected in the form but is proposing changes to Section 1 of the form on instructions to streamline the process for submitting the completed form.

DHS uses the form to collect civil rights related information from all recipients of federal financial assistance from the Department. Recipients are

non-federal entities that receive federal financial assistance in the form of a grant, cooperative agreement, or other type of financial assistance directly from the Department and not through another recipient or “pass-through” entity. This information collection does not apply to subrecipients, federal contractors (unless the contract includes the provision of financial assistance), nor the ultimate beneficiaries of services, financial aid, or other benefits from the Department.

Recipients are required to provide the information 30 days from acceptance of award. Recipient of multiple awards of DHS financial assistance only submit one completed form for their organization, not per award. Recipient are required to complete the form once every two years if they have an active award, not every time a grant is awarded. Entities whose award does not run a full two years are required to provide the information again if they receive a subsequent award more than two (2) years after the prior award. In responding to *Section 4: Required Information*, which contains the bulk of the information collection, if the recipient's responses have not changed in the two year period since their initial submission, the recipient does not need to resubmit the information. Instead, the recipient will indicate “no change” for each applicable item.

The purpose of the information collection is to advise recipients of their civil rights obligations and collect pertinent civil rights information to ascertain if the recipient has in place adequate policies and procedures to achieve compliance, and to determine what, if any, further action may be needed (technical assistance, training, compliance review, etc.) to ensure the recipient is able to meet its civil rights requirements and will carry out its programs and activities in a nondiscriminatory manner.

Over the past three years, DHS has used the information collected via the DHS Civil Rights Evaluation Tool to identify gaps and deficiencies in recipient programs and directly help recipients address these gaps and deficiencies by providing technical assistance on developing or improving policies and procedures to prevent discrimination and ensure accessibility.

DHS requires recipients to submit their completed forms and supporting information electronically, via email, to the Department, in an effort to minimize administrative burden on the recipient and the Department. DHS anticipates that records or files that will be used to respond to the information collection are already maintained in electronic

format by the recipient, so providing the information electronically further minimizes administrative burden. DHS allows recipients to scan and submit documents that are not already maintained electronically.

If the recipient is unable to submit their information electronically, alternative arrangements will be made to submit responses in hard copy.

DHS is pursuing further streamlining of the submission process through development of an online portal that would allow recipients to submit the data directly in a fully electronic form and eliminate the need for recipients to email the form and supporting documents as attachments.

The information collection will impact some small entities (e.g., non-profit service providers, local fire departments, etc.), however as described in response to Question 2, recipients will only be required to provide this information once every two years, not every time a grant is awarded. Additionally, in responding to Section 4: Required Information, if the recipient's responses have not changed in the two year period since their initial submission, the recipient does not need to resubmit the information. This will dramatically reduce the administrative burden on recipients after the initial submission. Additionally, DHS will further minimize burden on recipients by making available sample policies and procedures to assist recipients in completing Section 4 of the Form, and providing technical assistance directly to the recipient as needed.

In accordance with the authorities identified in Question 1, the Department is required to obtain a signed assurance of compliance from recipients and to ensure that its federally assisted programs and activities are administered in a nondiscriminatory manner. If the information collection is not conducted or is conducted less frequently, the Department will not be able to fulfill its obligations to ascertain recipient compliance and enforce nondiscrimination in recipient programs. This could lead to the award of federal financial assistance to recipients that are not complying with federal civil rights law, and the perpetuation of discrimination in the provision of benefits and services to members of the public.

There are no confidentiality assurances associated with this collection. The only privacy-sensitive information the form collects are the names of Point of Contacts (POCs) from recipient organizations. Coverage for the collection of this information is provided under a Department Privacy

Impact Assessment, DHS/ALL/PIA-006 General Contacts List.

DHS is seeking an extension of the form for another three-year period. DHS is not proposing any changes to the information collected in the form but is proposing changes to Section 1 of the form on instructions to streamline the process for submitting the completed form. The changes to Section 1 do not impact the burden analysis. The changes in costs in Item 14 reflect increased hourly rates for Federal staff as reported by Office of Personnel Management for 2020, as well as an increase in the number of staff participating in the review process. Despite these increases, because the number of recipients subject to the collection has decreased from the previous reporting period, the total costs reported in Item 13 and 14 have also decreased.

Analysis

Agency: Department of Homeland Security, (DHS).

Title: DHS Civil Rights Evaluation Tool.

OMB Number: 1601-0024.

Frequency: On Occasion.

Affected Public: State, Local and Tribal Government.

Number of Respondents: 2929.

Estimated Time per Respondent: 1 Hour.

Total Burden Hours: 11716.

Robert Dorr,

Executive Director, Business Management Directorate.

[FR Doc. 2021-04361 Filed 3-2-21; 8:45 am]

BILLING CODE 9112-FL-P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA-2001-11120]

Extension of Agency Information Collection Activity Under OMB Review: Imposition and Collection of Passenger Civil Aviation Security Service Fees

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652-0001, abstracted below to OMB for review and approval of an extension of the currently approved collection under the

Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection involves air carriers and foreign air carriers maintaining an accounting system to account for the passenger civil aviation security service fees collected and reporting this information to TSA on a quarterly basis, as well as retaining the data used for these reports for three fiscal years.

DATES: Send your comments by April 2, 2021. A comment to OMB is most effective if OMB receives it within 30 days of publication.

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: Christina A. Walsh, TSA PRA Officer, Information Technology (IT), TSA–11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598–6011; telephone (571) 227–2062; email TSAPRA@tsa.dhs.gov.

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on December 14, 2020, 85 FR 80131.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at <http://www.reginfo.gov> upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency’s estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using

appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Imposition and Collection of Passenger Civil Aviation Security Service Fees.

Type of Request: Extension of a currently approved collection.

OMB Control Number: 1652–0001.

Forms(s): TSA Form 2502.

Affected Public: Air carriers and foreign air carriers.

Abstract: TSA regulations, 49 CFR part 1510, require air carriers and foreign air carriers to collect the “September 11th Security Fee” from passengers and to remit the fee to TSA on a monthly basis. Air carriers and foreign air carriers are further required to submit quarterly reports to TSA that provide an accounting of the fees imposed, collected, refunded to passengers, and remitted to TSA and to retain this data for three years. TSA has temporarily suspended an additional requirement for air carriers with over 50,000 passengers to submit annual audits of its fee collections and remittance; this requirement may be reinstated in the future. In December 2013, the fee was statutorily restructured to be based on one-way trips rather than enplanements (the statute was further amended to state that the fee shall be \$5.60 per one-way trip or \$11.20 per round trip.) In 2014 and 2015, TSA published interim final rules to implement these amendments to 49 U.S.C. 44940. *See* 79 FR 35461 (June 20, 2014) and 80 FR 31850 (June 5, 2015), respectively. This information collection request covers both the quarterly reports and the estimated impact should annual audits be reinstated in the future.

Number of Respondents: 170.

Estimated Annual Burden Hours: An estimated 2,760 hours annually.

Dated: February 25, 2021.

Christina A. Walsh,

*TSA Paperwork Reduction Act Officer,
Information Technology.*

[FR Doc. 2021–04335 Filed 3–2–21; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

Notice To Resume the Preparation of a Final Environmental Impact Statement for the Construction and Operations Plan for Vineyard Wind LLC

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice to resume the preparation of a final environmental impact statement.

SUMMARY: The Bureau of Ocean Energy Management (BOEM) is resuming the preparation of a final environmental impact statement (FEIS) for the Construction and Operations Plan (COP) submitted by Vineyard Wind LLC (Vineyard Wind) concerning the construction and operation of an 800-megawatt wind energy facility offshore Massachusetts (Vineyard Wind 1 Project or Project).

DATES: Preparation of the FEIS resumed after BOEM completed its independent review of information provided in Vineyard Wind’s January 22, 2021, letter.

FOR FURTHER INFORMATION CONTACT: For further information, please contact: Michelle Morin, BOEM, Office of Renewable Energy Programs, 45600 Woodland Road, Sterling, Virginia 20166, (703) 787–1722 or michelle.morin@boem.gov.

SUPPLEMENTARY INFORMATION: In December 2017, Vineyard Wind submitted a COP to BOEM for the Vineyard Wind 1 Project. On December 7, 2018, BOEM published a draft EIS for the proposed Project in accordance with the National Environmental Policy Act (NEPA), as amended (42 U.S.C. 4321 *et seq.*). On June 12, 2020, BOEM published a supplement to the draft EIS in response to requests from the public, Federal agencies, and stakeholders for an expanded cumulative analysis and an analysis of fishing data previously unavailable to BOEM. On December 1, 2020, Vineyard Wind withdrew the COP “from further review and decision-making by BOEM pursuant to 30 CFR 585.628” to conduct additional technical and logistical reviews associated with the inclusion of the General Electric Haliade-X wind turbine generator in the final project design. In its letter, Vineyard Wind stated that it required additional time to review updated project parameters to confirm that the parameters fell within the project design envelope previously reviewed during the BOEM NEPA analysis.

In response to Vineyard Wind's December 1, 2020, letter, BOEM published a **Federal Register** notice on December 16, 2020, informing the public that "preparation of an Environmental Impact Statement" for the COP was "no longer necessary" for the sole reason that "the COP ha[d] been withdrawn from review and decisionmaking." See 85 FR 81486 (Dec. 16, 2020). Accordingly, BOEM "terminated" the "preparation and completion" of the EIS. *Id.*

On January 22, 2021, Vineyard Wind notified BOEM via letter that it had completed its technical and logistical due diligence review and had concluded that inclusion of the Haliade-X turbines did not warrant any modifications to the COP. Vineyard Wind therefore informed BOEM that it was rescinding its temporary withdrawal and asked BOEM to resume its review of the COP. Because Vineyard Wind has indicated that its proposed COP is "a decision pending before BOEM," BOEM is resuming its review of the COP under NEPA. *Id.* Vineyard Wind's COP and BOEM's draft and supplemental EISs can be found at: <https://www.boem.gov/vineyard-wind>.

Authority: This notice was prepared under NEPA (42 U.S.C. 4321 *et seq.*) and is published in accordance with Council on Environmental Quality regulations (40 CFR parts 1500–508).

William Y. Brown,

Chief Environmental Officer, Bureau of Ocean Energy Management.

[FR Doc. 2021–04392 Filed 3–2–21; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1203]

Notice of a Commission Determination To Issue a Limited Exclusion Order Against the Defaulting Respondent; Termination of the Investigation; Certain Rolled-Edge Rigid Plastic Food Trays

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined to issue a limited exclusion order against defaulted respondent Ningbo Linhua Plastic Co., Ltd. ("Ningbo"), the last remaining respondent. The Commission has also determined to impose a bond equal to one hundred percent (100%) of the

entered value of the infringing products imported during the period of Presidential review. The investigation is hereby terminated.

FOR FURTHER INFORMATION CONTACT:

Amanda Fisherow, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2737. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 23, 2020, based on a complaint filed by Clearly Clean Products, LLC of South Windsor, Connecticut and Converter Manufacturing, LLC of Orwigsburg, Pennsylvania ("Complainants"). 85 FR 37689–90 (June 23, 2020). The complaint alleges a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337"), by reason of infringement of certain claims of U.S. Patent Nos. 9,908,281 and 10,562,680. The notice of investigation named the following respondents: Eco Food Pak (USA), Inc. of Chino, California ("Eco") and Ningbo Linhua Plastic Co., Ltd. of Fenghua, China ("Ningbo"). The Commission's Office of Unfair Import Investigations ("OUII") also was named as a party.

Eco was terminated from the investigation on October 20, 2020, on the basis of a consent order and consent order stipulation. Comm'n Notice (Oct. 20, 2020).

Also on October 20, 2020, the Commission determined not to review an initial determination ("ID") (Order No. 7) granting Complainants' unopposed motion to find respondent Ningbo in default. Order No. 7 (Oct. 6, 2020), *unreviewed*, Comm'n Notice (Oct. 20, 2020). At that time, the Commission requested briefing on the issues of remedy, bonding, and the public interest with respect to Ningbo. 85 FR 67566–67 (Oct. 23, 2020).

On November 3, 2020, Complainants and OUII filed responses to the Commission's request for briefing. Both parties also filed reply submissions on

November 10, 2020. No other submissions were received.

Upon review of the record, and in the absence of any response from Ningbo or from other interested persons or government agencies, and having concluded that it would not be contrary to the public interest to do so, the Commission has determined to issue a limited exclusion order against Ningbo pursuant to Section 337(g)(1), 19 U.S.C. 1337(g)(1). However, the Commission declines to issue the requested cease and desist order against Ningbo because Complainants have not established that Ningbo maintains a commercially significant inventory in the U.S. or engages in significant commercial business operations in the United States, taking the allegations in the complaint as true, and as supported by the available circumstantial evidence. See *Certain Arrowheads with Deploying Blades and Components Thereof and Packaging Therefor*, Inv. 337–TA–997, Comm'n Op. at 16, 17–20 (Apr. 28, 2017). Exhibits 19 and 20 to the Complaint reflect shipments of "trays" to terminated Respondent Eco, which has entered into a consent order in this investigation, and thus do not suggest ongoing commercial operations necessitating a CDO. Even assuming the shipments to non-parties reflected in Exhibit 19 included infringing products, the latest arrival of said shipments occurred in May 2018, and likewise do not support the inference that Ningbo or its agents *maintain* any, much less commercially significant, inventory in the U.S. See Compl., Ex. 19 at 9; *cf.* *Certain Electric Skin Care Devices, Brushes and Chargers Therefor, and Kits Containing the Same*, Inv. No. 337–TA–959, Comm'n Op. at 32 (Feb. 13, 2017) (evidence of "short lead times between order placement and delivery" and low shipping costs supported the inference that "U.S. purchases of the foreign respondents' infringing products were made from U.S. inventories"). The Commission has determined to set a bond in the amount of one hundred percent (100%) of the entered value of the covered products.

Commissioner Karpel and Commissioner Schmidlein would issue both an LEO and a CDO directed to defaulting respondent Ningbo pursuant to Section 337(g)(1) because all requirements of this provision are met. Ningbo was named in the complaint and was served with the complaint and notice of investigation. See Order No. 7 (Oct. 6, 2020), *unreviewed*, Comm'n Notice (Oct. 20, 2020). The ALJ issued a show cause order ordering Ningbo to show cause why it should not be held in default for failing to respond to the

complaint and notice of investigation. See *id.* Ningbo did not file a response to the show cause order. *Id.* These findings satisfy subsections 337(g)(1)(A)–(D). Complainants requested an LEO and a CDO limited to Ningbo thus satisfying subsection 337(g)(1)(E). Given that subsections 337(g)(1)(A)–(E) are satisfied and Complainants requested these remedies, the statute directs the Commission to issue the requested LEO and CDO, subject to consideration of the public interest. Commissioner Karpel and Commissioner Schmittlein find that the public interest factors set forth in Section 337(g)(1) do not support a finding that these remedies would be contrary to the public interest.

The investigation is hereby terminated.

The Commission vote for this determination took place on February 25, 2021.

While temporary remote operating procedures are in place in response to COVID–19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission orders that the Complainants complete service for any party/parties without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

The authority for the Commission's determination is contained in Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: February 25, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–04312 Filed 3–2–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0104]

Agency Information Collection Activities; Proposed eCollection Comments Requested; Extension With Change, of a Previously Approved Collection District/Aviation Security Officers (DSO/ASO) Personal Qualifications Statement

AGENCY: U.S. Marshals Service, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), U.S. Marshals Service (USMS), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until May 3, 2021.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any additional information, please contact Nicole Timmons either by mail at CG–3, 10th Floor, Washington, DC 20530–0001, by email at Nicole.Timmons@usdoj.gov, or by telephone at 202–236–2646.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection (check justification or form 83):* Extension with change of a currently approved collection.

2. *The Title of the Form/Collection:* District/Aviation Security Officers (DSO/ASO) Personal Qualifications Statement.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): Form USM–234.

Component: U.S. Marshals Service, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: District/Aviation Security Officers Job Applicants.

Other (if applicable): [None].

Abstract: This form will primarily be used to collect applicant reference information. Reference checking is an objective evaluation of an applicant's past job performance based on information collected from key individuals (*e.g.*, supervisors, peers, subordinates) who have known and worked with the applicant. Reference checking is a necessary supplement to the evaluation of resumes and other descriptions of training and experience, and allows the selecting official to hire applicants with a strong history of performance. The questions on this form have been developed following the OPM, MSPB, and DOJ “Best Practice” guidelines for reference checking.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 1,000 respondents will utilize the form, and it will take each respondent approximately 60 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 1,000 hours, which is equal to (1,000 (total # of annual responses) * 1 (60 mins)).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: February 25, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–04323 Filed 3–2–21; 8:45 am]

BILLING CODE 4410–04–P

DEPARTMENT OF JUSTICE**[OMB Number 1125–0010]****Agency Information Collection Activities; Proposed Collection; Comments Requested; Notice of Appeal to the Board of Immigration Appeals From a Decision of a DHS Officer****AGENCY:** Executive Office for Immigration Review, Department of Justice.**ACTION:** 60-Day notice.**SUMMARY:** The Department of Justice (DOJ), Executive Office for Immigration Review (EOIR), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.**DATES:** Comments are encouraged and will be accepted for 60 days until May 3, 2021.**FOR FURTHER INFORMATION CONTACT:** If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2500, Falls Church, VA 22041, telephone: (703) 305–0289.**SUPPLEMENTARY INFORMATION:** Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g.,

permitting electronic submission of responses.

Overview of this information collection:

1. *Type of Information Collection:* Revision and extension of a currently approved collection.

2. *The Title of the Form/Collection:* Notice of Appeal to the Board of Immigration Appeals from a Decision of a DHS Officer.

3. *The agency form number:* EOIR–29 (OMB 1125–0010).

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: A party who appeals a decision of a DHS Officer to the Board of Immigration Appeals (Board).

Other: None.

Abstract: A party affected by a decision of a DHS Officer may appeal that decision to the Board, provided that the Board has jurisdiction pursuant to 8 CFR 1003.1(b). The party must complete the Form EOIR–29 and submit it to the DHS office having administrative control over the record of proceeding in order to exercise its regulatory right to appeal.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 1,664 respondents complete the form annually with an average of 30 minutes per response for completion.

6. *An estimate of the total public burden (in hours) associated with the collection:* 832 annual burden hours.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405B, Washington, DC 20530.

Dated: February 26, 2021.

Melody D. Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–04408 Filed 3–2–21; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF JUSTICE**[OMB Number 1110–0073]****Agency Information Collection Activities; Proposed eCollection, eComments Requested; Crime Data Explorer Feedback Survey****AGENCY:** Federal Bureau of Investigation, Department of Justice.**ACTION:** 30-Day notice.

SUMMARY: The Department of Justice, Federal Bureau of Investigation, Criminal Justice Information Services Division, will be submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until April 2, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Federal Bureau of Investigation, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Crime Data Explorer Feedback Survey.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* There is no form number for this collection. The applicable component within the Department of Justice is the Criminal Justice Information Services

Division, in the Federal Bureau of Investigation.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Law enforcement, academia, and the general public.

Abstract: This survey is needed to collect feedback on the functionality of the Crime Data Explorer in order to make improvements to the application.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The Federal Bureau of Investigation Uniform Crime Reporting Program's Crime Data Explorer Burden Estimation: It is estimated the Crime Data Explorer will generate 200 feedback responses per year with an estimated response time of two minutes per response.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are approximately seven hours, annual burden, associated with this information collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: February 25, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021-04322 Filed 3-2-21; 8:45 am]

BILLING CODE 4410-02-P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA-21-0004; NARA-2021-020]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on [regulations.gov](https://www.regulations.gov) for records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: NARA must receive comments by April 19, 2021.

ADDRESSES: You may submit comments by either of the following methods. You must cite the control number, which appears on the records schedule in parentheses after the name of the agency that submitted the schedule.

• *Federal eRulemaking Portal:* <http://www.regulations.gov>.

• *Mail:* Records Appraisal and Agency Assistance (ACR); National Archives and Records Administration; 8601 Adelphi Road, College Park, MD 20740-6001.

FOR FURTHER INFORMATION CONTACT: Kimberly Keravuori, Regulatory and External Policy Program Manager, by email at regulation_comments@nara.gov. For information about records schedules, contact Records Management Operations by email at request.schedule@nara.gov, by mail at the address above, or by phone at 301-837-1799.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule.

We have uploaded the records schedules and accompanying appraisal memoranda to the [regulations.gov](https://www.regulations.gov) docket for this notice as "other" documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the [regulations.gov](https://www.regulations.gov) portal, you may contact request.schedule@nara.gov for

instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we will post on [regulations.gov](https://www.regulations.gov) a "Consolidated Reply" summarizing the comments, responding to them, and noting any changes we have made to the proposed records schedule. We will then send the schedule for final approval by the Archivist of the United States. You may elect at [regulations.gov](https://www.regulations.gov) to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. If you have a question, you can submit it as a comment, and can also submit any concerns or comments you would have to a possible response to the question. We will address these items in consolidated replies along with any other comments submitted on that schedule.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at <https://www.archives.gov/records-mgmt/rcs>, after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the

Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of Homeland Security, Immigration and Customs Enforcement, Non-Evidentiary Video Audio Records (DAA-0567-2021-0001).

Laurence Brewer,
Chief Records Officer for the U.S.
Government.

[FR Doc. 2021-04311 Filed 3-2-21; 8:45 am]

BILLING CODE 7515-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91211; File No. SR-CBOE-2021-011]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend an Exchange Rule Relating to Inactive Nominees

February 25, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on February 19, 2021, Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b-4(f)(6) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") proposes to amend an Exchange Rule relating to Inactive Nominees. The text of the proposed rule change is provided below.

(additions are *italicized*; deletions are [bracketed])

* * * * *

Rules of Cboe Exchange, Inc.

* * * * *

Rule 3.9. Responsible Persons and Nominees

* * * * *

(e) A TPH organization may designate one or more inactive nominees. An "inactive nominee" of a TPH organization is an individual who is eligible to become an effective nominee of that organization with respect to any Floor Broker Trading Permit or Market-Maker Floor Trading Permit which the organization holds. The following requirements shall apply to inactive nominees:

(1) To become an inactive nominee of a TPH organization, an individual must be approved to be a Trading Permit Holder and become an effective nominee of the TPH organization, with authorized trading functions, within 90 days of the approval to be a Trading Permit Holder;

(2) an individual may be an inactive nominee of only one TPH organization; and

(3) an inactive nominee shall have no rights or privileges of a Trading Permit Holder and shall have no right of access to the trading floor of the Exchange to trade as a Trading Permit Holder, unless and until the inactive nominee becomes an effective Trading Permit Holder pursuant to Rule 3.11.1; and

(4) if at any time an individual remains an inactive nominee for 9 consecutive months, the individual's eligibility to be a Trading Permit Holder will be terminated and the individual must reapply to be a Trading Permit Holder in order to again become eligible for inactive nominee status.]

* * * * *

The text of the proposed rule change is also available on the Exchange's website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend a certain requirement related to inactive nominees. Specifically, the Exchange

proposes to amend Cboe Options Rule 3.9 (Responsible Persons and Nominees) with respect to inactive nominee status. By way of background, an inactive nominee is an individual who is eligible to become an effective nominee of that organization with respect to any Floor Broker Trading Permit or Market-Maker Floor Trading Permit which the organization holds.⁵ An inactive nominee shall have no rights or privileges of a TPH and shall have no right of access to the trading floor of the Exchange to trade as a TPH, unless and until the inactive nominee becomes an effective TPH.⁶ To become an inactive nominee of a TPH organization, an individual must be approved to be a TPH and become an effective nominee of the TPH organization, with authorized trading functions, within 90 days of the approval to be a TPH.⁷ Additionally, if at any time an individual remains an inactive nominee for 9 consecutive months, the individual's eligibility to be a TPH will be terminated and the individual must reapply to be a TPH in order to again become eligible for inactive nominee status.⁸

The Exchange proposes to eliminate Rule 3.9(e)(4) which provides that if an individual remains an inactive nominee for 9 consecutive months, the individual's eligibility to be a TPH will be terminated and the individual must reapply to be a TPH in order to again become eligible for inactive nominee status. Particularly, the Exchange doesn't believe the 9-month inactive status deadline adds any meaningful value, but rather is an arbitrary administrative requirement that the Exchange believes is unnecessary and no longer wishes to (nor does it believe is required to) maintain. For example, if a TPH organization wishes to add a new inactive nominee, such organization can merely request that the Exchange make that individual "effective" in the System and then request that the nominee be switched to the inactive status in the system just moments later to restart the clock. The Exchange does not believe such a deadline is necessary and therefore does not wish to maintain it.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange

⁵ See Cboe Rule 3.9(e).

⁶ See Cboe Rule 3.9(e)(3).

⁷ See Cboe Rule 3.9(e)(1).

⁸ See Cboe Rule 3.9(e)(4).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b-4(f)(6).

and, in particular, the requirements of Section 6(b) of the Act.⁹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁰ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹¹ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system by eliminating an arbitrary and administrative process that the Exchange believes is outdated and an administrative burden to both TPHs and the Exchange. As noted above, the Exchange also does not believe such requirement adds meaningful value. The Exchange also does not believe it's required to maintain the requirement and notes that other exchanges similarly do not include such requirement. The Exchange notes that it is not substantively changing any rights or obligations of nominees of floor Trading Permits.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed change applies to all TPHs. The proposed rule change also does not address competitive issues, but rather, amends a requirement relating to nominees, particularly inactive nominees, to eliminate a practice that the Exchange no longer believes is necessary. The Exchange does not

believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed change only affects TPHs of Cboe Options.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹² and Rule 19b-4(f)(6) thereunder.¹³ Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; or (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁴ and Rule 19b-4(f)(6)(iii) thereunder.¹⁵

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CBOE-2021-011 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

¹² 15 U.S.C. 78s(b)(3)(A)(iii).

¹³ 17 CFR 240.19b-4(f)(6).

¹⁴ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁵ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has complied with this requirement.

Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-CBOE-2021-011. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. All submissions should refer to File Number SR-CBOE-2021-011 and should be submitted on or before March 24, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-04309 Filed 3-2-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94-409, that the Securities and Exchange Commission Investor Advisory Committee will hold a public meeting on Thursday, March 11, 2021. The meeting will begin at 10:00 a.m. (ET) and will be open to the public.

¹⁶ 17 CFR 200.30-3(a)(12).

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

¹¹ *Id.*

PLACE: The meeting will be conducted by remote means and/or at the Commission's headquarters, 100 F St. NE, Washington, DC 20549. Members of the public may watch the webcast of the meeting on the Commission's website at www.sec.gov.

STATUS: This Sunshine Act notice is being issued because a majority of the Commission may attend the meeting. On February 17, 2021, the Commission published notice of the Committee meeting (Release Nos. 33–10927, 34–91150), indicating that the meeting is open to the public and inviting the public to submit written comments to the Committee.

MATTER TO BE CONSIDERED: The agenda for the meeting includes: Welcome remarks; approval of previous meeting minutes; a follow-on panel discussion regarding self-directed individual retirement accounts (IRAs); a panel discussion regarding special purpose acquisition companies (SPACs); a discussion of a recommendation regarding minority and underserved inclusion; a discussion of a recommendation regarding credit rating agencies; subcommittee reports; and a non-public administrative session.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Dated: March 1, 2021.

Vanessa A. Countryman,
Secretary.

[FR Doc. 2021–04490 Filed 3–1–21; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91214; File No. 265–33]

Asset Management Advisory Committee

AGENCY: Securities and Exchange Commission.

ACTION: Notice of meeting.

SUMMARY: Notice is being provided that the Securities and Exchange Commission Asset Management Advisory Committee (“AMAC”) will hold a public meeting on March 19, 2021, by remote means. The meeting will begin at 9 a.m. (ET) and will be open to the public via webcast on the Commission's website at www.sec.gov. Persons needing special accommodations to take part because of a disability should notify the contact person listed below. The public is

invited to submit written statements to the Committee. The meeting will include a discussion of matters in the asset management industry relating to: (1) The ESG Subcommittee, including a panel discussion on that Subcommittee's potential recommendations of December 1, 2020; (2) the Diversity & Inclusion and Private Investments Subcommittees, including potential recommendations from those Subcommittees; and (3) AMAC's agenda for 2021.

DATES: The public meeting will be held on March 19, 2021. Written statements should be received on or before March 15, 2021.

ADDRESSES: The meeting will be held by remote means and webcast on www.sec.gov. Written statements may be submitted by any of the following methods. To help us process and review your statement more efficiently, please use only one method. At this time, electronic statements are preferred.

Electronic Statements

- Use the Commission's internet submission form (<http://www.sec.gov/rules/other.shtml>); or
- Send an email message to rule-comments@sec.gov. Please include File Number 265–33 on the subject line; or

Paper Statements

- Send paper statements to Vanessa Countryman, Federal Advisory Committee Management Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. 265–33. This file number should be included on the subject line if email is used. The Commission will post all statements on the Commission's website at (<http://www.sec.gov/comments/265-33/265-33.htm>).

Statements also will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Room 1580, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. For up-to-date information on the availability of the Public Reference Room, please refer to <https://www.sec.gov/fast-answers/answerspublicdocshrm.html> or call (202) 551–5450.

All statements received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Christian Broadbent, Senior Special Counsel, or Jay Williamson, Branch Chief, at (202) 551–6720, Division of Investment Management, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–3628.

SUPPLEMENTARY INFORMATION: In accordance with Section 10(a) of the Federal Advisory Committee Act, 5 U.S.C.-App. 1, and the regulations thereunder, Sarah ten Siethoff, Designated Federal Officer of the Committee, has ordered publication of this notice.

Dated: February 26, 2021.

Vanessa A. Countryman,

Committee Management Officer.

[FR Doc. 2021–04394 Filed 3–2–21; 8:45 am]

BILLING CODE P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91210; File No. SR–NYSEArca–2021–14]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Regarding the Listing and Trading Rule for Shares of the Alger 25 ETF

February 25, 2021.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (“Act”) ² and Rule 19b–4 thereunder, ³ notice is hereby given that, on February 22, 2021, NYSE Arca, Inc. (“NYSE Arca” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to update certain representations regarding the Alger 25 ETF (the “Fund”). The Securities and Exchange Commission (“Commission”) has approved listing and trading of shares of the Fund on the Exchange under NYSE Arca Rule 8.900–E (Managed Portfolio Shares). ⁴ Shares of the Fund have not commenced listing and trading on the Exchange. The

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

⁴ See note 5, *infra*.

proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Commission has approved a proposed rule change relating to listing and trading on the Exchange of shares ("Shares") of the Fund under NYSE Arca Rule 8.900–E,⁵ which governs the listing and trading of Managed Portfolio Shares on the Exchange.⁶ The Shares of the Fund were to be issued by The Alger ETF Trust (the "Trust"), which is registered with the Commission as an

⁵ See Securities Exchange Act Release No. 90528 (November 30, 2020), 85 FR 78389 (December 4, 2020) (SR–NYSEArca–2020–80) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 2, to List and Trade Shares of Alger Mid Cap 40 ETF and Alger 25 ETF under NYSE Arca Rule 8.900–E) (the "Prior Order"); see also Amendment No. 2 to SR–NYSEArca–2020–80, available at <https://www.sec.gov/comments/sr-nysearca-2020-80/srnysearca202080-7985015-225090.pdf> (the "Prior Filing").

⁶ NYSE Arca Rule 8.900–E provides that a Managed Portfolio Share is security that (a) represents an interest in an investment company registered under the Investment Company Act of 1940 ("Investment Company") organized as an open-end management investment company that invests in a portfolio of securities selected by the Investment Company's investment adviser consistent with the Investment Company's investment objectives and policies; (b) is issued in a Creation Unit, or multiples thereof, in return for a designated portfolio of instruments (and/or an amount of cash) with a value equal to the next determined net asset value and delivered to the Authorized Participant (as defined in the Investment Company's Form N–1A filed with the Commission) through a Confidential Account; (c) when aggregated into a Redemption Unit, or multiples thereof, may be redeemed for a designated portfolio of instruments (and/or an amount of cash) with a value equal to the next determined net asset value delivered to the Confidential Account for the benefit of the Authorized Participant; and (d) the portfolio holdings for which are disclosed within at least 60 days following the end of every fiscal quarter.

open-end management investment company.⁷ Shares of the Fund have not commenced listing and trading on the Exchange.

The Exchange proposes to update two representations made in the Prior Filing and the Prior Order relating to the Fund. The Exchange proposes to (1) update the name of the Fund to the Alger 35 ETF and (2) update the number of holdings that the Fund will generally own to approximately 35, rather than approximately 25 as represented in the Prior Filing. The Prior Filing represented that the Fund's primary objective is to seek long-term capital appreciation and that the Fund will primarily invest in equity securities of growth companies of any market capitalization listed on U.S. exchanges, including common or preferred stocks, and these representations are unchanged with respect to the Alger 35 ETF. The Alger 35 ETF will differ from the Fund only in that it will generally own approximately 35 holdings, instead of approximately 25 holdings.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)⁸ that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

This proposed rule change merely updates the name of the Fund and the approximate number of holdings that the Fund will own, in accordance with the Registration Statement. Other than this proposed change, all statements in the Prior Filing remain unchanged, including that the Alger 35 ETF will have the same investment objectives as

⁷ The Trust is registered under the Investment Company Act of 1940 (the "1940 Act"). On August 17, 2020, the Trust filed a registration statement on Form N–1A under the Securities Act of 1933 (the "1933 Act") and the 1940 Act for the Alger Mid Cap 40 ETF and the Alger 25 ETF (File No. 811–23603). On February 19, 2021, the Trust filed an amended registration statement on Form N–1A under the 1933 Act and 1940 Act for the Alger Mid Cap 40 ETF and the Alger 35 ETF (File Nos. 811–23603 and 333–248085) (the "Registration Statement"). In response to the Trust's application for exemptive relief (File No. 812–15117), the Commission issued an order granting such relief to the Trust under the 1940 Act on May 19, 2020 (Investment Company Act Release No. 33869). The description of the operation of the Trust and the Alger 35 ETF, formerly known as the Alger 25 ETF, herein is based, in part, on the Registration Statement. The Exchange will not commence trading in shares of the Alger 35 ETF until the Registration Statement is effective.

⁸ 15 U.S.C. 78f(b)(5).

the Fund and will invest in the same types of securities as the Fund. Accordingly, the Exchange believes that this proposed rule change raises no novel regulatory issues.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The proposed change does not introduce a new product, but rather proposes to update representations regarding the Fund that would not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act⁹ and Rule 19b–4(f)(6) thereunder.¹⁰ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)¹¹ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),¹² the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing to accommodate the listing and trading of the Shares of the Alger 35

⁹ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁰ 17 CFR 240.19b–4(f)(6).

¹¹ 17 CFR 240.19b–4(f)(6).

¹² 17 CFR 240.19b–4(f)(6)(iii).

ETF on the Exchange prior to 30 days after the date of the filing. The Shares of the Fund have not yet commenced listing and trading, and the proposed changes to the rule governing their listing and trading raise no novel or regulatory issues. For these reasons, the Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest, and the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing.¹³

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSEArca-2021-14 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-NYSEArca-2021-14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than

those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEArca-2021-14 and should be submitted on or before March 24, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-04308 Filed 3-2-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91212; File No. SR-NASDAQ-2020-100]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Modify the Quorum Requirement for Non-U.S. Companies Under Certain Limited Circumstances

February 25, 2021.

On December 31, 2020, the Nasdaq Stock Market LLC filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to modify the quorum requirement applicable to a non-U.S. company where such company's home country law is in direct conflict with Nasdaq's quorum requirement. The proposed rule change was published for comment in the **Federal Register** on January 15, 2021.³ The Commission has received no

comment letters on the proposed rule change.

Section 19(b)(2) of the Act⁴ provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and published its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for the proposed rule change is March 1, 2021. The Commission is extending this 45-day period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, pursuant to Section 19(b)(2) of the Act,⁵ the Commission designates April 15, 2021, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change (File No. SR-NASDAQ-2020-100).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021-04310 Filed 3-2-21; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-91208; File No. SR-NASDAQ-2021-009]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Proposed Rule Change To Amend Rule 4754 Relating to the Limit-Up Limit-Down Closing Cross

February 25, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on February 11, 2021, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission

¹³ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹⁴ 17 CFR 200.30-3(a)(12).

¹⁵ 15 U.S.C. 78s(b)(1).

¹⁷ 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 90883 (January 11, 2021), 86 FR 4158.

⁴ 15 U.S.C. 78s(b)(2).

⁵ 15 U.S.C. 78s(b)(2).

⁶ 17 CFR 200.30-3(a)(31).

¹⁵ 15 U.S.C. 78s(b)(1).

²⁷ 17 CFR 240.19b-4.

(“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 4754 to introduce price protections for the Limit-Up Limit-Down (“LULD”) Closing Cross³ that are similar to the protections currently employed by the standard Nasdaq Closing Cross,⁴ and to make other changes related to the LULD Closing Cross.

The text of the proposed rule change is available on the Exchange’s website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rules>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend Rule 4754 to introduce price protections for the LULD Closing Cross that are similar to the protections currently employed by the standard Nasdaq Closing Cross, and to make other changes related to the LULD Closing Cross. With the proposed changes, the Exchange’s LULD and standard Closing Cross processes will be more harmonized, which the Exchange believes will promote a more consistent

experience for members and investors participating in the close and reduce any potential confusion regarding Nasdaq’s closing processes.

Background

The Nasdaq Closing Cross is a transparent auction process that determines a single price for the close. The price determined by the Closing Cross is also the Nasdaq Official Closing Price (“NOCP”) for securities that participate in the cross. Members can submit Limit on Close (“LOC”) Orders,⁵ Market on Close (“MOC”) Orders,⁶ and Imbalance Only (“IO”) Orders⁷ that are available to participate in the Closing Cross along with other Close Eligible Interest.⁸ At 4:00 p.m. ET, the Exchange will execute the Nasdaq Closing Cross at a price determined in accordance with Rule 4754(b)(2).

When the Closing Cross price is calculated as described in Rule 4754(b)(2), the Exchange applies a boundary within which the cross must execute to ensure that the closing price derived does not exceed a price reasonably tied to the prevailing market at the time. Specifically, the Exchange applies a threshold amount to a benchmark value that, when applied to an individual security, determines the threshold price range that a security may cross, outside of which the closing price of a security may not occur.⁹ If the Closing Cross price of a security would otherwise be outside of this threshold range, the Exchange will adjust the Closing Cross price of the security to a price within the threshold range that best satisfies the normal process for determining the Closing Cross price.¹⁰ This adjustment happens automatically prior to execution of the Closing Cross. All unexecuted shares designated to expire upon the conclusion of the Closing Cross,¹¹ including those that fall

outside of the calculated threshold price range, are cancelled.

The threshold amounts and benchmarks are set by Nasdaq management in advance and communicated to market participants. Nasdaq may adjust the threshold amounts and benchmarks from time to time based on Nasdaq’s experience with the Closing Cross. Nasdaq publishes this information publicly on its website, and sets the threshold amount so that repricing of a security is rare.¹² Currently, Nasdaq applies a threshold amount that is the greater of \$0.50 or 10%, which is applied to the Nasdaq Best Bid and Offer (“QBBO”) midpoint and is added to the Nasdaq Offer and subtracted from the Nasdaq Bid to establish the threshold range. For example, if the QBBO is \$10.00 × \$11.00, then the midpoint is \$10.50 and the threshold amount is 10%, resulting in a threshold value of \$1.05 (10% of 10.50 = 1.05). This value is then added to the offer and subtracted from the bid to obtain the Closing Cross’s threshold price range. In this example, it would result in a lower threshold of \$8.95 (10.00 – 1.05 = 8.95) and an upper threshold of \$12.05 (11.00 + 1.05 = 12.05), thus creating a range between \$8.95 to \$12.05, within which the Closing Cross can occur. This means \$8.95 is the lowest price at which the cross can occur, and \$12.05 is the highest price at which it can occur. The threshold range is dynamic; as the QBBO changes, the threshold price range changes. The Exchange believes that the foregoing price thresholds for the standard Closing Cross has been effective at facilitating price discovery and ensuring that the closing price of a security is reasonably based on current market conditions in the security, and therefore proposes to adopt similar thresholds for its LULD Closing Cross.

Today, in addition to the standard Nasdaq Closing Cross described above, the Exchange operates a LULD Closing Cross that provides an alternative process for executing closing trades on Nasdaq. The Exchange conducts this process (instead of the standard Closing Cross) for Nasdaq-listed securities when a Trading Pause pursuant to Rule 4120(a)(12) exists at or after 3:50 p.m.

continuous order book and a Closing Cross order book. Orders in the Closing Cross order book may execute only in the Closing Cross process, while Orders in the continuous book may execute in regular market hours or in the Closing Cross if the Order has a time-in-force that will allow it to remain active.

¹² See http://www.nasdaqtrader.com/content/ProductsServices/Trading/Crosses/openclose_faqs.pdf.

⁵ A “Limit On Close Order” or “LOC Order” is an Order Type entered with a price that may be executed only in the Nasdaq Closing Cross, and only if the price determined by the Nasdaq Closing Cross is equal to or better than the price at which the LOC Order was entered. See Rule 4702(b)(12).

⁶ A “Market On Close Order” or “MOC Order” is an Order Type entered without a price that may be executed only during the Nasdaq Closing Cross. See Rule 4702(b)(11).

⁷ An “Imbalance Only Order” or “IO Order” is an Order entered with a price that may be executed only in the Nasdaq Closing Cross and only against MOC Orders or LOC Orders. See Rule 4702(b)(13).

⁸ “Close Eligible Interest” shall mean any quotation or any order that may be entered into the system and designated with a time-in-force of SDAY, SGTC, MDAY, MGTC, SHEX, or GTMC. See Rule 4754(a)(1).

⁹ See Rule 4754(b)(2)(E).

¹⁰ See Rules 4754(b)(2)(A)–(D).

¹¹ These are: MOC, LOC, and IO Orders designated to participate in the Closing Cross. Prior to the Closing Cross, the Exchange maintains a

³ The LULD Closing Cross is the Exchange’s auction process for executing closing trades in Nasdaq-listed securities when a Trading Pause pursuant to Rule 4120(a)(12) exists at or after 3:50 p.m. and before 4:00 p.m. ET. See Rule 4754(b)(6).

⁴ “Nasdaq Closing Cross” shall mean the process for determining the price at which orders shall be executed at the close and for executing those orders. See Rule 4754(a).

and before 4:00 p.m. ET.¹³ The LULD Closing Cross price will be the NOCP for Nasdaq-listed securities that participate in the LULD Closing Cross. Unlike the standard Closing Cross, the LULD Closing Cross currently occurs at 4:00 p.m. ET, with no price thresholds, and may be extended pursuant to Rule 4754(b)(6)(A)(iii) if there is an order imbalance. In this case, the Exchange would extend the time of the LULD Closing Cross in one minute increments until the order imbalance no longer exists.¹⁴ If this condition persists until 5:00 p.m., Nasdaq would not conduct a cross in that security and would instead use the last-sale on Nasdaq as the NOCP in that security for that trading day.

Price Thresholds

The Exchange now proposes to introduce price protections to the LULD Closing Cross that will be similar to the protections used today for the standard Closing Cross, and will ensure that the LULD Closing Cross price is reasonably related to current market conditions.

The proposed price thresholds will be calculated by applying a threshold amount set by Nasdaq management in advance and communicated to market participants ("LULD Price Thresholds"). The LULD Price Thresholds, like the thresholds presently used for the standard Closing Cross, will be published on Nasdaq's public website. The LULD Price Thresholds will be applied to a benchmark associated with the LULD Band that triggered the Trading Pause to calculate the benchmark price range within which the LULD Closing Cross price must fall ("Benchmark Prices"). The Benchmark Prices will be published via the SIP and Exchange proprietary data feeds. Nasdaq will initially set the LULD Price Thresholds at the greater of \$1.00 or 10% for securities with a reference price greater than \$1.00 (or \$0.50 for securities with a benchmark equal to or less than \$1.00), which will be applied to the last disseminated LULD Auction Collar, or the LULD Band that triggered the Trading Pause in the direction of the trading that invoked the Trading Pause.

To effect these changes, the Exchange proposes in new paragraph (E) of Rule

4754(b)(6)¹⁵ to provide that the Benchmark Prices within which the LULD Closing Cross price must fall is established by adding (or subtracting) a threshold amount from the:

(i) Upper (or lower) Auction Collar that was last updated for any security that enters a Trading Pause that was extended prior to 3:50 p.m. ET, rounded to the nearest minimum price increment;

(ii) Upper Auction Collar for a Limit Up triggered pause (or lower Auction Collar for a Limit Down triggered pause) for any security that entered a Trading Pause that was not extended prior to 3:50 p.m. ET, rounded to the nearest minimum price increment; or

(iii) [sic] Upper Band for a Limit Up triggered pause (or Lower Band for a Limit Down triggered pause) for any security that entered a Trading Pause at or after 3:50 p.m. ET, rounded to the nearest minimum price increment.

Nasdaq management shall set and modify such thresholds from time to time upon prior notice to market participants.

As applied, for securities that entered a Trading Pause prior to 3:50 p.m. ET and for which the Trading Pause was subsequently extended, the Exchange will calculate the lower and upper Benchmark Prices as follows:

- If the lower Auction Collar was the collar that was last widened for the security subject to the Trading Pause, the lower Benchmark Price will be calculated by subtracting 10% of the last updated lower Auction Collar price (or \$1.00 (or \$0.50 if the lower Auction Collar price is equal to or below \$1.00), whichever is greater) from the last updated lower Auction Collar price (rounded to the nearest minimum price increment). The upper Benchmark Price will be equal to the last updated upper Auction Collar price that was updated with the lower Auction Collar price used to calculate the lower Benchmark Price.

- If the upper Auction Collar was the collar that was last widened for the security subject to the Trading Pause, the upper Benchmark Price will be calculated by adding 10% of the last updated upper Auction Collar price (or \$1.00 (or \$0.50 if the upper Auction Collar price is equal to or below \$1.00), whichever is greater) to the last updated upper Auction Collar price (rounded to the nearest minimum price increment). The lower Benchmark Price will be equal to the last updated lower Auction Collar price that was updated with the

upper Auction Collar price used to calculate the upper Benchmark Price.

For securities that entered a Trading Pause that was not extended prior to 3:50 p.m. ET,¹⁶ the Exchange will calculate the lower and upper Benchmark Prices as follows:

- For a Limit Down triggered pause, the lower Benchmark Price will be calculated by subtracting 10% of the lower Auction Collar price (or \$1.00 (or \$0.50 if the lower Auction Collar price is equal to or below \$1.00), whichever is greater) from the lower Auction Collar price (rounded to the nearest minimum price increment). The upper Benchmark Price will be equal to the upper Auction Collar price that was disseminated with the lower Auction Collar price used to calculate the lower Benchmark Price.

- For a Limit Up triggered pause, the upper Benchmark Price will be calculated by adding 10% of the upper Auction Collar price (or \$1.00 (or \$0.50 if the upper Auction Collar price is equal to or below \$1.00), whichever is greater) to the upper Auction Collar price (rounded to the nearest minimum price increment). The lower Benchmark Price will be equal to the lower Auction Collar price that was disseminated with the upper Auction Collar price used to calculate the upper Benchmark Price.

For securities that entered a Trading Pause at or after 3:50 p.m. ET, the Exchange will calculate the lower and upper Benchmark Prices as follows:

- For a Limit Down triggered pause, the lower Benchmark Price will be calculated by subtracting 10% of the Lower LULD Band (or \$1.00 (or \$0.50 if the Lower LULD Band is equal to or below \$1.00), whichever is greater) from the Lower LULD Band (rounded to the nearest minimum price increment). The upper Benchmark Price will be equal to Upper LULD Band in place at the time the Trading Pause was triggered.

- For a Limit Up triggered pause, the upper Benchmark Price will be calculated by adding 10% of the Upper LULD Band (or \$1.00 (or \$0.50 if the Upper LULD Band is equal to or below \$1.00), whichever is greater) to the Upper LULD Band (rounded to the nearest minimum price increment). The lower Benchmark Price will be equal to Lower LULD Band in place at the time the Trading Pause was triggered.

At 4:00 p.m. ET, Nasdaq will conduct the LULD Closing Cross, and if the cross price would fall outside of the Benchmark Prices as calculated above, the LULD Closing Cross will execute all

¹³ See Rule 4754(b)(6). While the current language indicates that the "stock" will resume trading via the LULD Closing Cross, the Exchange will amend this Rule to make clear that the LULD Closing Cross will apply only for Nasdaq-listed securities.

¹⁴ Specifically, if the expected cross price moves the greater of 5% or 50 cents, or if all market orders will not be executed in the cross, Nasdaq will delay the execution of the LULD Closing Cross pursuant to Rule 4754(b)(6)(A)(iii). These volatility checks are governed by Rule 4120(c)(7)(C).

¹⁵ With the proposed change, current paragraphs (C) and (D) will be renumbered as paragraphs (F) and (G).

¹⁶ This would occur if, for example, a security entered a Trading Pause between 3:45 and 3:50 p.m. ET, and the LULD Auction Collar had not yet been updated.

available orders at a price within or equal to the Benchmark Prices. Any unexecuted orders intended for the Closing Cross (*i.e.*, MOC, LOC, and IO Orders), including those that fall outside of the Benchmark Prices, will be cancelled. This will be similar to the current standard Closing Cross functionality as described above. All other orders not executed in the LULD Closing Cross will be processed according to the entering firm's instructions, consistent with the current LULD Closing Cross rule.

The following illustrate how the proposed Benchmark Prices will be calculated:

Example 1: Security Enters Trading Pause Prior to 3:50 p.m.

Assume:

Symbol ABC is a Tier 1 security
Last sale/reference price: \$100
LULD price bands: $\$95 \times \105
NBBO updates to $\$94.50 \times \95

At 3:38 p.m., Symbol ABC enters a Trading Pause

LULD Auction Collars calculated:

Upper Collar: \$105

Lower Collar: \$90.25

At 3:43 p.m., due to a market order imbalance, the LULD halt cross will not occur and the LULD Auction Collars (1st extension) are calculated:

Upper Collar: \$105

Lower Collar: \$85.50

At 3:48 p.m., due to a market order imbalance, the LULD halt cross will not occur and the LULD Auction Collars (2nd extension) are calculated:

Upper Collar: \$105

Lower Collar: \$80.75

At 3:50 p.m., the security enters a LULD Closing Cross and the Benchmark Prices will be calculated:

Upper Benchmark Price: \$105

Lower Benchmark Price: \$72.68

Here, the lower Auction Collar is the collar that was widened in the last dissemination of the LULD Auction Collars message, so the Benchmark Prices will be calculated from the last updated lower Auction Collar (\$80.75). The threshold amount is 8.075 (10% of $80.75 = 8.075$), which is subtracted from the last updated Auction Collar (rounded to the nearest price increment) to calculate the lower Benchmark Price of 72.68 ($80.75 - 8.075 = 72.675$) (*i.e.*, 72.68 when rounded to the nearest price increment). The upper Benchmark Price of \$105 is equal to the last updated upper Auction Collar price that was disseminated with the lower Auction Collar price used to calculate the lower Benchmark Price. Thus, \$72.68 is the lowest price at which the LULD Closing

Cross can occur, and \$105 is the highest price at which the cross can occur.

Example 2: Security Enters Trading Pause After 3:50 p.m.

Assume:

Symbol ABC is a Tier 1 security

Last sale/reference price: \$100

LULD price bands: $\$95 \times \105

NBBO updates to $\$94.50 \times \95

At 3:53 p.m., Symbol ABC enters a Trading Pause and will go through a LULD Closing Cross.

The Benchmark Prices will be calculated:

Upper Benchmark Price: \$105

Lower Benchmark Price: \$85.50

Here, the security entered a Limit Down triggered pause, so the Benchmark Prices will be calculated from the Lower LULD Band (\$95). The threshold amount is 9.50 (10% of $95 = 9.50$), which is subtracted from the Lower LULD Band to calculate the lower Benchmark Price of 85.50 ($95 \times 9.50 = 85.50$). The upper Benchmark Price of \$105 is equal to the Upper LULD Band in place at the time the Trading Pause was triggered. Thus, \$85.50 is the lowest price at which the LULD Closing Cross can occur, and \$105 is the highest price at which the cross can occur.

Execution Processing

In connection with the changes proposed above to introduce price protections for the LULD Closing Cross, the Exchange proposes to amend the methodology for determining the LULD cross price. Specifically, the Exchange proposes the following in new paragraph (D) of Rule 4754(b)(6):

(D)(i) The LULD Closing Cross will occur at the price within the benchmark prices established pursuant to paragraph (E) below ("Benchmark Prices") that maximizes the number of shares of Eligible Interest in the Nasdaq Market Center to be executed.

(ii) If more than one price exists under subparagraph (i), the LULD Closing Cross shall occur at the price within the Benchmark Prices that minimizes any Imbalance.

(iii) If more than one price exists under subparagraph (ii), the LULD Closing Cross shall occur at the entered price within the Benchmark Prices at which shares will remain unexecuted in the cross.

(iv) If there is no price within the Benchmark Prices that satisfies the above conditions, then the LULD Closing Cross shall occur at:

(a) If an Imbalance exists, a price equal to the upper (lower) Benchmark Price for a buy (sell) Imbalance; or
(b) if no Imbalance exists, a price that minimizes the distance from the last

published Upper Band (Lower Band) for a Limit Up (Limit Down) Trading Pause.

Today, the LULD Closing Cross price is determined by the same execution algorithm as currently used by the standard Closing Cross.¹⁷ As discussed below, the proposed execution algorithm retains many aspects of the standard cross methodology with certain intended differences.

The first tiebreaker in new paragraph (D)(i) will be substantially similar to the existing tiebreaker in Rule 4754(b)(2)(A),¹⁸ except that the proposed language will specify the LULD cross price must also fall within the proposed Benchmark Prices established pursuant to new paragraph (E) of Rule 4754(b)(6). In connection with this change, the Exchange also proposes to add a definition for "Eligible Interest," which is currently undefined in this Rule. Specifically, the Exchange proposes to add in new paragraph (A)(i) of Rule 4754(b)(6) that for purposes of the LULD Closing Cross rule, Eligible Interest shall have the same meaning as "Close Eligible Interest" in Rule 4754(a), with the addition of any new orders, with an eligible underlying Order Type and Attribute, entered during the Trading Pause. The proposed change reflects current system behavior, and indicates that there is an additional category of orders that may participate in the LULD Closing Cross (*i.e.*, new incoming orders, with an eligible underlying Order Type and Attribute, entered during the Trading Pause), which are not fully applicable in the context of the standard close. The Exchange therefore believes that using the proposed definition throughout the LULD Closing Cross rule (instead of "Close Eligible Interest" as currently used in the standard Closing Cross) will better align the rule to the current operation of the system.

The second tiebreaker in new paragraph (D)(ii) will be based on the same principle as the existing tiebreaker in Rule 4754(b)(2)(B) (*i.e.*, to minimize the number of shares that cannot be matched in the cross).¹⁹ However, the new tiebreaker will specify that the LULD Closing Cross price must be within the proposed Benchmark Prices

¹⁷ See Rule 4754(b)(2)(A)-(D).

¹⁸ Rule 4754(b)(2)(A) currently provides that the Nasdaq Closing Cross will occur at the price that maximizes the number of shares of Eligible Interest in the Nasdaq Market Center to be executed.

¹⁹ Rule 4754(b)(2)(B) currently provides that if more than one price exists under subparagraph (A), the Nasdaq Closing Cross shall occur at the price that minimizes the number of shares of buy or sell MOC or LOC orders that cannot be matched with other MOC or LOC, Close Eligible interest, or IO order shares.

and at the price that minimizes any Imbalance, which will be defined in new paragraph (A)(ii) of Rule 4754(b)(6) as the number of shares of buy or sell MOC or LOC orders or Eligible Interest that cannot be matched with other MOC, LOC, or IO order shares or Eligible Interest at a particular price at any given time. The Exchange notes that the proposed change to state that the LULD cross price must minimize any Imbalance within the second tiebreaker is a corrective change to more accurately reflect how the system in the LULD Closing Cross currently behaves. Specifically, the change addresses that during a LULD Closing Cross, the Exchange considers all orders when calculating the Imbalance, whereas the standard Closing Cross considers orders specifically designated for participation in the Closing Cross (*i.e.*, MOC, LOC, or IO orders). This reflects current system behavior, which automatically designates all orders (whether resting on the book, or new incoming orders entered during the cross) for participation in LULD Closing Cross.

The third tiebreaker in new paragraph (D)(iii) will be substantially similar to the existing tiebreaker in Rule 4754(b)(2)(C),²⁰ except that the proposed language will specify the LULD cross price must also fall within the proposed Benchmark Prices.

The fourth and final tiebreaker in new paragraph (D)(iv) will be used if there is no price within the proposed Benchmark Prices that satisfies the conditions described above in (D)(i)–(iii), and speaks to two possible outcomes. The first outcome is reached when an Imbalance exists, in which case the LULD cross price would be the upper (lower) Benchmark Price for a buy (sell) Imbalance. The Exchange believes that this outcome is the appropriate result in the presence of an Imbalance as it best reflects current market forces while also making it clear to market participants that the imbalance exists. The second outcome is reached when there is no Imbalance, in which case the LULD Closing Cross would occur at a price that minimizes the distance from the last published Upper Band (Lower Band) for a Limit Up (Limit Down) Trading Pause. This tiebreaker is similar to the existing tiebreaker in Rule 4754(b)(2)(D)²¹ in

that the price that minimizes the distance from the last published Upper or Lower Band is effectively considered the midpoint price for the LULD Closing Cross. Unlike the existing tiebreaker, which uses the price that minimizes the distance from the System bid-ask midpoint, the proposed tiebreaker will use the relevant LULD Band. The Exchange believes this is the more appropriate result because unlike a standard Closing Cross, there is no continuous market just prior to the execution of the LULD Closing Cross, so using the relevant LULD Band more accurately reflects current market conditions as opposed to the System bid-ask midpoint.

Timing of LULD Closing Cross

The Exchange also proposes to amend the LULD Closing Cross Rule to remove all provisions relating to extending the cross past 4:00 p.m. ET as this language will no longer be necessary with the changes proposed herein. In particular, the Exchange proposes to delete Rule 4754(b)(6)(A)(iii) as this provision relates to how the Exchange would extend the time of the LULD Closing Cross. Further, the Exchange proposes to amend current Rule 4754(b)(6)(C)(iii) (renumbered to Rule 4754(b)(6)(D)(iii) [sic] under this proposal) to delete the last two sentences, which provide how certain new orders may be entered or modified after 4:00 p.m. ET.

MOC/LOC/IO Order Handling

The Exchange also proposes other aligning changes to the LULD Closing Cross that would more closely harmonize this process with the current standard Closing Cross. In Rule 4754(b)(6)(C)(iii) (renumbered to Rule 4754(b)(6)(D)(iii) [sic]), the Exchange proposes to remove the parenthetical that excludes MOC and LOC orders from being entered, modified, and cancelled in the LULD Closing Cross. The Exchange proposes to allow MOC and LOC orders to participate in the LULD Closing Cross in order to align with the regular Closing Cross where such orders may participate pursuant to Rules 4702(b)(11) and 4702(b)(12). The Exchange similarly proposes to allow IO orders to participate in the LULD Closing Cross in the same manner as in the regular Closing Cross (*i.e.*, pursuant to Rule 4702(b)(13)). Accordingly, the Exchange will add that MOC, LOC and IO orders may be entered, modified, and cancelled pursuant to Rules 4702(b)(11), 4702(b)(12) and 4702(b)(13). The Exchange will also delete current Rule

4754(b)(6)(C)(i), which sets forth special handling instructions for MOC, LOC, and IO orders in an LULD Closing Cross. In particular, this Rule stipulates that in the event of an LULD Closing Cross, MOC, LOC and IO orders intended for the closing cross entered into the system and placed on the book prior to the Trading Pause will remain on the book to participate in the LULD Closing Cross, and that such orders may not be modified or cancelled. With the proposed changes to allow MOC, LOC, and IO orders to participate in the LULD Closing Cross in the same way as a standard Closing Cross, this provision is no longer necessary.

Net Order Imbalance Indicator

The Exchange proposes to amend Rule 4754(b)(6)(B), which governs the Net Order Imbalance Indicator (“NOII”) message for the LULD Closing Cross and disseminates information about MOC, LOC, IO, and Close Eligible Interest and the price at which those orders would execute at the time of dissemination. The Rule currently provides that Nasdaq shall continue disseminating the NOII every second until After Hours Trading begins. The Exchange notes, however, that it recently updated its Closing Cross to allow for the dissemination of abbreviated NOII data (*i.e.*, Early Order Imbalance Indicator)²² every 10 seconds between 3:50 p.m. ET and 3:55 p.m. ET, which would be followed by the dissemination of regular NOII data between 3:55 and market close.²³ This change should have been reflected in the LULD Closing Cross rule in Rule 4754(b)(6)(B) as well. Accordingly, the Exchange proposes to amend the Rule to more accurately reflect current System behavior, and provide that Nasdaq shall continue disseminating the NOII pursuant to Rule 4754(b)(1) until After Hours Trading begins.

The Rule also indicates that the NOII message displays the Near Price, Far Price, and Reference Prices, which all currently represent the price at which the LULD Closing Cross would execute should the cross conclude at that time. With the proposed changes to implement the new Benchmark Prices, the Near Price and Reference Price will both represent the price at which the LULD Closing Cross would execute, bounded by the Benchmark Prices, at

²⁰ Rule 4754(b)(2)(C) currently provides that if more than one price exists under subparagraph (B), the Nasdaq Closing Cross shall occur at the entered price at which shares will remain unexecuted in the cross.

²¹ Rule 4754(b)(2)(D) currently provides that if more than one price exists under subparagraph (C), the Nasdaq Closing Cross shall occur at: A price that minimizes the distance from the System bid-

ask midpoint at the time of the Nasdaq Closing Cross.

²² “Early Order Imbalance Indicator” shall mean a message disseminated by electronic means containing the same information as the Order Imbalance Indicator, except that it will exclude information about indicative prices, as set forth in subparagraph (a)(7)(E) of Rule 4754. See Rule 4754(a)(10).

²³ See Securities Exchange Act Release No. 85292 (March 12, 2019), 84 FR 9848 (March 18, 2019) (SR-NASDAQ-2019-010).

the time of dissemination. The Far Price will represent the price at which the LULD Closing Cross would execute if the cross were not bounded by the Benchmark Prices. The Far Price will be different from the Near Price and Reference Price to indicate that not all marketable orders can be filled within the Benchmark Prices. To effect this change, Rule 4754(b)(6)(B) will be amended to provide that the Near Price and Reference Prices contained in the NOII will represent the price at which the LULD Closing Cross would execute should the cross conclude at that time, and the Far Price will represent the price at which Eligible Interest would execute.

Corrective Changes

The Exchange proposes a corrective change in Rule 4754(b)(6)(A)(i), which currently contains language relating to Trading Pauses “triggered” at or after 3:50 and before 4:00 p.m. The Exchange previously amended paragraph (b)(6) of Rule 4754 in 2017 to provide that the cross is employed when a Trading Pause *exists* at or after 3:50 and before 4:00 p.m., but inadvertently did not make a similar change in paragraph (b)(6)(A)(i) of this Rule.²⁴ The Exchange now proposes to amend this provision accordingly.

Lastly, the Exchange proposes to update obsolete cross-cites to Rule 4751 within Rules 4756(c)(3)(B) and 4763(b). Rule 4751 was previously relocated as part of a prior rule filing, so the proposed changes will update the obsolete references to their current locations in the Rulebook.²⁵

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,²⁶ in general, and furthers the objectives of Section 6(b)(5) of the Act,²⁷ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The Exchange believes that its proposal will promote just and equitable principles of trade because it will implement price protections for the LULD Closing Cross that are similar to the protections used today for the

standard Closing Cross. As explained above, the Exchange currently calculates and applies a price threshold range within which the standard Closing Cross must execute. The Exchange believes that this mechanism has been effective in facilitating a fair and orderly price discovery process at the close, and ensuring that the cross price derived does not exceed a price reasonably tied to the prevailing market at the time. The Exchange has therefore determined to apply similar protections for the LULD Closing Cross. The Exchange believes that its proposal will benefit members and investors by facilitating price discovery. Additionally, introducing price protections to the LULD Closing Cross in the manner discussed above will further harmonize the Exchange’s LULD and standard Closing Cross processes, thereby promoting a more consistent experience for members and investors, and reducing any potential confusion regarding Nasdaq’s closing processes. The Exchange believes that calculating price thresholds associated with the LULD band that triggered the Trading Pause as discussed above will ensure that the LULD Closing Cross executes at a reasonable level relative to the last disseminated LULD Auction Collar, or the LULD band itself, thereby mitigating price dislocations in the cross. The Exchange also believes that allowing members to enter, modify and cancel new MOC, LOC and IO orders pursuant to Rules 4702(b)(11), 4702(b)(12), and 4702(b)(13) in the LULD Closing Cross will keep these close order type functionality consistent with the standard close behavior, and will facilitate a more efficient closing auction by allowing additional interest to participate in the close.

The Exchange believes that the amended execution algorithm for the LULD Closing Cross is consistent with the Act because it is substantially similar to the execution logic that is used for the cross today, with certain intended differences. The proposed tiebreakers in new paragraphs (D)(i)–(iii) of Rule 4754(b)(6) are designed to preserve to the extent possible the current tiebreakers in paragraphs (B)(2)(A)–(C) of Rule 4754(b)(2) while accommodating the proposed Benchmark Prices. The proposed changes to add the definitions of Eligible Interest and Imbalance as used in the proposed first and second tiebreakers are consistent with the protection of investors and the public interest because these changes will more accurately describe how the LULD Closing Cross price will be determined pursuant to the tiebreakers in proposed

Rule 4754(b)(6)(A) and (B). As it relates to the fourth tiebreaker proposed in new paragraph (D)(iv) of Rule 4754(b)(6), the Exchange believes that using the Benchmark Price in the presence of an Imbalance is appropriate and best reflects current market forces while also making it clear to market participants that the Imbalance exists. The Exchange also believes that using the price that minimizes the distance from the last published LULD Band more accurately reflects current market conditions as opposed to using the existing tiebreaker based on the System bid-ask midpoint as there is no continuous market just prior to the execution of the LULD Closing Cross.

With respect to not extending a LULD Closing Cross past 4:00 p.m. ET, the Exchange believes that the clarity that comes from requiring that the LULD Closing Cross occur at 4:00 p.m. ET will help reduce uncertainty for members participating in the cross. While the Exchange recognizes the reasons for extending the LULD Closing Cross may exist where there are unmatched market orders or dramatic price movements during the cross, the Exchange believes based on its experience with the cross that these concerns are outweighed by the importance of providing members and the investing public with a definitive market close and a NOCP at 4:00 p.m. ET. Taken together with the proposed price thresholds, the Exchange believes that the LULD Closing Cross process, as amended, will reduce unnecessary confusion by providing certainty that the LULD Closing Cross will occur at a specified time, and will occur at a price that is reasonably based on current market conditions.

The Exchange also believes that it is appropriate to amend Rule 4754(b)(6)(B) to specify the contents of the NOII message for LULD Closing Cross. The proposed changes will bring greater transparency around what information is disseminated for the LULD Closing Cross, and is therefore consistent with the public interest and the protection of investors.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Today, the standard Nasdaq Closing Cross provides a transparent auction process for executing member interest at the close. The proposed rule change is designed to further align the Exchange’s LULD Closing Cross with the standard Closing Cross to promote a more consistent

²⁴ See Securities Exchange Act Release No. 79876 (January 25, 2017), 82 FR 8888 (January 31, 2017) (SR–NASDAQ–2016–131).

²⁵ See Securities Exchange Act Release No. 75252 (June 22, 2015), 80 FR 36865 (June 26, 2015) (SR–NASDAQ–2015–024).

²⁶ 15 U.S.C. 78f(b).

²⁷ 15 U.S.C. 78f(b)(5).

experience for members and investors, and reducing any potential confusion regarding Nasdaq's closing processes. Further, the proposed changes will allow additional interest (i.e., new MOC, LOC, and IO orders) to participate in the LULD Closing Cross, and thereby provide a more efficient process for executing closing interest, and enhancing price discovery during the close.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove the proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NASDAQ-2021-009 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.
- All submissions should refer to File Number SR-NASDAQ-2021-009. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the

submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NASDAQ-2021-009 and should be submitted on or before March 24, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁸

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2021-04307 Filed 3-2-21; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16882 and #16883; Oklahoma Disaster Number OK-00145]

Presidential Declaration of a Major Disaster for the State of Oklahoma

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Oklahoma (FEMA-4587-DR), dated 02/24/2021. Incident: Severe Winter Storms. Incident Period: 02/08/2021 through 02/20/2021.

DATES: Issued on 02/24/2021.

Physical Loan Application Deadline Date: 04/26/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 11/24/2021.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and

Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 02/24/2021, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Canadian, Carter, Cherokee, Comanche, Cotton, Hughes, Jefferson, Le Flore, McIntosh, Oklahoma, Okmulgee, Osage, Pittsburg, Stephens, Tulsa, Wagoner.

Contiguous Counties (Economic Injury Loans Only):

Oklahoma: Adair, Atoka, Blaine, Caddo, Cleveland, Coal, Creek, Delaware, Garvin, Grady, Haskell, Johnston, Kay, Kingfisher, Kiowa, Latimer, Lincoln, Logan, Love, Marshall, Mayes, McClain, McCurtain, Murray, Muskogee, Noble, Okfuskee, Pawnee, Pontotoc, Pottawatomie, Pushmataha, Rogers, Seminole, Sequoyah, Tillman, Washington.

Arkansas: Polk, Scott, Sebastian.

Kansas: Chautauqua, Cowley.

Texas: Clay, Montague, Wichita.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	2.500
Homeowners without Credit Available Elsewhere	1.250
Businesses with Credit Available Elsewhere	6.000
Businesses without Credit Available Elsewhere	3.000
Non-Profit Organizations with Credit Available Elsewhere ...	2.000
Non-Profit Organizations without Credit Available Elsewhere	2.000
<i>For Economic Injury:</i>	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	3.000
Non-Profit Organizations without Credit Available Elsewhere	2.000

The number assigned to this disaster for physical damage is 16882 7 and for economic injury is 16883 0.

²⁸ 17 CFR 200.30-3(a)(12).

(Catalog of Federal Domestic Assistance Number 59008)

Cynthia Pitts,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2021-04313 Filed 3-2-21; 8:45 am]

BILLING CODE 8026-03-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16884 and #16885; Louisiana Disaster Number LA-00109]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Louisiana

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Louisiana (FEMA-4577-DR), dated 02/25/2021.

Incident: Hurricane Zeta.

Incident Period: 10/26/2020 through 10/29/2020.

DATES: Issued on 02/25/2021.

Physical Loan Application Deadline Date: 04/26/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 11/26/2021.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 02/25/2021, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Parishes: Jefferson, Lafourche, Orleans, Plaquemines, Saint Bernard, Saint Charles, Saint Tammany, Terrebonne.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Non-Profit Organizations with Credit Available Elsewhere ...	2.750

	Percent
Non-Profit Organizations without Credit Available Elsewhere	2.750
<i>For Economic Injury:</i>	
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 16884 8 and for economic injury is 16885 0.

(Catalog of Federal Domestic Assistance Number 59008)

Cynthia Pitts,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2021-04391 Filed 3-2-21; 8:45 am]

BILLING CODE 8026-03-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16876 and #16877; Texas Disaster Number TX-00591]

Presidential Declaration Amendment of a Major Disaster for the State of Texas

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Texas (FEMA-4586-DR), dated 02/19/2021.

Incident: Severe Winter Storms.

Incident Period: 02/11/2021 and continuing.

DATES: Issued on 02/25/2021.

Physical Loan Application Deadline Date: 04/20/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 11/19/2021.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of TEXAS, dated 02/19/2021, is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Atascosa, Bandera, Brooks, Duval, Eastland, Ector, Goliad, Howard, Jim Hogg, Karnes, Kleberg, Leon, Llano, Newton, Robertson, Trinity, Webb, Willacy

Contiguous Counties/Parishes

(Economic Injury Loans Only):

Texas: Andrews, Crane, Dawson, Glasscock, La Salle, Martin, McMullen, Midland, Real, Upton, Ward, Winkler, Zapata.

Louisiana: Beauregard, Vernon.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Cynthia Pitts,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2021-04390 Filed 3-2-21; 8:45 am]

BILLING CODE 8026-03-P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested members of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before April 2, 2021.

ADDRESSES: Written comments and recommendations for this information collection request should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection request by selecting "Small Business Administration"; "Currently Under Review," then select the "Only Show ICR for Public Comment" checkbox. This information collection can be identified by title and/or OMB Control Number.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the information collection and supporting documents from the Agency Clearance Office at Curtis.Rich@sba.gov; (202) 205-7030, or from www.reginfo.gov/public/do/PRAMain.

SUPPLEMENTARY INFORMATION:

Applicants for SBA-guaranteed leverage commitments must complete these forms as part of the application process. SBA uses the information to make informed and proper credit decisions and to establish the SBIC's eligibility for leverage and need for funds.

Solicitation of Public Comments

Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

OMB Control Number: 3245–0081.

Title: Form 25 LLGP Model Limited Liability General Partner Certificate, Form 25 PCGP Model Resolution SBIC organized as Corporate General Partnership, Form 25 PC Model Resolution SBIC organized as Corporation, Form 33 Instructions for the Authorization to Disburse Proceeds, Form 34 Bank Identification, Form 1065 Applicant Licensee's Assurance of Compliance for the Public Interest.

SBA Form Number: SBA Forms 25 LLGP, 25 PCGP, 25 PC, 33, 34, 1065.

Description of Respondents: Eligible SBICs.

Estimated Number of Respondents: 60.

Estimated Annual Responses: 60.

Estimated Annual Hour Burden: 41.

Curtis Rich,

Management Analyst.

[FR Doc. 2021–04314 Filed 3–2–21; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE**[Delegation of Authority No. 512]****Delegation of Authority To Concur With Requests From DoD To Enter Into Public-Private Partnerships With Foreign Governments**

By virtue of the authority vested in me as Secretary of State by the laws of the United States, including 22 U.S.C. 2651a, I hereby delegate to the Assistant Secretary for Political-Military Affairs, to the extent authorized by law, the authority to concur on behalf of the Department on future requests from the Department of Defense to enter into public-private partnerships with foreign governments or foreign entities under 10 U.S.C. 1501a.

Exercise of this authority is subject to clearance by the relevant regional bureau(s) and the Office of the Legal Adviser. Any act, regulation, or procedure subject to, or affected by, this delegation shall be deemed to be such act, regulation, or procedure as amended from time to time.

The Secretary, Deputy Secretary, Deputy Secretary for Management and

Resources, and the Under Secretary for Arms Control and International Security may exercise any function or authority delegated by this delegation.

This memorandum shall be published in the **Federal Register**.

Dated: February 22, 2021.

Antony J. Blinken,

Secretary of State, Department of State.

[FR Doc. 2021–04317 Filed 3–2–21; 8:45 am]

BILLING CODE 4710–25–P

SURFACE TRANSPORTATION BOARD**Release of Waybill Data**

The Surface Transportation Board has received a request from the East Central Wisconsin Regional Planning Commission (WB21–16—2/16/21) for permission to use select data from the Board's 2018–2019 masked Carload Waybill Sample. A copy of this request may be obtained from the Board's website under docket no. WB21–16.

The waybill sample contains confidential railroad and shipper data; therefore, if any parties object to these requests, they should file their objections with the Director of the Board's Office of Economics within 14 calendar days of the date of this notice. The rules for release of waybill data are codified at 49 CFR 1244.9.

Contact: Alexander Dusenberry, (202) 245–0319.

Regena Smith-Bernard,

Clearance Clerk.

[FR Doc. 2021–04389 Filed 3–2–21; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****Aviation Rulemaking Advisory Committee; Meeting**

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Aviation Rulemaking Advisory Committee (ARAC) meeting.

SUMMARY: This notice announces a meeting of the ARAC.

DATES: The meeting will be held on Thursday, March 18, 2021, from 1:00 p.m. to 4:00 p.m. Eastern Standard Time.

Requests to attend the meeting must be received by Monday, February 22, 2021.

Requests for accommodations to a disability must be received by Monday, March 1, 2021.

Requests to submit written materials to be reviewed during the meeting must

be received no later than Monday, February 22, 2021.

ADDRESSES: The meeting will be held virtually. Members of the public who wish to observe the meeting must RSVP by emailing 9-awa-arac@faa.gov. General committee information including copies of the meeting minutes will be available on the FAA Committee website at https://www.faa.gov/regulations_policies/rulemaking/committees/documents/.

FOR FURTHER INFORMATION CONTACT:

Lakisha Pearson, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, telephone (202) 267–4191; email 9-awa-arac@faa.gov. Any committee-related request should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:**I. Background**

The ARAC was created under the Federal Advisory Committee Act (FACA), in accordance with Title 5 of the United States Code (5 U.S.C. App. 2) to provide advice and recommendations to the FAA concerning rulemaking activities, such as aircraft operations, airman and air agency certification, airworthiness standards and certification, airports, maintenance, noise, and training.

II. Agenda

At the meeting, the agenda will cover the following topics:

- Status Report from the FAA
- Status Updates:
 - Active Working Groups
 - Transport Airplane and Engine (TAE) Subcommittee
- Recommendation Reports
- Any Other Business

Detailed agenda information will be posted on the FAA Committee website address listed in the **ADDRESSES** section at least one week in advance of the meeting.

III. Public Participation

The meeting will be open to the public on a first-come, first-served basis, as space is limited. Please confirm your attendance with the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Please provide the following information: Full legal name, country of citizenship, and name of your industry association, or applicable affiliation. If you are attending as a public citizen, please indicate so.

For persons participating by telephone, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section by email or phone for the teleconference call-in number and

passcode. Callers are responsible for paying long-distance charges.

The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

The FAA is not accepting oral presentations at this meeting due to time constraints. Any member of the public may present a written statement to the committee at any time. The public may present written statements to the Aviation Rulemaking Advisory Committee by providing a copy to the Designated Federal Officer via the email listed in the **FOR FURTHER INFORMATION CONTACT** section.

Issued in Washington, DC, on February 26, 2021.

Brandon Roberts,

Executive Director Office of Rulemaking.

[FR Doc. 2021-04404 Filed 3-2-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice To Rescind a Notice of Intent To Prepare an Environmental Impact Statement: Peoria, Tazewell and Woodford Counties, Illinois

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice to rescind a notice of intent to prepare an environmental impact statement.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement (EIS) will not be prepared for the Eastern Bypass Study, a proposed highway within Peoria, Tazewell and Woodford Counties in Illinois. The termini for the bypass were proposed to be Interstate 74, east of the city of East Peoria, and Illinois Route 6, north of the City of Peoria. The FHWA is rescinding its notice of intent (NOI) to prepare a Tier I EIS which was published in the **Federal Register** on May 8, 2014.

FOR FURTHER INFORMATION CONTACT: For FHWA: Arlene K. Kocher, Division Administrator, Federal Highway Administration, 3250 Executive Park Drive, Springfield, Illinois 62703; telephone: (217) 492-4600; email address: Arlene.Kocher@dot.gov. For Illinois Department of Transportation:

Kensil Garnett, P.E., Region 3 Engineer, Illinois Department of Transportation, 401 Main Street, Peoria, Illinois 61602-1111; telephone: (309) 671-3333; email: kensil.garnett@illinois.gov.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Illinois Department of Transportation (IDOT), issued an NOI to prepare a Tier I EIS for the proposed Eastern Bypass Study on May 8, 2014 (79 FR 26497). The project was being considered in order to improve vehicular mobility and access across the Illinois River between Tazewell and Woodford Counties. The FHWA is rescinding the NOI because IDOT has no plans to continue the project study and no further activities will occur in its development.

Comments or questions concerning this notice should be directed to FHWA or the IDOT contacts provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program).

Authority: 42 U.S.C. 4321 *et seq.*; 23 CFR part 771.

Dated: February 25, 2021.

Arlene K. Kocher,

Division Administrator, Federal Highway Administration, Springfield, Illinois.

[FR Doc. 2021-04321 Filed 3-2-21; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT:

OFAC: Associate Director for Global Targeting, tel.: 202-622-2420; Assistant

Director for Sanctions Compliance & Evaluation, tel.: 202-622-2490; Assistant Director for Licensing, tel.: 202-622-2480; or Assistant Director for Regulatory Affairs, tel.: 202-622-4855.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (<https://www.treasury.gov/ofac>).

Notice of OFAC Action(s)

On February 22, 2021, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individuals

1. KYAW, Maung Maung, Burma; DOB 23 Jul 1964; nationality Burma; Gender Male; National ID No. 12/BAHANA(N)010023 (Burma) (individual) [BURMA-EO14014].

Designated pursuant to section 1(a)(iii)(A) of Executive Order 14014 of February 10, 2021, "Blocking Property With Respect To The Situation In Burma" ("E.O. 14014") for being a foreign person who is or has been a leader of the military or security forces of Burma or any successor entity to any of the foregoing.

2. TUN, Moe Myint, Burma; DOB 24 May 1968; nationality Burma; Gender Male; National ID No. 7/KATAKHA(N)007836 (Burma) (individual) [BURMA-EO14014].

Designated pursuant to section 1(a)(iii)(A) of E.O. 14014 for being a foreign person who is or has been a leader of the military or security forces of Burma or any successor entity to any of the foregoing.

Dated: February 22, 2021.

Bradley T. Smith,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2021-04343 Filed 3-2-21; 8:45 am]

BILLING CODE 4810-AL-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in

property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT:

OFAC: Associate Director for Global Targeting, tel.: 202-622-2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202-622-2490; Assistant Director for Licensing, tel.: 202-622-2480; or Assistant Director for Regulatory Affairs, tel.: 202-622-4855.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (<https://www.treasury.gov/ofac>).

Notice of OFAC Actions

On February 11, 2021, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individuals

1. AUNG, Ye, Burma; DOB 08 Jun 1960; POB Chauk, Burma; Gender Male (individual) [BURMA-E.O.].

Designated pursuant to section 1(a)(iii)(A) of Executive Order of February 10, 2021, "Blocking Property With Respect To The Situation In Burma" ("the Order") for being a foreign person who is or has been a leader of the military or security forces of Burma or any successor entity to any of the foregoing.

2. HLAING, Min Aung, Burma; DOB 03 Jul 1956; POB Dawei, Burma; Gender Male (individual) [GLOMAG] [BURMA-E.O.].

Designated pursuant to section 1(a)(iii)(A) of the Order for being a foreign person who is or has been a leader of the military or security forces of Burma or any successor entity to any of the foregoing.

3. HTUT, Soe, Burma; DOB 1960; Gender Male (individual) [BURMA-E.O.].

Designated pursuant to section 1(a)(iii)(A) of the Order for being a foreign person who is or has been a leader of the military or

security forces of Burma or any successor entity to any of the foregoing.

4. SWE, Myint, Burma; DOB 24 May 1951; Gender Male (individual) [BURMA-E.O.].

Designated pursuant to section 1(a)(iii)(A) of the Order for being a foreign person who is or has been a leader of the military or security forces of Burma or any successor entity to any of the foregoing.

5. WIN, Soe, Burma; DOB 01 Mar 1960; Gender Male (individual) [GLOMAG] [BURMA-E.O.].

Designated pursuant to section 1(a)(iii)(A) of the Order for being a foreign person who is or has been a leader of the military or security forces of Burma or any successor entity to any of the foregoing.

6. WIN, Sein, Burma; DOB Jul 1956; POB Pyin Oo Lwin, Burma; Gender Male (individual) [BURMA-E.O.].

Designated pursuant to section 1(a)(iii)(A) of the Order for being a foreign person who is or has been a leader of the military or security forces of Burma or any successor entity to any of the foregoing.

7. DWE, Aung Lin (a.k.a. DWAY, Aung Lin), Burma; DOB 31 May 1962; Gender Male (individual) [BURMA-E.O.].

Designated pursuant to section 1(a)(iii)(A) of the Order for being a foreign person who is or has been a leader of the military or security forces of Burma or any successor entity to any of the foregoing.

8. OO, Mya Tun, Burma; DOB 04 May 1961; alt. DOB 05 May 1961; Gender Male (individual) [BURMA-E.O.].

Designated pursuant to section 1(a)(ii)(c)(i) of the Order for being a foreign person who is or has been a leader of the military or security forces of Burma or any successor entity to any of the foregoing.

9. OO, Ye Win, Burma; DOB 21 Feb 1966; Gender Male (individual) [BURMA-E.O.].

Designated pursuant to section 1(a)(iii)(A) of the Order for being a foreign person who is or has been a leader of the military or security forces of Burma or any successor entity to any of the foregoing.

10. SAN, Tin Aung, Burma; DOB 16 Oct 1960; Gender Male (individual) [BURMA-E.O.].

Designated pursuant to section 1(a)(iii)(A) of the Order for being a foreign person who is or has been a leader of the military or security forces of Burma or any successor entity to any of the foregoing.

Entities:

1. CANCRI GEMS & JEWELLERY CO., LTD. (a.k.a. CANCRI GEMS & JEWELLERY

COMPANY LIMITED; a.k.a. CANCRI GEMS AND JEWELLERY CO., LTD.; a.k.a. CANCRI GEMS AND JEWELLERY COMPANY LIMITED; a.k.a. PHU SHA STAR), Burma; Company Number 113099127 (Burma) issued 24 Jul 2012 [BURMA-E.O.].

Designated pursuant to section 1(a)(vii) of the Order for being a foreign person that is owned or controlled by, or has acted or purported to act for or on behalf of, directly or indirectly, the military or security forces of Burma or any person whose property and interests in property are blocked pursuant to the Order.

2. MYANMAR IMPERIAL JADE CO., LTD. (a.k.a. MYANMAR IMPERIAL JADE GEMS & JEWELLERY CO., LTD.; a.k.a. MYANMAR IMPERIAL JADE GEMS & JEWELLERY COMPANY LIMITED; a.k.a. MYANMAR IMPERIAL JADE GEMS AND JEWELLERY CO., LTD.; a.k.a. MYANMAR IMPERIAL JADE GEMS AND JEWELLERY COMPANY LIMITED), Burma; Company Number 176227869 (Burma) issued 13 Sep 1996 [BURMA-E.O.].

Designated pursuant to section 1(a)(vii) of the Order for being a foreign person that is owned or controlled by, or has acted or purported to act for or on behalf of, directly or indirectly, the military or security forces of Burma or any person whose property and interests in property are blocked pursuant to the Order.

3. MYANMAR RUBY ENTERPRISE (a.k.a. MYANMAR RUBY ENTERPRISE GEMS & JEWELLERY CO., LTD.; a.k.a. MYANMAR RUBY ENTERPRISE GEMS & JEWELLERY COMPANY LIMITED; a.k.a. MYANMAR RUBY ENTERPRISE GEMS AND JEWELLERY CO., LTD.; a.k.a. MYANMAR RUBY ENTERPRISE GEMS AND JEWELLERY COMPANY LIMITED), Burma; Company Number 100941821 (Burma) issued 14 Feb 1996 [BURMA-E.O.].

Designated pursuant to section 1(a)(vii) of the Order for being a foreign person who is owned or controlled by, or has acted or purported to act for or on behalf of, directly or indirectly, the military or security forces of Burma or any person whose property and interests in property are blocked pursuant to the Order.

Dated: February 11, 2021.

Bradley T. Smith,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2021-04341 Filed 3-2-21; 8:45 am]

BILLING CODE 4810-AL-P

Reader Aids

Federal Register

Vol. 86, No. 40

Wednesday, March 3, 2021

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations

General Information, indexes and other finding aids **202-741-6000**

Laws **741-6000**

Presidential Documents

Executive orders and proclamations **741-6000**

The United States Government Manual **741-6000**

Other Services

Electronic and on-line services (voice) **741-6020**

Privacy Act Compilation **741-6050**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: www.govinfo.gov.

Federal Register information and research tools, including Public Inspection List and electronic text are located at: www.federalregister.gov.

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to <https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new>, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to <http://listserv.gsa.gov/archives/publaws-l.html> and select *Join or leave the list (or change settings)*; then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: fedreg.info@nara.gov

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, MARCH

11847-12078.....	1
12079-12256.....	2
12257-12514.....	3

CFR PARTS AFFECTED DURING MARCH

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.

3 CFR

Proclamations:
10149.....11847

Executive Orders:
14017.....11849
14018.....11855

5 CFR

532.....11857

7 CFR

Proposed Rules:
800.....12119

9 CFR

Proposed Rules:
149.....12293
307.....12122
350.....12122
352.....12122
354.....12122
362.....12122
381.....12122
533.....12122
590.....12122
592.....12122

12 CFR

302.....12079

14 CFR

39.....12086
71.....11859, 11860
Proposed Rules:
39.....12127, 12294
71.....12129

16 CFR

317.....12091

18 CFR

157.....12257
Proposed Rules:
35.....12132
284.....12132

21 CFR

1308.....11862, 12257
Proposed Rules:
1308.....12296

22 CFR

Proposed Rules:
213.....11905

33 CFR

Proposed Rules:
96.....11913

34 CFR

Proposed Rules:
Ch. III.....12136

40 CFR

49.....12260
52.....11867, 11870, 11872,
11873, 11875, 11878, 12092,
12095, 12107, 12263, 12265,
12270
62.....12109
81.....12107
141.....12272
282.....12110

Proposed Rules:

52.....11913, 11915, 12143,
12305, 12310
62.....11916
282.....12145

44 CFR

64.....12117

46 CFR

Proposed Rules:
71.....11913
115.....11913
176.....11913

47 CFR

25.....11880
Proposed Rules:
1.....12146, 12312
9.....12399
27.....12146
63.....12312
73.....12161, 12162, 12163

49 CFR

209.....11888
211.....11888
389.....11891

50 CFR

17.....11892
635.....12291
679.....11895
680.....11895
Proposed Rules:
622.....12163, 12166

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 January 25, 2021

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly enacted public laws. To subscribe, go to [https://](https://listserv.gsa.gov/cgi-bin/wa.exe?SUBED1=PUBLAWS-L&A=1)

listserv.gsa.gov/cgi-bin/wa.exe?SUBED1=PUBLAWS-L&A=1

Note: This service is strictly for email notification of new laws. The text of laws is not available through this service.

PENS cannot respond to specific inquiries sent to this address.