AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 84 Thursday,
No. 172 September 5, 2019

Pages 46653–46874

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: 84 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.*

Printed on recycled paper.

Contents

Federal Register

Vol. 84, No. 172

Thursday, September 5, 2019

Agricultural Marketing Service
RULES
Establishment of a Milk Donation Reimbursement Program, 46653–46661

Agriculture Department
See Agricultural Marketing Service
See Forest Service

Army Department
RULES
The Army Privacy Program, 46681–46682

Centers for Disease Control and Prevention
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 46733–46735

Coast Guard
RULES
Special Local Regulation:
Lake Havasu City, AZ, 46682–46684
NOTICES
Environmental Assessments; Availability, etc.:
Proposed Construction of Railroad Bridges Across Sand Creek and Lake Pend Oreille at Sandpoint, Bonner County, ID, 46747–46749
Recertification:
Cook Inlet Regional Citizens' Advisory Council, 46749

Commerce Department
See First Responder Network Authority
See Foreign-Trade Zones Board
See International Trade Administration
See National Oceanic and Atmospheric Administration
See National Telecommunications and Information Administration

Defense Department
See Army Department
RULES
Defense Threat Reduction Agency Privacy Program, 46681

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Federal Family Education Loan/Direct Loan/Perkins Military Service Deferment/Post-Active Duty Student Deferment Request, 46717
Meetings:
National Advisory Council on Indian Education, 46717–46718

Employment and Training Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Fidelity Bonding Demonstration, 46762–46763
Youthful Offender Grants Management Information System, 46761–46762

Energy Department
See Federal Energy Regulatory Commission
See National Nuclear Security Administration
RULES
Energy Conservation Program:
Definition for General Service Lamps, 46661–46676
PROPOSED RULES
Energy Conservation Program:
Energy Conservation Standards for General Service Incandescent Lamps, 46830–46862
NOTICES
Application to Export Electric Energy:
Enel Trading North America, LLC, 46718–46719
Meetings:
Biological and Environmental Research Advisory Committee, 46719–46720
Environmental Management Site-Specific Advisory Board, Northern New Mexico, 46719

Environmental Protection Agency
RULES
National Oil and Hazardous Substances Pollution Contingency Plan:
National Priorities List; Deletion of the Strasburg Landfill Superfund Site, 46684–46685
NOTICES
Certain New Chemicals:
Receipt and Status Information for July 2019, 46723–46731

Farm Credit Administration
NOTICES
Meetings; Sunshine Act, 46731–46732

Federal Accounting Standards Advisory Board
NOTICES
Exposure Draft of a Proposed Technical Bulletin, Loss Allowance for Intragovernmental Receivables, 46732

Federal Aviation Administration
NOTICES
Environmental Impact Statements; Availability, etc.:
Battle Area Complex Restricted Area R–2201 (BAX R–2201), etc.; Modernization and Enhancement of Ranges, Airspace, and Training Areas in the Joint Pacific Alaska Range Complex, AK, 46775–46776
Petition for Exemption; Summary of Petition Received:
A-Cam Aerials, LLC, 46775
Helinet Aviation Services, LLC, 46773, 46776–46777
University of Florida Unmanned Aircraft Systems Research Program, 46774–46775
Wing Aviation, LLC, 46774

Federal Communications Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 46732–46733

Federal Emergency Management Agency
RULES
Suspension of Community Eligibility, 46685–46686

Federal Energy Regulatory Commission
NOTICES
Application:
Northern Natural Gas Co., 46721–46722
Combined Filings, 46720–46723
Environmental Assessments; Availability, etc.:
Village of Lyndonville Electric Department, 46722

Federal Highway Administration
NOTICES
Environmental Impact Statements; Availability, etc.:
Proposed Combined Highway and Transit Project on I–285, Cobb, Fulton, and DeKalb Counties, GA; Withdrawal, 46777

Federal Maritime Commission
NOTICES
Agreements Filed, 46733

Federal Railroad Administration
NOTICES
Petition for Waiver of Compliance, 46777–46778

Federal Reserve System
NOTICES
Change in Bank Control:
Acquisitions of Shares of a Bank or Bank Holding Company, 46733

First Responder Network Authority
NOTICES
Meetings:
Combined Committee and Board, 46708–46709

Fish and Wildlife Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Captive Wildlife Safety Act, 46752–46753

Food and Drug Administration
PROPOSED RULES
List of Bulk Drug Substances that Can Be Used to Compound Drug Products in Accordance with Section 503A of the Federal Food, Drug, and Cosmetic Act, 46688–46703
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Accreditation Scheme for Conformity Assessment Pilot Program, 46737–46740
Applications for Approval to Market a New Drug—Patent Submission and Listing Requirements, 46735–46737
Guidance for Industry on E6(R2) Good Clinical Practice; International Council for Harmonisation, 46742–46744
Determination of Regulatory Review Period for Purposes of Patent Extension:
GIAPREZA, 46740–46742

Foreign Assets Control Office
NOTICES
Blocking or Unblocking of Persons and Properties, 46782–46785

Foreign-Trade Zones Board
NOTICES
Authorization of Production Activity:
Coreworks, LLC (Brazed Aluminum Heat Exchangers and Cryogenic Equipment) Katy, TX; Foreign-Trade Zone 84, Harris County, TX, 46709
LLFlex, LLC (Aluminum and Steel Cable Wraps) Louisville, KY; Foreign-Trade Zone 29, Louisville, KY, 46710
STIHL, Inc. (Outdoor Power Equipment), Virginia Beach, VA; Foreign-Trade Zone 20, Norfolk, VA, 46709
Proposed Production Activity:
Gulfstream Aerospace Corp. (Disassembly of Aircraft), Dallas, TX; Foreign-Trade Zone 168, Dallas/Fort Worth, TX, 46709

Forest Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Recreation Special Uses and Trail Program Administration, 46706–46707
Environmental Impact Statements; Availability, etc.:
Forest Plan Revision for the Nez Perce-Clearwater National Forests, ID, 46706
Meetings:
Black Hills National Forest Advisory Board, 46707–46708

Health and Human Services Department
See Centers for Disease Control and Prevention
See Food and Drug Administration
See National Institutes of Health

Homeland Security Department
See Coast Guard
See Federal Emergency Management Agency
See U.S. Customs and Border Protection

Indian Affairs Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Native Language Immersion Grant, 46753–46754

Interior Department
See Fish and Wildlife Service
See Indian Affairs Bureau
See Land Management Bureau
See Surface Mining Reclamation and Enforcement Office

Internal Revenue Service
RULES
Partnership Representative under the Centralized Partnership Audit Regime and Election to Apply the Centralized Partnership Audit Regime; Correction, 46681
NOTICES
Senior Executive Service Performance Review Board, 46786

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China, 46712
Certain Hot-Rolled Steel Flat Products from Japan, 46713–46715
Polyethylene Terephthalate Film, Sheet, and Strip from the United Arab Emirates, 46713

Determination in the Less-Than-Fair-Value Investigation:
Ceramic Tile from the People's Republic of China, 46711–46712
Export Trade Certificate of Review, 46710–46711
Meetings:
United States Investment Advisory Council, 46710

International Trade Commission
NOTICES
Complaints:
Certain Balanced Armature Devices, Products Containing the Same, and Components Thereof, 46757–46759
Investigations; Determinations, Modifications, and Rulings, etc.:
Fresh Tomatoes from Mexico, 46756–46757
Mattresses from China, 46757
Meetings; Sunshine Act, 46756–46757

Justice Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Immigration Practitioner Complaint Form, 46759–46760
Request by Organization for Accreditation or Renewal of Accreditation of Non-Attorney Representative (Form EOIR–31A), 46760–46761
Request for New Recognition, Renewal of Recognition, Extension of Recognition of a Non-Profit Religious, Charitable, Social Service, or Similar Organization, 46759

Labor Department
See Employment and Training Administration

Land Management Bureau
NOTICES
Meetings:
Southeast Oregon Resource Advisory Council, 46755
Plats of Survey:
California, 46754–46755
New Mexico; Oklahoma; and Texas, 46755–46756

National Endowment for the Humanities
NOTICES
Meetings:
National Council on the Humanities, 46763

National Foundation on the Arts and the Humanities
See National Endowment for the Humanities

National Institutes of Health
NOTICES
Meetings:
Center for Scientific Review, 46745–46747
National Institute of Diabetes and Digestive and Kidney Diseases, 46745
Sexual and Gender Minority Research Listening Session, 46744

National Nuclear Security Administration
NOTICES
Meetings:
Defense Programs Advisory Committee, 46720

National Oceanic and Atmospheric Administration
RULES
Fisheries of the Exclusive Economic Zone off Alaska:
Pacific Cod in the Aleutian Islands Subarea of the Bering Sea and Aleutian Islands Management Area, 46686–46687
Taking and Importing Marine Mammals:
Alaska Fisheries Science Center Fisheries Research, 46788–46827
NOTICES
Meetings:
Groundfish Operational Assessment Peer Review, 46715–46716

National Telecommunications and Information Administration

NOTICES
Meetings:
Combined Committee and Board, 46708–46709

Nuclear Regulatory Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, 46763–46764

Overseas Private Investment Corporation
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 46764–46765

Personnel Management Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Reemployment of Annuitants, 46765

Presidential Documents
PROCLAMATIONS
Special Observances:
Labor Day (Proc. 9920), 46871–46872
National Alcohol and Drug Addiction Recovery Month (Proc. 9917), 46863–46866
National Childhood Cancer Awareness Month (Proc. 9918), 46867–46868
National Preparedness Month (Proc. 9919), 46869–46870
EXECUTIVE ORDERS
Committees; Establishment, Renewal, Termination, etc.:
Quantum Initiative Advisory Committee, National; Establishment (EO 13885), 46873–46874

Securities and Exchange Commission
NOTICES
Self-Regulatory Organizations; Proposed Rule Changes:
Cboe BZX Exchange, Inc., 46765–46767
Cboe EDGX Exchange, Inc., 46767–46769

Small Business Administration
NOTICES
Privacy Act; Systems of Records, 46769–46771

State Department
NOTICES
Culturally Significant Objects Imported for Exhibition:
Alonso Berruguete: First Sculptor of Renaissance Spain, 46772–46773

Andy Warhol: From A to B and Back Again, 46771
Designing the New: Charles Rennie Mackintosh and the Glasgow Style, 46772
Ernst Ludwig Kirchner, 46771
Rachel Harrison Life Hack, 46771–46772
Rayyane Tabet: Alien Property, 46772
Sahel: Art and Empires on the Shores of the Sahara, 46773

Surface Mining Reclamation and Enforcement Office
PROPOSED RULES
Regulatory Program:
Ohio, 46703–46705

Transportation Department
See Federal Aviation Administration
See Federal Highway Administration
See Federal Railroad Administration
NOTICES
Privacy Act; Systems of Records, 46779–46782

Treasury Department
See Foreign Assets Control Office
See Internal Revenue Service

U.S. Customs and Border Protection
RULES
Amendment to Statement Processing and Automated Clearinghouse, 46678–46681
Technical Correction to Centers of Excellence and Expertise Regulations, 46676–46678
NOTICES
Modification and Clarification of the National Customs Automation Program Test Regarding Periodic Monthly Statements, 46749–46752

Separate Parts In This Issue

Part II
Commerce Department, National Oceanic and Atmospheric Administration, 46788–46827

Part III
Energy Department, 46830–46862

Part IV
Presidential Documents, 46863–46874

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, 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.

3 CFR

Proclamations:

9917 46865
9918 46867
9919 46869
9920 46871

Executive Orders:

13885 46873

7 CFR

1146 46653

10 CFR

430 46661

Proposed Rules:

430 46830

19 CFR

12 46676
24 46678
141 46676

21 CFR

Proposed Rules:

216 46688

26 CFR

301 46681

30 CFR

Proposed Rules:

935 46703

32 CFR

318 46681
505 46681

33 CFR

100 46682

40 CFR

300 46684

44 CFR

64 46685

50 CFR

219 46788
679 46686

Rules and Regulations

Federal Register

Vol. 84, No. 172

Thursday, September 5, 2019

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 AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1146

RIN 0581–AD87

[Doc. No. AMS–DA–19–0001]

Establishment of a Milk Donation Reimbursement Program

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule establishes the Milk Donation Reimbursement Program. Under the program, eligible dairy organizations that account to a Federal milk marketing order marketwide pool and incur qualified expenses related to certain fluid milk product donations may apply for and receive limited reimbursements to cover those expenses. A provision of the 2018 Farm Bill requires establishment of this program. The program is intended to reduce food waste and provide nutrition assistance to individuals in low-income groups.

DATES: Effective: September 16, 2019.

FOR FURTHER INFORMATION CONTACT: Emily DeBord, Marketing Specialist, AMS Dairy Program, USDA; 1400 Independence Avenue SW, Room 2958–S, Washington, DC 20250; telephone: (202) 720–5567; email: *mdrp@usda.gov*.

SUPPLEMENTARY INFORMATION: A provision of the Agricultural Improvement Act of 2018 (Pub. L. 115–334) (2018 Farm Bill) repealed the Dairy Product Donation Program specified in Section 1431 of the Agricultural Act of 2014 (Pub. L. 113–79) (2014 Farm Bill) and amended title I, subtitle D, part III of the 2014 Farm Bill to require establishment of the Milk Donation Program.

Section 1601(c)(2)(A) of the 2014 Farm Bill provides for the promulgation of the regulations to implement the Dairy Product Donation Program to be made without regard to the notice and comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. 553. Section 1701 of the 2018 Farm Bill extends that Congressional direction to the establishment of a milk donation program to replace the Dairy Product Donation Program. AMS, therefore, is issuing this final rule without prior notice or public comment.

Amended section 1431 of the 2014 Farm Bill (amended statute) authorizes the Secretary of Agriculture (Secretary) to establish a program to reimburse eligible dairy organizations for a portion of the value of fluid milk products they donate to eligible non-profit organizations for distribution to individuals in low-income groups. The Secretary delegated authority to establish and administer this program to the Agricultural Marketing Service (AMS). This rule outlines the provisions of the new Milk Donation Reimbursement Program (MDRP) codified at 7 CFR part 1146. Program provisions are intended to encourage the donation of fluid milk products to provide nutrition assistance to individuals in low-income groups and to reduce food waste.

Background

Under Federal milk marketing orders (FMMOs), regulated milk handlers receiving dairy farmers' milk account to a marketwide pool on their end-use classification of the milk. FMMO milk end-use classifications are generally as follows: Class I for beverage fluid milk products such as whole, skim, nonfat, and flavored milks; Class II for soft products such as yogurt and ice cream; Class III for spreadable and hard cheeses; and Class IV for butter and evaporated, condensed, and non-fat dried milk. Class I milk products typically carry the highest value in the marketplace. Monthly FMMO classified prices reflect surveyed end-product wholesale market prices. An FMMO generally requires that classified values for pooled milk be accounted for and paid to individual farmers or cooperative associations of farmers on the basis of a uniform, or average, price. Thus, all eligible dairy farmers whose milk is pooled share in the marketwide use-values of milk by regulated handlers.

FMMOs consider all packaged milk product deliveries to be commercial transactions and require regulated handlers to account to the FMMO pool at the Class I value for milk in all unreturned deliveries of packaged fluid milk products. Regulated handlers who elect to donate packaged fluid milk are required to account to a pool for milk contained in donated fluid milk products at Class I values. Thus, handlers may have found dumping surplus milk a more financially sound alternative than donation because they would avoid an FMMO pool obligation. Under the MDRP outlined in this rule, eligible handlers who account to FMMO pools and donate packaged fluid milk products to eligible non-profit organizations may claim reimbursements for all or part of the FMMO cost difference between the Class I value at the plant, and the lowest classified value for the month. Under the provisions of the MDRP, handlers may not claim reimbursements for other costs related to donating fluid milk products, such as the costs for processing, bottling, and transporting donated milk. The intent of the MDRP is to encourage handlers to make donations to food assistance programs and reduce food waste.

As provided by the amended statute (Sec. 1431(j)), total program funding in fiscal year 2019 is $9 million, and $5 million for each fiscal year thereafter. Using 2018 average FMMO classified prices and the weighted average FMMO Class I differential, AMS estimates that, had the program been in place in fiscal year 2018, $9 million could have reimbursed eligible distributors for milk donations of approximately 28 million gallons of fresh fluid milk (assuming a reimbursement rate of 100 percent of the difference between the Class I price and the lowest classified price). AMS further estimates that 28 million gallons of fresh fluid milk represented less than 0.6 percent of all FMMO Class I sales during 2018.

Program Provisions

This rule outlines the provisions of the MDRP established as required by the amended statute.

Definitions

The amended statute includes definitions for terms used in the statute. Similarly, § 1146.1 of the rule provides definitions of those terms as they are used in the new program. Key terms are ''eligible dairy organization,'' ''eligible

distributor,'' ''eligible milk,'' ''eligible partnership,'' and ''participating partnership.''

Eligible dairy organization. The amended statute specifies that a dairy organization eligible to participate in the program is a dairy farmer, either individually or as part of a cooperative, or a dairy processor, that accounts to an FMMO pool and incurs qualified expenses by accounting to the pool for fluid milk product donations. *See* Sec. 1431(a)(1)(A) and (B). Under FMMOs, only producer cooperatives acting as handlers by receiving the milk of dairy farmers and delivering it to regulated processing plants and handlers who operate regulated dairy processing plants must account to the marketwide pools. *See* 7 CFR 1000.9. Only handlers regulated under an FMMO are required to account to the pool at FMMO classified prices for all their Class I (fluid milk) purchases. Therefore, to ensure reimbursements requested under the program are properly applied only to qualified expenses, § 1146.1 defines ''eligible dairy organization'' as a dairy farmer cooperative or a dairy processor that accounts to the FMMO marketwide pool and incurs qualified expenses described in § 1146.108.

Eligible distributor. The amended statute specifies a distributor eligible to receive donated milk under the program must be a public or private non-profit organization able to distribute donated milk. *See* Sec. 1431(a)(2). Section 1146.1 of the rule likewise defines ''eligible distributor'' as a public or private non-profit organization that distributes donated eligible milk. Under the new program, participating non-profit organizations are required to verify their non-profit status and affirm they have appropriate facilities and processes for distributing donated milk to individuals in low-income groups.

Eligible milk. The amended statute specifies only Class I fluid milk products produced and processed in the United States are eligible for donation to eligible distributors and reimbursements under the program. *See* Sec. 1431(a)(3). As explained earlier, ''Class I'' is the FMMO classification for fluid milk products intended for use as beverages, such as whole, skim, nonfat, and flavored milks. *See* 7 CFR 1000.15. The amended statute requires eligible milk under the program be produced and processed in the United States. *See* Sec. 1431(a)(3). For use under the program, eligible milk must meet the commodity specifications and processing and packaging standards as provided in the commodity specification documents maintained on the AMS website, as required in § 1146.3 of the rule and discussed later in this document. Section 1146.1 of the rule defines ''eligible milk'' as Class I fluid milk products produced and processed in the United States meeting the commodity specifications referenced in § 1146.3.

Eligible partnership. The amended statute specifies participation in the MDRP requires application for the program by a partnership between an eligible dairy organization and an eligible distributor. *See* Sec. 1431(a)(4). Each partnership is required to submit a joint Milk Donation and Distribution Plan (Plan) containing information about their respective roles to AMS. Requiring the parties to apply as a partnership ensures that all aspects of the program requirements will be met, and an agreed-upon structure will be in place when eligible milk is available for donation and distribution. Thus, § 1146.1 of the rule defines ''eligible partnership'' as a partnership between an eligible dairy organization and an eligible distributor.

AMS recognizes some eligible dairy organizations may have processing plants in more than one location and each may be regulated under different FMMOs. As well, eligible distributors may have more than one distribution site, for example, several food pantries operated by one umbrella organization. Thus, under § 1146.102(a) of the rule, the eligible partnership can submit one Plan to cover multiple plants and/or distribution points as long as only one eligible dairy organization and one eligible distributor are represented. Individual eligible dairy organizations and eligible distributors can also form other partnerships, but they are required to submit separate Plans for each partnership.

Participating partnership. The amended statute specifies that a participating partnership is one whose Plan has been approved by AMS. *See* Sec. 1431(a)(5). Once an eligible partnership's Plan has been approved by AMS pursuant to § 1146.104 of the rule, the partnership is considered a participant in the MDRP. Documentation from both partners will be necessary to validate claims by the eligible dairy organization for reimbursement under the program, as specified in § 1146.106. Thus, § 1146.1 of the rule defines ''participating partnership'' as an eligible partnership for which AMS has approved a Milk Donation and Distribution Plan for eligible milk under § 1146.104.

Additional terms necessary for administration of the program are defined in § 1146.1.

Commodity Specifications

As with AMS programs related to commodity purchases, the commodity specifications for fluid milk products under the MDRP are contained in a separate document available on the AMS website. Maintaining the specifications as an online document allows AMS to keep the specifications current and provide updated links to other relevant industry references, such as AMS's current Commercial Item Description for fluid milk products,[1] the U.S. Food and Drug Administration's (FDA) Grade A Pasteurized Milk Ordinance,[2] and FDA's Interstate Milk Shippers List.[3] These references provide guidance pertaining to the proper identification, manufacture, packaging, transportation, and storage of fluid milk products. The dairy industry is familiar with these references and the frequency with which they can be revised, sometimes several times each year. Therefore, § 1146.3(a) of the rule provides that eligible milk donations must meet the commodity specifications in effect on the date the milk is shipped from the processor to the eligible distributor, and § 1146.3(b) requires AMS to maintain current commodity specifications for donated milk on its website.

Program Eligibility and Participation

Section 1146.100 of the rule provides that an eligible dairy organization must be a member of a participating partnership to be eligible for reimbursements under the MDRP. As explained in the Definitions section above, a participating partnership is one whose Plan has been approved by AMS. Program reimbursements cannot exceed 100 percent of the eligible dairy organization's qualified expenses.

The amended statute requires the Secretary to review Plans at least annually and determine whether to approve those Plans. *See* Sec. 1431(c)(2). Further, the amended statute requires the Secretary to, at least annually, preapprove an amount for reimbursement of qualified expenses under each Plan based on an assessment of the Plan's feasibility and the extent to which the Plan advances the purposes of the program. *See* Sec. 1431(f)(1). Finally, Sec. 1431(c)(1) of the amended statute specifies the information that

[1] *https://www.ams.usda.gov/sites/default/files/media/CIDMilkFluid.pdf,* accessed August 29, 2019.

[2] *https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/UCM612027.pdf;* accessed August 29, 2019.

[3] *https://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2007965.htm#sld,* accessed August 29, 2019.

eligible partnerships must supply with their Plans. Sections 1146.102 and 1146.104 of the rule address these statutory requirements and are described in detail below.

Section 1146.102 of the rule outlines requirements for submission of Plans to AMS in order to be considered for the program. Eligible partnerships must apply or reapply for program participation each fiscal year by the deadline announced by AMS to be assured of consideration. Eligible partnerships must estimate the amount of eligible milk the dairy organization partner will donate to the distributor partner for distribution to persons in low-income groups. Such amounts should include planned milk donations that a dairy organization might make on an anticipated schedule, as well as plans for contingency donations the dairy organization might make under certain situations, such as when the distributor partner identifies a specific need for additional milk donations. Plans submitted to AMS for program approval must include a signed affirmation regarding the partnership's ability to supply, transport, store, and distribute eligible donated milk products consistent with the requirements in the commodity specifications under § 1146.3 of the rule. Finally, the eligible partnership is required to propose the rate at which qualified expenses under the program will be reimbursed to the eligible dairy organization member. Such information will enable AMS to determine whether each partnership's Plan is feasible and likely to fulfill the statutory purposes of the program. As specified in § 1146.208 of the rule, AMS will only collect information deemed necessary to determine whether an eligible partnership's Plan should be approved. All proprietary business information submitted will be used only for the purposes of the program and will be kept confidential by AMS.

Section 1146.104 of the rule specifies the process AMS will use to review applications to the program and determine whether to approve Plans submitted by eligible partnerships. Within 45 days of the application deadline, AMS will review the Plans, determine whether to approve or disapprove them, and notify the eligible partnership of AMS's determination. In making determinations, AMS will consider under § 1146.104(a)(1) the total amount of funding available for the program each fiscal year. The amended statute specifies that the Secretary shall use $9 million dollars to carry out the provisions of the program for fiscal year 2019, and $5 million dollars for each fiscal year thereafter. *See* Sec. 1431(j). Under § 1146.104(a)(2), AMS will consider the feasibility of each Plan by determining whether available funding will cover the total amount of donations at the reimbursement rate proposed by the partnership. As well, AMS will review the information submitted by the partnership, including the signed confirmation that the partnership can meet the requirements related to proper processing, transport, and storage of donated milk products until they are distributed. Under § 1146.104(a)(3), AMS will consider the extent to which the Plan would advance the statutory purposes of the MDRP, namely whether it would encourage the donation of eligible milk, provide nutrition assistance to individuals in low-income groups, and reduce food waste. *See* amended statute at Sec. 1431(f)(B)(ii). Finally, the amended statute specifies that preference will be given to eligible partnerships where the dairy organization provides funding and in-kind contributions in addition to the eligible milk donations for which the dairy organization will seek reimbursement. *See* Sec. 1431(f)(2). Section 1146.104(a)(4) incorporates that factor for Plan consideration.

Under § 1146.104(b) of the rule, participating partnerships can apply for continued program participation in subsequent fiscal years and can either notify AMS that there are no changes to the previous fiscal year's Plan, or they can submit a revised Plan for consideration. Section 1431(f)(2) of the amended statute specifies that preference will be given to eligible partnerships who provide funding and in-kind contributions in addition to the donations for which they are reimbursed. Accordingly, § 1146.104(b) of the rule allows for participating partnerships desiring to continue in the program to submit additional information about funding and in-kind donations the dairy organization partner made during the previous fiscal year.

Section 1146.104(c) of the rule provides that AMS will determine whether to approve new or continuing Plans for all or a portion of each Plan's proposed donations and reimbursements, depending on the amount of funds available for allocation to all participating partnerships during the fiscal year. In their Plans, partnerships will include a rate at which they propose to be reimbursed for milk donations. For example, the Plan may request reimbursement at a rate of 75 percent of the difference between Class I and the lowest class price for eligible milk in each month they make donations. Upon Plan approval, AMS will specify the approved rate, as well as the total amount the partnership can receive in reimbursements during the fiscal year. The approved total amount will be dependent upon the number of approved program partnerships and available funding. The partnership may submit reimbursement claims any time during the fiscal year or up to 90 days after the close of the fiscal year. Once the partnership's reimbursements for the year reach the total dollar amount approved for that partnership, reimbursements under their Plan will not be approved for the remainder of the fiscal year, unless an adjustment or increase is provided as described below.

The amended statute specifies that the Secretary shall adjust or increase amounts approved for reimbursement based on performance and demand. *See* Sec. 1431(f)(3)(A). Section 1146.104(d) of the rule provides that AMS will review the status of each approved Plan during the applicable fiscal year. AMS may adjust the amount of reimbursements available under a participating partnership's Plan based on the partnership's performance under their Plan to date, the availability of program funds, or changes in demand for fluid milk donations. For example, in the aftermath of a hurricane that displaces numerous people, AMS could determine that demand for milk donations may increase in that area and AMS could make adjustments to the Plans of participating partnerships in the affected area to allow for additional reimbursements to support increased milk donations, if the partnerships are willing to do so. In another example, during its routine review of approved Plans, AMS might observe that one partnership has been unable to donate the amount of eligible milk it originally estimated because the distributor partner's food pantry closed. Under § 1146.104(d)(2) of the rule, AMS could reduce that partnership's approved reimbursement amount and reassign the unused funds to another participating partnership who has indicated it is interested in making additional donations. AMS will provide affected participating partnerships 30 days' notice prior to adjusting their approved Plans.

The amended statute further requires the Secretary to establish a procedure for participating partnerships to request increases to the amount approved for reimbursement under their Plans based on changes in conditions. *See* Sec. 1431(f)(3)(B). Section 1146.104(e) of the rule establishes the process for making such requests. To support requests for increases in reimbursement amounts, participating partnerships are required

to submit information about the change in conditions that would warrant increases. The partnership is required to indicate whether it is seeking a long-term increase to address a permanent change in conditions, such as the addition of a second food pantry by the distributor partner, or whether it is seeking only a short-term increase to address a temporary change in conditions. Examples of temporary changes in conditions might include a plant receiving excess milk during the spring flush or a plant being temporarily shut down. AMS will notify the requester within 30 days of its determination regarding the requested increase, which will be based on AMS's evaluation of the reported change in conditions and the availability of funds.

Additionally, if a natural disaster or other unforeseen event occurs during the fiscal year, AMS may accept new Plan applications in order to facilitate donations to meet an immediate need. In this case, AMS may choose to publish the opportunity to accept new Plans, or a partnership can request AMS review a new Plan. New Plans must meet the criteria under § 1146.102 of the rule, and approval is subject to available remaining program fiscal year funds.

Under § 1146.104(e)(3) of the rule, AMS can give interim approval of the requested increase and approve incremental increases to the approved reimbursement amount prior to making a final determination regarding the increase, as authorized under Section 1431(f)(3)(B)(ii) of the amended statute.

Reimbursements and Qualified Expenses

Section 1431(d) of the amended statute specifies that the Secretary shall reimburse the eligible dairy organization member of a participating partnership for qualified expenses under the program on receipt of appropriate documentation. Section 1146.106(a) of the rule provides the process and describes the necessary information and documentation AMS will require to verify the dairy organization's claims for reimbursement. For each month in which the dairy organization makes donations and submits claims for reimbursement, the dairy organization must report the amount of eligible milk donated to the eligible distributor, the location of the plant where the milk was processed, the dates the donated milk was shipped to and received by the eligible distributor, and the applicable FMMO milk prices for that location for the month the milk was pooled on an FMMO. The dairy organization must also provide adequate documentation to verify the eligible distributor received the donated milk. Such documentation could include, but is not limited to, processing and shipping records, bills of lading, storage records, and receiving records from the eligible distributor. As specified in § 1146.208 of the rule, AMS will only collect the information and documentation needed to verify the dairy organization's claims for reimbursement. Under FMMOs, the United States Department of Agriculture (USDA) is required to keep all proprietary business information, confidential.[4] Confidentiality of such information is extended to its use in administering the MDRP.

Section 1146.106(b) of the rule specifies that a participating partnership can submit reimbursement requests anytime up to 90 days after the close of the fiscal year. Under § 1146.106(c), AMS will review, process, and issue payments for reimbursement claims on a quarterly basis. Under § 1146.106(d), AMS will return incomplete claims to the submitter so they can be completed and resubmitted. As authorized by the amended statute (Sec. 1431(d)(2)(B)), AMS may verify the accuracy of documentation submitted with reimbursement claims with spot checks and audits under § 1146.206 of the rule.

Section 1431(e) of the amended statute specifies the amount of reimbursement that can be claimed for qualified expenses under the program. As explained in the Background section of this document, only the dairy organization's expenses related to its FMMO pool obligation can be reimbursed under the MDRP. Reimbursement rates are limited to no more than 100 percent of the difference between the Class I milk price at the plant location where the donated milk was processed and the lowest classified milk price for the applicable month (either Class III or Class IV). Section 1146.108(a) of the rule provides that reimbursements will be determined by multiplying the following: [the amount of eligible milk donated] times [the approved rate for reimbursement determined pursuant to §§ 1146.102(d) and 1146.104(c)] times [the difference in the Class I price at the processing plant location and the lowest FMMO classified price (either Class III or Class IV) for the month the donation occurred]. Total reimbursements for a fiscal year cannot exceed the amount approved by AMS for each participating partnership.

Administrative Provisions

The amended statute requires the Secretary to publicize opportunities to participate in the MDRP. *See* Sec. 1431(h). Accordingly, § 1146.200 of the rule requires AMS to publish notices inviting interested parties to apply for program participation on the AMS website. AMS will announce the total amount of funding available for each fiscal year and will specify the format for submitting applications for new or continuing program participation. If, after its review and approval of the applications submitted, AMS determines that additional funds are available for the fiscal year, it will publicize further announcements and invitations on its website.

Section 1431 (j) of the amended statute specifies that program funds are to remain available until expended. Under § 1146.202 of the rule, if reimbursement monies remain after all fiscal year reimbursement claims have been approved and distributed, the remaining monies will remain available to fund reimbursement claims in subsequent fiscal years.

The amended statute prohibits the sale of eligible milk products donated under the MDRP back into commercial markets and specifies that eligible distributors who violate that prohibition will not be eligible for future participation in the program. *See* Sec. 1431(g). Section 1146.204 of the rule implements the statutory prohibition and penalty for violation.

Section 1431(i) of the amended statute directs the Secretary to conduct appropriate reviews or audits to ensure the integrity of the MDRP. Section 1431(d)(2)(B) of the amended statute further authorizes the Secretary to verify the accuracy of documentation submitted with claims for reimbursement through spot checks and audits. Section 1146.206 of the rule provides that AMS will verify that the donated milk for which reimbursement is being sought was pooled on an FMMO. The section further provides for the review, audit, and spot checks of information submitted.

As mentioned in the above discussions, § 1146.208 of the rule requires AMS to maintain confidentiality regarding information it collects to administer the program, and to use the information only for program purposes.

Finally, § 1146.210 of the rule specifies that milk products sold or donated under any other USDA commodity purchase or donation program are not eligible for reimbursement under the MDRP. From time to time, USDA may purchase fluid milk products for use in nutrition assistance programs or other uses, but vendors are compensated for those

[4] See 7 U.S.C. 608d(2).

purchases through funding under those program provisions. One of the main purposes of the MDRP is to reduce food waste by encouraging the donation of additional milk to similar outlets. Thus, eligible dairy organizations who have received compensation for milk purchases under other USDA programs may not receive reimbursements for the same milk under the MDRP.

Paperwork Reduction Act

Section 1601(c)(2)(B) of the 2014 Farm Bill provides that the administration of the Dairy Product Donation Program shall be made without regard to the Paperwork Reduction Act (PRA), 44 U.S.C. Chapter 35. Section 1701 of the 2018 Farm Bill extends that Congressional direction to the establishment of the MDRP replacing the Dairy Product Donation Program. Thus, any information collection conducted for the MDRP is not subject to the PRA.

Implementation of this program will place information collection requirements on participating entities. AMS estimates twenty partnerships will be involved in the program during each fiscal year. Each participating partnership will be required to submit a Milk Donation and Reimbursement Plan. Claims will be processed quarterly, thus participating partnerships can submit four Reimbursement Claim Forms per year. AMS estimates it will take participating partnerships 2 hours per year to complete a Milk Donation and Reimbursement Plan Form, and 6 hours per year to complete the Reimbursement Claim Form (1.5 hours each reporting quarter). Assuming the reporting burden will be completed by an administrative assistant employee, at an hourly salary rate of $20, AMS estimates an annual reporting cost of $160 per participating partnership, for a total annual program reporting cost of $3,200 (assuming 20 participating partnerships).

E-Government Act

USDA is committed to complying with the E-Government Act (44 U.S.C. 3601, *et seq.*) by promoting the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes. The application and reimbursements can be filed though *www.ams.usda.gov/mdrp.*

Executive Orders 12866 and 13771

AMS is issuing this rule in conformance with Executive Order 12866—Regulatory Planning and Review, which directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity.

AMS considered alternative methods for allocating available funds under the program, including whether to allocate reimbursements equally across all the geographic areas of the United States covered by FMMOs or to target specific regions in need of milk donations. Ultimately AMS determined that because the primary purpose of the program is to reduce waste associated with the disposition of surplus milk, the industry would be best served by allowing those who are more likely to have surplus milk and who are in a position to make donations to apply for the program without consideration of geographic location.

This rule has been designated a significant regulatory action under Executive Order 12866. This rule is not expected to have any quantified cost or benefits, rather the rule is expected to result in transfers consistent with the following table:

TABLE 1—ACCOUNTING STATEMENT

	Primary estimate	Year dollar	Discount rate (percent)	Period covered
Benefits—				
Annualized Monetized ($millions/year)	0	2019	7	FY 2019–2023
	0	2019	3	
Costs—				
Annualized Monetized ($millions/year)	0	2019	7	FY 2019–2023
	0	2019	3	
Transfers—From the Federal Government to an eligible partnership				
Annualized Monetized ($millions/year)	$6.33	2019	7	FY 2019–2023
	$6.02	2019	3	

As the program is voluntary, eligible partnerships are expected to only participate if their individual circumstances deem it beneficial. The transfers will be reimbursements in the form of Federal payments to program participants to help offset costs associated with eligible milk donations.

This rule is not subject to the requirements of E.O. 13771 because this rule results in no more than *de minimis* costs.

AMS does not anticipate this program will impact milk prices. Milk donated to non-profit organizations to feed needy people is already priced under the FMMO system. Implementation of this program will not change FMMO milk prices as it relates to donated milk. Furthermore, this program is expected to have a negligible impact on retail milk sales. Typically, needy populations that receive nutrition assistance from non-profit organizations do not buy milk at retail outlets. Consequently, fluid milk donations through this program are not expected to become a substitution for retail milk sales.

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

Regulatory Flexibility Analysis

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601, *et seq.*), AMS considered the economic impact of the action on small entities. Accordingly, AMS has prepared this final Regulatory Flexibility Analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be unduly or disproportionately burdened. Small dairy farm businesses have been defined by the Small Business Administration (SBA) (13 CFR 121.601) as those businesses having annual gross receipts of less than $750,000. The SBA's definition of small agricultural service firms, which includes handlers that are regulated under FMMOs, varies depending on the product manufactured. Small fluid beverage

milk product manufacturers are defined as having 1,000 or fewer employees.

The milk of 31,435 U.S. dairy farms was pooled on an FMMO for the month of December 2018. AMS estimates that 28,920 dairy farms, or 92 percent, would be considered small businesses. Dairy farmers of all sizes whose milk is pooled on an FMMO may benefit from the program because it will encourage donations of milk which will be pooled on an FMMO at its Class I value.

During December 2018 there were 233 regulated fluid milk processing plants (distributing plants) pooling Class I milk on an FMMO. AMS estimates 18 percent were operated by dairy-farmer cooperatives, while the remaining were independently owned. AMS assumes that fluid milk processing plants, whether cooperative or independently owned, are the entities most likely to qualify as eligible dairy organizations under the MDRP, as they are regulated and typically have FMMO pool obligations. AMS estimates 120 different entities operated the 233 fluid milk processing plants pooling milk in December 2018. AMS believes 120 to be the universe of fluid milk processing plants eligible to participate in the MDRP. Of the 120, 63 percent would be considered small businesses, based on their numbers of employees.

Participating in the MDRP will not unduly or disproportionately burden small fluid milk processing plants. All entities, regardless of size, can apply for the program if they incur qualified expenses as defined by program provisions. Program provisions are administered without regard for business size. Small fluid milk processing plants not accounting to an FMMO pool have no obligations that would qualify as reimbursable expenses under the MDRP and are not eligible to participate.

The definition of an eligible distributor is a public or non-profit organization that distributes donated milk. AMS was unable to obtain reliable data regarding the size of public or private non-profit organizations distributing food for nutrition assistance. Therefore, the business sizes of eligible distributors could not be estimated. Eligible distributors, regardless of size, can voluntarily participate in the MDRP if they are able to form a partnership with an eligible dairy organization. The voluntary nature of the program allows any eligible distributor to stop participating if they find the program causes an undue or disproportionate burden.

AMS has determined establishment of this program will not have a significant economic impact on a substantial number of small entities. Program provisions will be applied uniformly to both large and small businesses and are not expected to unduly or disproportionately burden small entities.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175—Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on: (1) Policies that have tribal implications, including regulations, legislative comments, or proposed legislation; and (2) other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The Office of Tribal Relations (OTR) has reviewed this rule and determined that consultation is not required at this time. If a tribe requests consultation AMS will work with the OTR to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

Executive Order 12988

This rule has been reviewed under Executive Order 12988—Civil Justice Reform. This final rule may have retroactive effect because milk donations made during fiscal year 2019 prior to the effective date of the rule may be eligible for reimbursement if the eligible partnership's fiscal year 2019 Plan is approved for reimbursements and if the partnership meets all other program requirements. Fiscal year 2019 extends from October 1, 2018, to September 30, 2019. Milk donations made prior to October 1, 2018, are not eligible for reimbursement under the program. There are no administrative procedures that must be exhausted prior to judicial challenges to the provisions of this rule.

Effective Date

The APA requires the publication of a substantive rule 30 days before its effective date, unless the rule grants or recognizes an exemption or relieves a restriction (5 U.S.C. 553(d)(1)), or the agency finds good cause for excepting the rule from the 30-day notice requirement (5 U.S.C. 553(d)(3).) AMS finds that it is unnecessary and contrary to the public interest to postpone the effective date of this rule for 30 days after publication in the **Federal Register**. The Congressional mandate to establish the program specifies funding for the 2019 fiscal year, which began October 1, 2018. To take full advantage of the program, participants will need as much time as possible to submit Plans and receive approval from AMS. Furthermore, participation in the program is intended to reduce food waste by offering milk handlers alternative outlets for excess milk, which is produced primarily in the spring and summer months due to the normal seasonal variations in milk production. It would be contrary to the public interest to delay implementation of the MDRP, thereby potentially delaying donations of milk to food assistance programs and prolonging food waste. Moreover, postponing the effective date of the final rule for 30 days is unnecessary to allow for adjustment of behavior because participation in the program is voluntary. Therefore, good cause exists for making this rule effective 10 days after publication in the **Federal Register**.

List of Subjects in 7 CFR Part 1146

Milk, Donations, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR Subtitle B Chapter X is amended by adding part 1146 to read as follows:

PART 1146—MILK DONATION REIMBURSEMENT PROGRAM

Subpart A—General Provisions

Sec.
1146.1 Definitions.
1146.3 Commodity specifications.

Subpart B—Program Participation

1146.100 Program eligibility.
1146.102 Milk donation and distribution plans.
1146.104 Review and approval.
1146.106 Reimbursement claims.
1146.108 Reimbursement calculation.

Subpart C—Administrative Provisions

1146.200 Opportunities to participate.
1146.202 Rollover of fiscal year funds.
1146.204 Prohibition on resale of products.
1146.206 Enforcement.
1146.208 Confidentiality.
1146.210 Milk for other programs.

Authority: Sec. 1431, Pub. L. 113–79, 128 Stat. 695, as amended.

Subpart A—General Provisions

§ 1146.1 Definitions.

AMS means the Agricultural Marketing Service of the United States Department of Agriculture.

Eligible dairy organization means a dairy farmer cooperative or a dairy processor that

(1) Is regulated under a Federal milk marketing order (FMMO);

(2) Accounts to the FMMO marketwide pool; and

(3) Incurs qualified expenses described in § 1146.108.

Eligible distributor means a public or private non-profit organization that distributes donated eligible milk.

Eligible milk means Class I fluid milk products produced and processed in the United States that meet the specifications referenced in § 1146.3.

Eligible partnership means a partnership between an eligible dairy organization and an eligible distributor.

Fiscal year means the twelve-month period beginning October 1 of any year and ending September 30 of the following year.

Participating partnership means an eligible partnership for which AMS has approved a Milk Donation and Distribution Plan (Plan) for eligible milk under § 1146.104.

Program means the Milk Donation Reimbursement Program established in this part.

Secretary means the Secretary of the United States Department of Agriculture or a representative authorized to act in the Secretary's stead.

§ 1146.3 Commodity specifications.

(a) Eligible milk donations must meet the commodity specifications pursuant to (b) in effect on the date the milk products are shipped from the plant.

(b) AMS shall maintain on its website current commodity specifications for fluid milk products eligible for donation and reimbursement under the Milk Donation Reimbursement Program.

Subpart B—Program Participation

§ 1146.100 Program eligibility.

An eligible dairy organization must be a member of a participating partnership pursuant to § 1146.1 to be eligible to receive reimbursements for qualified expenses related to voluntary fluid milk donations, subject to the requirements and limitations specified in §§ 1146.102 and 1146.104.

§ 1146.102 Milk donation and distribution plans.

New and continuing program participants must submit completed Milk Donation and Distribution Plans to AMS in the form and manner established by AMS prior to the published deadline to be eligible for program consideration. The completed Milk Donation and Distribution Plans must –

(a) Include the physical location(s) of the eligible dairy organization's processing plant(s) and the eligible distributor's distribution site(s);

(b) Include an affirmation signed by both eligible partners regarding the partnership's ability to supply, transport, store, and distribute donated milk products consistent with the commodity specifications under § 1146.3;

(c) Include an estimate of the quantity of eligible milk that the eligible dairy organization plans to donate each year, based on –

(1) Preplanned donations and

(2) Contingency plans to address unanticipated donations; and

(d) Describe the rate at which the eligible dairy organization will be reimbursed, not to exceed 100 percent of qualified expenses pursuant to § 1146.108.

§ 1146.104 Review and approval.

(a) *Program application and review.* Within 45 days of the announced application deadline, AMS will review all timely submitted applications and notify applicants regarding approval or disapproval for program participation during the applicable fiscal year. AMS's review will include the following considerations:

(1) Total annual funds available for program administration, including an appropriate reserve to cover costs related to increases in milk prices and emergencies including, but not limited to, natural disasters;

(2) The feasibility of the Milk Donation and Distribution Plan;

(3) The extent to which the Milk Donation and Distribution Plan –

(i) Promotes the donation of eligible milk,

(ii) Provides nutrition assistance to individuals in low-income groups, and

(iii) Reduces food waste; and

(4) The amount of funding and in-kind contributions the eligible dairy organization plans to provide to the eligible distributor in addition to the donations for which it will seek reimbursements.

(b) *Continued program participation.* Within 45 days of the announced application deadline, AMS will review and notify applicants regarding approval or disapproval of all timely submitted requests for continued program participation. AMS's review of requests for continued program participation will be based on consideration of the factors in paragraphs (a) and (b)(1) through (3) of this section:

(1) Eligible partnerships requesting continued program participation for a subsequent fiscal year can include information about the extent to which they provided funding and in-kind contributions in addition to eligible milk donations for which they were reimbursed through the program for the previous fiscal year.

(2) If there are no changes to the eligible partnership's approved Milk Donation and Distribution Plan from the previous fiscal year, the eligible partnership must request that AMS consider the partnership's previously approved Plan and provide the additional information described in paragraph (b)(1) of this sectoin, if applicable.

(3) If there are changes to the eligible partnership's approved Milk Donation and Distribution Plan from the previous fiscal year, the eligible partnership must submit a new Plan as described in paragraph (a) and provide the additional information described in paragraph (b)(1) of this section, if applicable.

(c) *Plan approval.* Subject to the provisions in paragraph (a) of this section, AMS will determine whether to approve new and continuing Milk Donation and Distribution Plans for all or a proportion of each Plan's proposed donations and reimbursements. For each approved Plan, AMS will determine:

(1) A reimbursement rate applicable to each claim for reimbursement during the fiscal year, and

(2) A total dollar amount available for reimbursement during the fiscal year.

(d) *Adjustments.* AMS will review the activity of approved Milk Donation and Distribution Plans during the fiscal year to determine whether adjustments should be made to the reimbursement amounts approved under paragraph (c) of this section.

(1) Determinations about adjustments will be based on –

(i) The participating partnership's performance,

(ii) Availability of program funds, and

(iii) Demand for eligible milk donations.

(2) AMS will provide 30 days' notice to participating partnerships prior to adjusting reimbursement amounts in their respective approved Milk Donation and Distribution Plans.

(e) *Request for increase.* Eligible partnerships with approved Milk Donation and Distribution Plans during any fiscal year may request an increase in the amount of reimbursement approved under paragraph (c) of this section based on changes in conditions.

(1) Requests for an increase must be submitted to AMS in the manner and form established by AMS, and must –

(i) Describe the change in conditions that would warrant an increase in reimbursement,

(ii) Indicate whether the requested increase is intended to be a long-term revision to the eligible partnership's approved Milk Donation and Distribution Plan or a short-term increase to respond to temporary conditions, and

(iii) Specify the amount of increased reimbursement requested.

(2) Within 30 days of receipt, AMS will review the request for an increase and will notify the requester regarding approval or disapproval of the request. AMS's determination about whether such an increase is feasible will be based on its evaluation of the factors described in paragraph (e)(1) of this section and the availability of funds.

(3) Based on the change in conditions identified by the requester, AMS will determine whether to provide interim approval of an increase requested under paragraph (e)(1) of this section and an incremental increase to the amount of reimbursement approved under paragraph (c) of this section prior to making a final determination regarding approval of the requested increase.

§ 1146.106 Reimbursement claims.

(a) In order for the eligible dairy organization partner to receive reimbursements for qualified expenses pursuant to § 1146.108, the participating partnership must submit a report and appropriate supporting documentation to AMS.

(1) *For each month* of the fiscal year pertaining to an approved Milk Donation and Distribution Plan (including the months prior to AMS's review and approval of the Plan), the report must include:

(i) The amount of eligible milk donated to the eligible distributor;

(ii) The location of the plant where the donated milk was processed;

(iii) The date the donated milk was shipped from the plant where the milk was processed;

(iv) The date the donated milk was received by the eligible distributor; and

(v) The applicable announced Federal milk marketing order prices for the month the milk was pooled:

(A) The Class I price at the plant location where the milk was processed; and

(B) The lowest classified price (either Class III or Class IV).

(2) Appropriate documentation to support the report required in paragraph (a)(1) of this section may include, but is not limited to, copies of processing records, shipping records, bills of lading, warehouse receipts, distribution records, or other documents that demonstrate the reported amount of eligible milk was processed, donated, and distributed in accordance to the approved Milk Donation and Distribution Plan and as reported in the eligible dairy organization's report.

(b) Reimbursement requests may be submitted to AMS at any time during the fiscal year and for up to 90 days after the close of the fiscal year.

(c) AMS will review and process reimbursement requests on a quarterly basis, including those submitted by the last day of the month following the end of each quarter of the fiscal year.

(d) Incomplete reimbursement requests will be returned to the submitter for revision or completion and resubmission as necessary.

§ 1146.108 Reimbursement calculation.

(a) For each reimbursement claim submitted by a participating partnership, the amount of reimbursement under § 1146.106 shall be the product of:

(1) The quantity of eligible milk donated by the eligible dairy organization to the eligible distributor member of the participating partnership;

(2) The rate described in the approved Milk Donation and Distribution Plan under § 1146.102(d); and

(3) The difference between the FMMO Class I price at the plant location and the lowest classified price (either Class III or Class IV), for the month in which the donation was pooled on a Federal Milk Marketing Order.

(b) Expenses eligible for reimbursement under § 1146.106 shall not exceed the value that an eligible dairy organization incurred by accounting to the Federal milk marketing order pool at the difference between the announced Class I milk price at the location of the plant where the milk was processed and the lower of the Class III or Class IV milk price for the applicable month.

(c) Claim reimbursements are subject to the limitations specified in paragraph (b) of this section.

(d) Total plan reimbursements are subject to the limitations specified in § 1146.104(c)(2).

Subpart C—Administrative Provisions

§ 1146.200 Opportunities to participate.

(a) AMS will announce opportunities to participate in the Milk Donation Reimbursement Program and the amount of program funding available for each fiscal year on the AMS website. The announcements will include invitations for interested parties to submit new or revised Milk Donation and Distribution Plans and will specify the manner and form in which program applications should be submitted.

(b) If, after making approval determinations for the fiscal year about each submitted program application, AMS determines that additional reimbursement funds are available, AMS will publish an announcement to that effect and invite further requests for Plan approvals pursuant to § 1146.104(a) through (c) or for increases in reimbursement amounts pursuant § 1146.104(e).

§ 1146.202 Rollover of fiscal year funds.

If reimbursement monies remain after all fiscal year reimbursement claims have been approved and distributed, the remaining monies will be available to fund reimbursement claims in subsequent fiscal years.

§ 1146.204 Prohibition on resale of products.

(a) *Prohibition in general.* An eligible distributor that receives eligible milk products donated under the Milk Donation Reimbursement Program may not sell the donated milk products back into commercial markets.

(b) *Prohibition on future participation.* An eligible distributor that AMS determines has violated the prohibition in paragraph (a) of this section shall not be eligible for any future participation in the Milk Donation Reimbursement Program.

§ 1146.206 Enforcement.

AMS will verify the donated milk for which reimbursement is sought was pooled on a FMMO. AMS will also conduct spot checks, reviews, and audits of the reports and documentation submitted pursuant to § 1146.106(a) to verify their accuracy and to ensure the integrity of the Milk Donation Reimbursement Program.

§ 1146.208 Confidentiality.

AMS will collect only that information deemed necessary to administer the Milk Donation Reimbursement Program and will use the information only for that purpose. AMS will keep all proprietary business information collected under the program confidential.

§ 1146.210 Milk for other programs.

Milk sold or donated under other commodity or food assistance programs administered by the United States Department of Agriculture is not eligible for reimbursement under the Milk Donation Reimbursement Program in this part.

Dated: August 29, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–19090 Filed 9–4–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF ENERGY

10 CFR Part 430

RIN 1904–AE26

Energy Conservation Program: Definition for General Service Lamps

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

ACTION: Final rules; withdrawal.

SUMMARY: On February 11, 2019, the U.S. Department of Energy (DOE) published a notice of proposed rulemaking (NOPR) proposing to withdraw the revised definitions of general service lamp (GSL), general service incandescent lamp (GSIL) and other supplemental definitions, that were to go into effect on January 1, 2020. DOE responds to comments received on the NOPR in this final rule and maintains the existing regulatory definitions of GSL and GSIL, which are the same as the statutory definitions of those terms.

DATES: The final rules published on January 19, 2017 (82 FR 7276 and 82 FR 7322), are withdrawn effective October 7, 2019.

ADDRESSES: The docket 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 may not be publicly available, such as those containing information that is exempt from public disclosure.

The docket web page can be found at: *http://www.regulations.gov/docket?D=EERE-2018-BT-STD-0010*. The docket web page contains instructions on how to access all documents in the docket.

FOR FURTHER INFORMATION CONTACT: Appliance Standards staff, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1445. Email: *ApplianceStandardsQuestions@ee.doe.gov*.

Ms. Celia Sher, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–6122. Email: *celia.sher@hq.doe.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Authority and Background
II. Synopsis of Final Rule
III. Discussion of Comments
A. Scope of Products Included in the Definitions of GSIL and GSL
1. Imposition of the Backstop
2. EPCA's Anti-Backsliding Provision
B. Withdrawal of Revised GSL and GSIL Definitions
1. General Authority
2. Five Specialty Incandescent Lamps
3. Incandescent Reflector Lamps
4. T-Shape, B, BA, CA, F, G16–1/2, G25, G30, S, M–14 and Candelabra Base Lamps
5. Supplemental Definitions
C. Additional Issues
1. Preemption
2. Manufacture Date in Lieu of Sales Prohibition
3. Consumer/Environmental Harm
4. Data
IV. Procedural Issues and Regulatory Review
A. Review Under Executive Orders 12866 and 13563
B. Review Under Executive Order 13771
1. Analytical Approach
2. Cost Estimate
3. Results
C. Review Under the Regulatory Flexibility Act
D. Review Under the Paperwork Reduction Act of 1995
E. Review Under the National Environmental Policy Act of 1969
F. Review Under Executive Order 13132
G. Review Under Executive Order 12988
H. Review Under the Unfunded Mandates Reform Act of 1995
I. Review Under the Treasury and General Government Appropriations Act, 1999
J. Review Under Executive Order 12630
K. Review Under the Treasury and General Government Appropriations Act, 2001
L. Review Under Executive Order 13211
M. Congressional Notification
V. Approval of the Office of the Secretary

I. Authority and Background

Title III, Part B of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94–163 (42 U.S.C. 6291–6309, as codified), established the Energy Conservation Program for Consumer Products Other Than Automobiles, a program covering most major household appliances (collectively referred to as ''covered products''), which includes general service lamps (GSLs), the subject of this final rule. Amendments to EPCA in the Energy Independence and Security Act of 2007 (EISA) directed DOE to conduct two rulemaking cycles to evaluate energy conservation standards for GSLs. (42 U.S.C. 6295(i)(6)(A)–(B)) GSLs are currently defined in EPCA to include general service incandescent lamps (GSILs), compact fluorescent lamps (CFLs), general service light-emitting diode (LED) lamps and organic light-emitting diode (OLED) lamps, and any other lamps that the Secretary of Energy (Secretary) determines are used to satisfy lighting applications traditionally served by general service incandescent lamps. (42 U.S.C. 6291(30)(BB))

For the first rulemaking cycle, Congress instructed DOE to initiate a rulemaking process prior to January 1, 2014, to consider two questions: (1) Whether to amend energy conservation standards for general service lamps and (2) whether ''the exemptions for certain incandescent lamps should be maintained or discontinued.'' (42 U.S.C. 6295(i)(6)(A)(i)) Further, if the Secretary determines that the standards in effect for GSILs should be amended, EPCA provides that a final rule must be published by January 1, 2017, with a compliance date at least 3 years after the date on which the final rule is published. (42 U.S.C. 6295(i)(6)(A)(iii)) In developing such a rule, DOE must consider a minimum efficacy standard of 45 lumens per watt (lm/W). (42 U.S.C. 6295(i)(6)(A)(ii)) If DOE fails to complete a rulemaking in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv) or a final rule from the first rulemaking cycle does not produce savings greater than or equal to the savings from a minimum efficacy standard of 45 lm/W, the statute provides a ''backstop'' under which DOE must prohibit sales of GSLs that do not meet a minimum 45 lm/W standard beginning on January 1, 2020. (42 U.S.C. 6295(i)(6)(A)(v))

The EISA-prescribed amendments further directed DOE to initiate a second rulemaking cycle by January 1, 2020, to determine whether standards in effect for GSILs should be amended with more-stringent requirements and if the exemptions for certain incandescent lamps should be maintained or discontinued. (42 U.S.C. 6295(i)(6)(B)(i)) For this second review of energy conservation standards, the scope is not limited to incandescent lamp technologies. (42 U.S.C. 6295(i)(6)(B)(ii))

DOE initiated the first GSL standards rulemaking process by publishing in the **Federal Register** a notice of public meeting and availability of the framework document. 78 FR 73737 (Dec. 9, 2013); *see also* 79 FR 73503 (Dec. 11, 2014) (notice of public meeting and availability of preliminary technical support document). DOE later issued a NOPR to propose amended energy conservation standards for GSLs. 81 FR 14528, 14629–14630 (Mar. 17, 2016) (the March 2016 NOPR). The March 2016 NOPR focused on the first question

that Congress directed DOE to consider—whether to amend energy conservation standards for general service lamps. (42 U.S.C. 6295(i)(6)(A)(i)(I)) In the March 2016 NOPR proposing energy conservation standards for GSLs, DOE stated that it would be unable to undertake any analysis regarding GSILs and other incandescent lamps because of a then applicable congressional restriction (the Appropriations Rider) [1] on the use of appropriated funds to implement or enforce 10 CFR 430.32(x). 81 FR 14528, 14540–14541 (Mar. 17, 2016). Notably, the Appropriations Rider was readopted and extended continuously in multiple subsequent legislative actions, and only expired on May 5, 2017, when the Consolidated Appropriations Act of 2017 was enacted.[2]

In response to comments to the March 2016 NOPR, DOE conducted additional research and published a notice of proposed definition and data availability (NOPDDA), which proposed to amend the definitions of GSIL and GSL. 81 FR 71794, 71815 (Oct. 18, 2016). DOE explained that the October 2016 NOPDDA related to the second question that Congress directed DOE to consider—whether ''the exemptions for certain incandescent lamps should be maintained or discontinued,'' and stated explicitly that the NOPDDA was not a rulemaking to establish an energy conservation standard for GSLs. (42 U.S.C. 6295(i)(6)(A)(i)(II)); *see also* 81 FR 71798. The relevant ''exemptions,'' DOE explained, referred to the 22 categories of incandescent lamps that are statutorily excluded from the definitions of GSIL and GSL. 81 FR 71798. In the NOPDDA, DOE clarified that it was defining what lamps constitute GSLs so that manufacturers could understand how any potential energy conservation standards might apply to the market. *Id.*

On January 19, 2017, DOE published two final rules concerning the definition of GSL. 82 FR 7276; 82 FR 7322. The January 2017 definition final rules amended the definitions of GSIL and GSL by bringing certain categories of lamps that had been excluded by statute from the definition of GSIL within the definitions of GSIL and GSL. Like the October 2016 NOPDDA, DOE stated that the January 2017 definition final rules related only to the second question that Congress directed DOE to consider, regarding whether to maintain or discontinue certain ''exemptions.'' (42 U.S.C. 6295(i)(6)(A)(i)(II)). That is, neither of the two final rules issued on January 19, 2017, established, or even purported to establish, energy conservation standards applicable to GSLs. Although the two final rules were published on January 19, 2017, neither rule has yet gone into effect because the effective date was set as January 1, 2020.

With the removal of the Appropriations Rider in the Consolidated Appropriations Act, 2017, DOE was no longer restricted from undertaking the analysis and decision making required to address the first question presented by Congress, *i.e.,* whether to amend energy conservation standards for general service lamps, including GSILs. Thus, on August 15, 2017, DOE published a notice of data availability and request for information (NODA) seeking data for GSILs and other incandescent lamps. 82 FR 38613. The purpose of this NODA was to assist DOE in making a decision on the first question posed to DOE by Congress; *i.e.,* a determination regarding whether standards for GSILs should be amended. Comments submitted in response to the NODA also led DOE to re-consider the decisions it had already made with respect to the second question presented to DOE; *i.e.,* whether the exemptions for certain incandescent lamps should be maintained or discontinued. As a result of the comments received in response to the NODA, DOE also re-assessed the legal interpretations underlying certain decisions made in the January 2017 definition final rules. Accordingly, DOE issued a NOPR on February 11, 2019 to withdraw the revised definitions of GSL, GSIL, and the supporting definitions established in the January 2017 definition rules (the February 2019 NOPR). 84 FR 3120. DOE held a public meeting on February 28, 2019 to hear oral comments and solicit information and data relevant to the February 2019 NOPR.

The following sections of this preamble respond to comments received on the February 2019 NOPR and during the NOPR public meeting.

II. Synopsis of Final Rule

In this rule, DOE withdraws the revised definitions of GSL and GSIL established in the January 2017 definition final rules which would otherwise take effect on January 1, 2020. These definitions included certain GSILs as GSLs in a manner that is not consistent with the best reading of the statute. Additionally, DOE withdraws the supplemental definitions established in the January 2017 definition final rules that are no longer necessary in light of the withdrawal of the revised definitions of GSL and GSIL. This rule maintains the existing definitions of GSL and GSIL currently found in DOE's regulations, which are the same as the statutory definition of those terms. Specifically, the rule maintains the statutory exclusions of specified lamps from the definition of GSIL, and thus, such lamps would not be GSLs. DOE does not make a determination in this rule whether standards for GSLs, including GSILs, should be amended. Rather, this rule establishes the scope of lamps to be considered in that determination. DOE will make that determination in a separate rulemaking.

III. Discussion of Comments

A. Scope of Products Included in the Definitions of GSIL and GSL

In the February 2019 NOPR, DOE proposed to retain the existing statutory exclusions from the GSIL definition by withdrawing the revised definition of GSL, which, among other lamps, included as GSILs the five specialty incandescent lamps regulated under 42 U.S.C. 6295(l)(4), namely rough service lamps, vibration service lamps, 3-way incandescent lamps, high lumen lamps and shatter-resistant lamps. Additionally, DOE proposed to maintain the existing exclusion of incandescent reflector lamps (IRLs) from the statutory definitions of GSIL and GSL, as well as T-shape lamps that use no more than 40 W or have a length of more than 10 inches, B, BA, CA, F, G16–1/2, G25, G30, S, and M–14 lamps of 40 W or less. Further, DOE proposed that candelabra base incandescent lamps not be considered GSL because the existing definition of GSIL applies only to medium screw base lamps. 84 FR 3122–3123. DOE noted in the February 2019 NOPR that, because it had not yet made a final determination on whether standards applicable to GSILs should be amended per 42 U.S.C. 6295(i)(6)(A)(iii), no backstop energy conservation standard has been imposed. 81 FR 3123. In response, DOE received numerous comments relating to whether the backstop requirement for GSLs in 42 U.S.C. 6295(i)(6)(A)(v) had been triggered and the applicability of EPCA's anti-backsliding provision in 42 U.S.C. 6295(o), which precludes DOE from amending an existing energy

[1] Section 312 of the Consolidated and Further Continuing Appropriations Act, 2016 (Pub. L. 114–113, 129 Stat. 2419) prohibits expenditure of funds appropriated by that law to implement or enforce: (1) 10 CFR 430.32(x), which includes maximum wattage and minimum rated lifetime requirements for GSILs; and (2) standards set forth in section 325(i)(1)(B) of EPCA (42 U.S.C. 6295(i)(1)(B)), which sets minimum lamp efficiency ratings for incandescent reflector lamps.

[2] See, the Consolidated Appropriations Act of 2017 (Pub. L. 115–31, div. D, tit. III); see also, Consolidated Appropriations Act, 2018 (Pub. L. 115–141).

conservation standard to permit greater energy use or a lesser amount of energy efficiency.

1. Imposition of the Backstop

DOE received comments from the National Electrical Manufacturers Association (NEMA), Westinghouse Lighting, Signify North America Corporation (Signify), GE Lighting, and the American Lighting Association (ALA) agreeing with DOE's statement in the February 2019 NOPR that the backstop standard in 42 U.S.C. 6295(i)(6)(A)(v) has not been triggered since the Secretary has not determined whether to amend GSIL standards under 42 U.S.C. 6295(i)(6)(A)(iii), and so there is no obligation yet to publish a rule in accordance with the 42 U.S.C. 6295(i)(6)(A)(i)–(iv). (NEMA, No. 329 at p. 40; Westinghouse Lighting, No. 360 at p. 1; Signify, No. 354 at p. 1; GE Lighting, No. 325 at p. 1; ALA, No. 308 at p. 2) Further, these commenters supported NEMA's assertion that the backstop is not self-executing, and, per EPCA, requires the Secretary to first make a prohibitory order under 42 U.S.C. 6295(i)(6)(A)(v), which the Secretary has not yet done because the conditions precedent to that prohibitory order in 42 U.S.C. 6295(i)(6)(A)(v) have not occurred. That is, NEMA asserted that the Secretary has not failed to complete a rulemaking in accordance with clauses (i) through (iv) or that such final rule does not produce savings that are greater than or equal to the savings from a minimum efficacy standard of 45 lm/W because the obligation to issue such a rule does not yet exist. (NEMA, No. 329 at p. 40)

There were also commenters who disagreed with DOE's preliminary determination in the February 2019 NOPR regarding the application of the backstop. Such commenters include Earthjustice, the Natural Resources Defense Council (NRDC), Sierra Club, U.S. Public Interest Research Group and Environment America (collectively, the Joint Commenters), the Appliance Standards Awareness Project and 13 co-signing organizations [3] (ASAP), the California Energy Commission (CEC), Pacific Gas and Electric Company (PG&E) and San Diego Gas and Electric (SDG&E), and the Attorney Generals of California, New York, New Jersey, Oregon, Colorado, Connecticut, Illinois, Maine, Maryland, Michigan, Minnesota, North Carolina, Vermont, Washington, the Commonwealth of Massachusetts, the District of Columbia and the City of New York (collectively, the State Attorneys General). These commenters assert the backstop standard was triggered by DOE's failure to complete a rulemaking in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv). Thus, beginning on January 1, 2020, the commenters believe that the sale of any GSLs having a luminous efficacy less than 45 lm/W is unlawful under EPCA. (*See* Joint Commenters, No. 335 at p. 4) Additionally, the Joint Commenters noted that DOE cannot use its inaction to complete a rulemaking as a result of the Appropriations Rider to allow it to indefinitely block the application of the backstop standard for GSLs. (Joint Commenters, No. 335 at p. 7) PG&E and SDG&E further noted that the pre-emption exemption in 42 U.S.C. 6295(i)(6)(A)(vi) would serve no purpose if DOE had no limitation on its timeline to complete the rulemaking. (PG&E and SDG&E, No. 348 at pp. 4–5) PG&E and SDG&E also discounted the argument that DOE needs to take an additional action to make the backstop enforceable. Instead, they stated the backstop was triggered by DOE's failure to comply with clauses (i)–(iv) in section 6295(i)(6)(A) of EPCA and that these provisions have binding effect without the need for prior notice and opportunity for comment, similar to the manner in which DOE finalized the backstop requirements for rough service and vibration service lamps, which were treated as a mere administrative formality. (PG&E and SDG&E, No. 348 at p. 5)

By law, the Secretary must initiate a rulemaking by January 1, 2014 to determine whether standards in effect for GSLs should be amended and whether exemptions for certain incandescent lamps should be maintained or discontinued based, in part, on exempted lamp sales. (42 U.S.C. 6295(i)(6)(A)(i)) If the Secretary determines that standards in effect for GSILs should be amended, the Secretary is obligated to publish a final rule establishing such standards no later than January 1, 2017. (42 U.S.C. 6295(i)(6)(A)(iii)) If the Secretary makes a determination that standards in effect for GSILs should be amended, failure by the Secretary to publish a final rule by January 1, 2017, in accordance with the criteria in the law, would result in the imposition of the backstop provision in 42 U.S.C. 6295(i)(6)(A)(v). That backstop requirement would require that the Secretary prohibit the sale of any GSL that does not meet a minimum efficacy standard of 45 lm/W.

DOE initiated the first GSL standards rulemaking process by publishing a notice of availability of a framework document in December 2013, which satisfied the requirements in 42 U.S.C. 6295(i)(6)(A)(i) to initiate a rulemaking by January 1, 2014. DOE subsequently issued the March 2016 NOPR proposing energy conservation standards for GSLs, but was unable to undertake any analysis regarding GSILs and other incandescent lamps in the NOPR because of a then-applicable Appropriations Rider. Now that the Appropriations Rider has been removed, DOE is able to undertake the analysis to determine whether standards for GSLs, including GSILs, should be amended per the requirements in 42 U.S.C. 6295(i)(6)(A)(i). DOE has issued a proposed determination published elsewhere in this issue of the **Federal Register** in order to complete its obligations under the statute that were precluded from being completed by DOE previously by application of the Appropriations Rider.

DOE received many comments pointing to DOE's failure, per 42 U.S.C. 6295(i)(6)(A)(iii), to publish a standards rulemaking for GSILs by January 1, 2017 as evidence that DOE has triggered the backstop provision, because DOE had not completed a rulemaking in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv). However, the statutory deadline on the Secretary to complete a rulemaking by January 1, 2017, is premised on the Secretary first making a determination that standards for GSILs should be amended. The Secretary only fails to meet the requirement in 42 U.S.C. 6295(i)(6)(A)(iii) if he determines that standards for GSILs should be amended and fails to publish a rule prescribing standards by January 1, 2017. That is, 42 U.S.C. 6295(i)(6)(A)(iii) does not establish an absolute obligation on the Secretary to publish a rule by a date certain, as is the case in numerous other provisions in EPCA. *See* 42 U.S.C. 6295(e)(4); 42 U.S.C. 6295(u)(1)(A); and 42 U.S.C. 6295(v)(1). Rather, the obligation to issue a final rule prescribing standards by a date certain applies if, and only if, the Secretary makes a determination that standards in effect for GSILs need to be amended. Interpreting the statute otherwise would suggest that, if the Secretary were to make a determination that standards in effect for GSILs do not need to be amended, the Secretary nonetheless has

[3] These co-signing organizations are the: American Council for an Energy Efficient Economy, Conservation Law Foundation, Consumer Federation of America, E4TheFuture, Florida Consumer Action Network, National Consumer Law Center, Natural Resources Defense Council, Northeast Energy Efficiency Partnerships, Southeast Energy Efficiency Alliance, Southwest Energy Efficiency Alliance, Texas Ratepayers Organization to Save Energy, Vermont Energy Investment Corporation, and Vermont Public Interest Research Group.

an obligation to issue a final rule setting standards for those lamps he determined did not necessitate amended standards. And, further, DOE disagrees with the assertion that the Secretary's failure to issue a rule the obligation for which does not yet exist would lead to imposition of a sales prohibition applicable to the very lamps about which the Secretary must still decide whether amended standards are needed. Although different readings of the statutory language have been suggested, DOE believes that the best reading of the statute is that Congress intended for the Secretary to make a predicate determination about GSILs, otherwise it could result in a situation where a prohibition is automatically imposed for a category of lamps that the Secretary may conclude is unnecessary. Since DOE has not yet made the predicate determination on whether to amend standards for GSILs, the obligation to issue a final rule by a date certain does not yet exist and, as a result, the condition precedent to the potential imposition of the backstop requirement does not yet exist and no backstop requirement has yet been imposed.

DOE disagrees that it does not need to take an additional action to make the backstop enforceable, similar to the manner in which it handled the final rule for rough and vibration service lamps.[4] DOE's final rule for rough and vibration service lamps was not an exercise of agency discretion, but merely codified the statutory requirements that already applied to those lamps. Congress codified a separate regulatory process for rough and vibration service lamps in 42 U.S.C. 6295(l)(4) that includes a distinct backstop provision for each of the five lamp types that is triggered if specific objective criteria are met, namely when annual sales grow to be more than 100 percent above an extrapolated level of historical sales. Once these sales benchmarks have been exceeded, DOE is required, without discretion, to develop its own energy conservation standard and if it fails to do so by a time certain the backstop is mandated by the statute. This is in direct contrast to the discretion accorded the Secretary before any backstop for GSLs is triggered, *i.e.,* the determination whether standards in effect for GSILs need to be amended. Presently, some further action is required on the part of DOE before any backstop is enforceable to GSLs. DOE acknowledges that it will need to address the backstop in a future rulemaking, should the Secretary make a determination that standards in effect for GSILs need to be amended. To that end, DOE has issued a proposed determination published elsewhere in this issue of the **Federal Register**.

2. EPCA's Anti-Backsliding Provision

NEMA, with the support of Westinghouse Lighting, Signify, GE Lighting, and ALA, agreed with DOE's position in the February 2019 NOPR that rescinding the January 19, 2017 definition of GSL is not backsliding within the meaning of 42 U.S.C. 6295(o)(1), because, in the case of DOE's 2017 definition of GSL, the government cannot illegally backslide from a position it could not legally stand upon in the first place. (NEMA, No. 329 at p. 41)

On the contrary, commenters including the Joint Commenters, ASAP, the National Association of State Utility Consumer Advocate (NASUCA), CEC, PG&E/SDG&E, the State Attorneys General, the United States Senators, Consumer Groups, Colorado Office of Consumer Counsel, Connecticut Dept. of Energy and Environmental Protection, and the Emmett Institute on Climate Change and the Environment at UCLA School of Law (Emmett Institute) all asserted that DOE's proposal in the February 2019 NOPR would violate the anti-backsliding provision in 42 U.S.C. 6295(o) of EPCA. By narrowing the scope of the term ''general service lamp,'' the Joint Commenters stated that DOE's proposed action will exempt from the backstop standard all lamp types excluded from the GSL definition in this rulemaking. Instead of meeting the 45 lm/W backstop standard level, each lamp of a type excluded from the definition of GSL will have to meet a weaker energy conservation standard, or no standard at all. Accordingly, in repealing the January 2017 final definitions, the Joint Commenters argued DOE is reducing the minimum energy efficiency required of those lamps that it is excluding from the term ''general service lamp,'' which is an action the anti-backsliding provision forbids. (Joint Commenters, No. 335 at p. 10) The Joint Commenters stated that the anti-backsliding provision applies not only to DOE actions that amend the numerical level of a standard, but also to actions that alter the scope of a standard by exempting products. (Joint Commenters, No. 335 at p. 4) Similarly, the State Attorneys General asserted that, according to the court in *Hearth, Patio and Barbecue Ass'n* v. *U.S. DOE,*[5] definitional changes can result in the imposition of otherwise inapplicable numerical standards. (State Attorneys General, No. 350 at p.7) The Emmett Institute cited *NRDC* v. *Abraham*[6] to support its anti-backsliding argument, noting that it is irrelevant that the GSL standards for the seven categories of lamps have not yet reached their effective date, as these lamps became subject to GSL standards at the time the January 2017 definition final rules were published. (Emmett Institute, No. 341 at pp. 4–5) The Joint Commenters rejected DOE's argument in the February 2019 NOPR that its proposal to withdraw the GSL and GSIL definitions could not be considered backsliding because the proposal does not constitute an amendment of an existing energy conservation standard. The Joint Commenters pointed out that in the February 2019 NOPR, DOE claimed that the proposed rule fit within a categorical exclusion from National Environmental Policy Act (NEPA) review that applies to certain rulemakings that establish energy conservation standards for consumer products and industrial equipment. These commenters asserted that DOE cannot simultaneously avail itself of this exemption while at the same time asserting that its instant action is not an energy conservation standard rulemaking, but rather a precursor to any standards development for GSLs. (Joint Commenters, No. 335 at p. 21; *see also* State Attorneys General, No. 350 at p. 28)

The anti-backsliding provision at 42 U.S.C. 6295(o)(1) precludes DOE from amending an existing energy conservation standard to permit greater energy use or a lesser amount of energy efficiency. This provision is inapplicable to the current rulemaking because DOE has not established an energy conservation standard for GSLs from which to backslide. Commenters' assertions that the anti-backsliding provision has been violated hinge on the assumption that the backstop requirement for GSLs in 42 U.S.C 6295(i)(6)(A)(v) has been triggered and is currently in effect. However, DOE makes clear in this rule that it has not yet made the predicate determination of whether to amend standards for GSILs, and therefore the backstop is not yet in effect—meaning that any discussion of backsliding is misplaced. For similar reasons, DOE disagrees with commenters' reliance on *NRDC* v. *Abraham* to support their anti-backsliding argument. In that case, the Second Circuit held that the publication date in the **Federal Register** of a final rule establishing an energy conservation standard operates as the point at which

[4] *See* Docket ID: EERE–2017–BT–STD–0057.

[5] 706 F.3d 499 (D.C. Cir. 2013).

[6] 355 F.3d 179 (2nd Cir. 2004).

EPCA's anti-backsliding provision applies to a new or amended standard. 355 F.3d at 196. This case is inapplicable to the present rulemaking since DOE has not yet published a final rule amending standards for GSLs, nor has DOE issued a final determination on whether GSIL standards should be amended or issued a rule codifying the statutory backstop in DOE's regulations. DOE has only published the January 2017 definition final rules, which constituted a decision only on whether to maintain or discontinue various lamp exclusions. The January 2017 definition final rules were explicit that they were not setting any standards. Moreover, the 2017 rules did not follow the statutory procedures for promulgating efficiency standards as would be required, because the rules were only defining terms, not setting standards. While these definition rules have an effective date of 2020, this date is irrelevant for purposes of whether anti-backsliding applies, since the rule did not establish a standard. Further, even if the backstop was triggered, it does not apply, by the terms of the statute, until January 1, 2020. DOE does not agree that the 2017 definition final rules amending the GSIL and GSL definitions, or this final rule withdrawing the 2017 final rules, constitutes a change in scope of a standard. But even under a theory that considers the GSIL and GSL definitions as changing the scope of a standard, the present circumstances still are in contrast with those in *Abraham.* As DOE has never published a final rule establishing a standard to serve as the starting point to consider anti-backsliding, DOE could change that scope prior to the date Congress chose for start of the supposed standard, *i.e.,* January 1, 2020, without violating the anti-backsliding provision.

Furthermore, even if the backstop requirement in EPCA were to apply, it would operate as a sales prohibition for any GSL that does not meet a minimum efficacy standard of 45 lm/W. The anti-backsliding provision states that the Secretary cannot prescribe any amended *standard* that would allow greater energy use or less efficiency. EPCA defines an energy conservation standard for consumer products as a performance standard that prescribes a minimum efficiency level or maximum quantity of energy usage for a covered product or, in certain circumstances, a design requirement. (42 U.S.C. 6291(6)) In contrast, a sales prohibition in EPCA is tied to whether a transaction in commerce can occur with respect to a covered product, but the prohibition is not itself a standard.[7] Because the scope of a sales prohibition is not the same as a standard, the minimum efficacy standard of 45 lm/W mandated by the backstop's sales prohibition is unchanged by this final rule. The anti-backsliding provision in 42 U.S.C. 6295(o) limits the Secretary's discretion only in prescribing standards, not sales prohibitions, and thus is inapplicable to the backstop requirement for GSLs in 42 U.S.C 6295(i)(6)(A)(v). Therefore, DOE has the authority to change the scope of what lamps would apply to any sales prohibition for GSLs, assuming the backstop applied.

DOE agrees with commenters that it did not use the appropriate NEPA categorical exclusion for the February 2019 NOPR (even though DOE did use the same categorical exclusion used in the 2017 definition final rules) and has corrected this oversight. In this final rule, DOE has referenced the applicable categorical exclusion, 10 CFR part 1021, subpart D, appendix A5, to more accurately reflect the effect of this rulemaking, which amends the previously proposed definition for GSLs to that of the original statutory language and does not change the environmental effect of the rule being amended See section III.C.3 for further explanation as to how correcting this oversight by utilizing the appropriate categorical exclusion does not result in environmental harm.

B. Withdrawal of Revised GSL and GSIL Definitions

1. General Authority

Several commenters objected generally to the DOE's lack of authority in the February 2019 NOPR to withdraw the GSL, GSIL and supplemental definitions. For example, the Joint Commenters asserted DOE's failure to explain the legal basis for its proposal, or even to provide supporting citations, violates the Administrative Procedure Act (APA) and is defective as a matter of law. The Joint Commenters further asserted that DOE must provide stakeholders notice and a meaningful opportunity to comment on the legal authority DOE believes authorizes this action. (Joint Commenters, No. 335 at p. 2) Additionally, PG&E and SDG&E commented that DOE is overstepping its authority from Congress by creating or reinstating lamp exemptions; pursuant to 42 U.S.C. 6295(i)(6)(A)(i)(II), DOE may only maintain or discontinue them. To the extent DOE re-exempts lamps from the GSIL and/or GSL definition, PG&E and SDG&E, and similarly, the State Attorneys General, stated that DOE will have acted beyond the express scope of its statutory authority. (PG&E and SDG&E, No. 348 at p. 4; *see also* State Attorneys General, No. 350 at p. 10)

The February 2019 NOPR invoked DOE's authority under the 2007 EISA-prescribed amendments to EPCA which directed DOE to consider whether ''the exemptions for certain incandescent lamps should be maintained or discontinued.'' 42 U.S.C. 6295(i)(6)(A)(i)(II). In the 2017 definition final rules, DOE interpreted the ''exemptions'' to refer to the 22 excluded lamp categories from the definition of GSL and concluded that it has authority to bring the excluded lamps within the definition of GSIL and GSL. 81 FR 71798; 82 FR 7277. As noted, DOE did not make any determinations with regard to amending standards for GSILs in the 2017 definition final rules because it was prohibited from doing so by the Appropriations Rider. When the Appropriations Rider was lifted in the Consolidated Appropriations Act, 2017, DOE regained its statutory authority to determine whether to amend standards for GSILs, and so issued the 2017 NODA seeking data for GSILs and other incandescent lamps. With the additional benefit of the comments and data arising from the 2017 NODA, DOE reviewed its earlier interpretation of the statute and subsequently identified fundamental inaccuracies underlying its determination to revise the definitions of GSL and GSIL in the 2017 definition final rules. As discussed in more detail in Section B. of this final rule, DOE has determined that its prior action of defining IRLs as GSLs is not consistent with the best reading of statute, because Congress explicitly stated in the statute, in two distinct provisions, that these reflector lamps are not within the scope of the definition of GSLs. Additionally, DOE has determined that its prior action of defining candelabra base incandescent lamps within the definition of GSIL is not consistent with the best reading of the statute, because the existing definition of GSIL applies only to medium screw base lamps that candelabra base lamps do not have. Further, DOE discovered that it had overestimated shipment numbers for candelabra base incandescent lamps by a factor of more than two. As a result of this new information gathering and the restoration of DOE's decision-making authority under the statute upon the removal of the Appropriations Rider, DOE reassessed its original legal

[7] *See* 42 U.S.C. 6302(a)(5) for another example of a sales prohibition.

interpretations which were based on an incomplete picture of GSILs. DOE believes maintaining the existing statutory exemptions for the 22 categories of lamps excluded from the definition of GSL is the best interpretation of the statute.

For purposes of the APA, this rulemaking is amending a rule previously published based on the receipt of additional and more accurate information, as well as based on a re-interpretation of the statute. To the extent that the APA issues raised in the comments are based on DOE's use of the word ''withdraw'' in both the proposed rule and this final rule, DOE points out that this word is a reflection of the status of the 2017 definition final rules and amendatory instruction requirements of the Office of the Federal Register. That is, because the 2017 definition final rules do not take effect until January 1, 2020, those rules cannot be ''amended'' for purposes of the **Federal Register** prior to January 1, 2020; rather a change to those rules prior to their January 1, 2020, effective date constitutes a ''withdrawal''.

2. Five Specialty Incandescent Lamps

In the February 2019 NOPR, DOE proposed to maintain the existing exclusions for rough service lamps, shatter-resistant lamps, 3-way incandescent lamps, high lumen incandescent lamps (2,601–3,300 lm) and vibration service lamps in the definition of GSIL and GSL. 84 FR 3124. DOE tentatively determined that since these lamps are subject to standards in accordance with a specific regulatory process under 42 U.S.C. 6295(l)(4), there is no need to undertake an additional process for determining whether to establish energy conservation standards for these lamp types as GSLs under 42 U.S.C. 6295(i)(6)(A)(i). Doing so would potentially subject these lamps types to two separate standards and create confusion among regulated entities as to which one applies. *Id.*

NEMA, with the support of other commenters such as Westinghouse Lighting, Signify, GE Lighting, and ALA, agreed with DOE's preliminary determination, and noted that DOE has already decided to discontinue the exemption of rough service lamps and vibration service incandescent lamps in accordance with the specific statutory regulatory regime for those lamps stated in the statute. NEMA stated the specific conditions precedent for the regulation of three other types of exempt incandescent lamps specifically called out by Congress in 42 U.S.C. 6295(l)(4) have not occurred, and therefore discontinuance of the exemptions for those three lamps is unwarranted under the statute. (NEMA, No. 329 at p. 41) DOE also received comments objecting to its proposed exemptions for the five specialty incandescent lamps on the grounds of ''double regulation.'' PG&E and SDG&E pointed out that GSLs are already defined by statute to include both GSILs and CFLs, both of which are also regulated by separate statute, and clearly intended by Congress to be subject to the backstop requirement. (PG&E and SDG&E, No. 348 at p. 6) PG&E and SDG&E stated that with DOE's interpretation of the statute, there is no scenario where these five lamp types could ever be considered GSLs, which is in direct conflict with Congress's instructions in 42 U.S.C. 6295(i)(6)(A)(i)(II) to DOE to consider discontinuing their exemptions statuses. Additionally, the Joint Commenters commented that the NOPR points to no evidence indicating that regulating the five tracked lamps as GSLs would create confusion, nor does it even begin to explore how the standards for GSLs would interact with the standards currently imposed for rough service and vibration service lamps. The Joint Commenters noted that EPCA requires that DOE provide justification for its conclusion to discontinue these five exempted lamps with substantial evidence per 42 U.S.C. 6306(b)(2). (Joint Commenters, No. 335 at p. 16)

Congress excluded these five categories of lamps from the definition of GSIL and GSL, and it codified a distinct regulatory process for these lamps in 42 U.S.C. 6295(l)(4). This final rule confirms what the statue already requires, that these lamps are subject to separate statutory requirements set forth in 42 U.S.C. 6295(l)(4). Thus, DOE is not additionally regulating these five lamp types as GSLs under 42 U.S.C. 6295(i)(6)(A)(i).

The regime for potential regulation of the five lamp types was added to the statute in the same enactment that required DOE to consider standards for GSLs, *i.e.,* the Energy Independence and Security Act of 2007, Public Law 110–140, *see* section 321(a)(4). Moreover, in both instances the criteria stated in the statute for consideration for standards was based on sales of the subject lamps. If Congress had intended for these five lamp types to be considered for potential inclusion under the GSL authority there would have been little reason to have also established a separate process for potential imposition of energy conservation standards using similar criteria. As such, DOE agrees that, using this logic, these five lamp types could not be GSLs. However, DOE disagrees that this interpretation conflicts with Congressional instruction in 42 U.S.C. 6295(i)(6)(A)(i)(II). Notably, the language in this section refers to ''exemptions for certain incandescent lamps.'' Thus, this provision still has meaning even if the five (l)(4) lamps are excluded from applicability.

3. Incandescent Reflector Lamps

In the first January 2017 definition final rule (the 2017 GSL Rule), DOE adopted a regulatory definition of GSL that maintained the existing exemption for IRLs. In the second definition final rule (the 2017 IRL Rule), issued simultaneously, DOE determined to discontinue the IRL exemption, and amended its definition of GSL and GSIL accordingly. In the February 2019 NOPR, DOE revisited its determination relating to the IRL exemption, and proposed to remove IRLs from the definition of GSIL established in the 2017 IRL Rule. In the February 2019 NOPR, DOE pointed out that since IRLs are twice excluded from the definition of GSL in 42 U.S.C. 6291(30)(BB)(ii)(II), it is clear that Congress did not want the Secretary to include IRLs within the definition of GSL. 84 FR 3124.

In response to DOE's proposal relating to IRLs, NEMA with the support of Westinghouse Lighting, Signify, GE Lighting, and ALA, reiterated its prior comments in the prior rulemaking proceeding and additionally noted that the general service incandescent lamp is the ''standard incandescent or halogen lamp type,'' 42 U.S.C. 6291(30)(D)(i), which is a reference to the standard pear-shape bulb that provides omnidirectional light output. (NEMA, No. 329 at p. 4) Thus, NEMA stated that the traditional general service incandescent lighting applications do not include light bulbs that provide focused or ''directional'' lighting such as reflector lamps.'' NEMA provided additional details about the different characteristics and applications of reflector lamps that deviate in a material way from the characteristics and lighting applications of a general service incandescent lamp as defined by Congress. (NEMA, No. 329 at pp. 18–21) Specifically, that reflector lamps are traditionally used in different applications compared to GSLs, normally recessed sockets that takes advantage of the bulb's unique direction downlight capacity to a task or area on a counter or workspace; in small recessed sockets where general service A-line lamp will not fit; in track lighting where directional light is narrowly focused to accent a spot on a wall; and in outdoor fixtures where illumination for security or accenting a garden area

is desired by a consumer. NEMA concluded that GSILs are not traditionally used in these directional lighting applications. (NEMA, No. 329 at p. 21)

The Joint Commenters responded that IRLs provide general lighting and should be included in the definition of GSLs and subject to the same standards. They commented that Congress's act of (allegedly) repeating itself in the definition of GSL by twice exempting IRLs should not undermine an otherwise broad grant of authority provided in 42 U.S.C. 6295(i)(6)(A)(i)(II) to remove these exemptions. (Joint Commenters, No. 335 at p. 17) PG&E and SDG&E also disagreed with DOE's interpretation of IRLs in the February 2019 NOPR, stating that it creates ambiguity by permanently preserving a GSL exemption that was otherwise left to DOE's discretion. (PG&E and SDG&E, No. 348 at p. 7) PG&E and SDG&E noted that DOE recognized in the prior rulemaking that the definitions of ''reflector lamps'' and ''IRL'' were meant to encompass a different range of lamps. (PG&E and SDG&E, No. 348 at p. 7) PG&E and SDG&E further commented that DOE's assertion that IRLs are regulated elsewhere in the statute and therefore should not be considered GSLs is inconsistent with the regulation of other lamp types such as GSILs and CFLs, which are explicitly GSLs and are also regulated elsewhere in EPCA. (PG&E and SDG&E, No. 348 at p. 7) Additionally, PG&E and SDG&E commented that DOE's definition of general service LEDs (GSLEDs), which are also explicitly GSLs, includes LED reflector lamps as well as LED omni-direction lamps. (PG&E and SDG&E, No. 348 at p.7) They noted that GSLEDs are not defined by directionality and that it would create further inconsistencies for LED reflector lamps to be defined as GSLs but not their incandescent counterparts. (PG&E and SDG&E, No. 348 at pp. 7–8)

DOE does not have the authority to regulate IRLs as GSLs, because the statute plainly states, in 42 U.S.C. 6291(30)(BB)(ii)(I), that the term ''general service lamp'' does not include the list of lamps that were excluded from the term general service incandescent lamp (which includes reflector lamps). The statute then continues by specifically excluding any general service fluorescent lamp or incandescent reflector lamp. 42 U.S.C. 6291(30)(BB)(ii)(II). The notion that DOE was given a ''broad grant of authority provided in 42 U.S.C. 6295(i)(6)(A)(i)(II) to remove these exemptions'' attempts to suggest that DOE has the authority by rule to amend a statute. Simply put, DOE does not have that authority. DOE has to implement the law as written. And, where Congress has spoken directly to an issue it is not within the agency's power to act in contravention of that statement. To the extent that one might argue the statute is unclear on this point, DOE believes that it is the best reading (and, consequently, a reasonable reading) of the statute that Congress's express statements in two distinct provisions that IRLs are not GSLs should be interpreted as meaning that Congress intended that DOE not consider IRLs to be GSLs. Apart from consideration as a GSL, DOE continues to have the authority to establish energy conservation standards applicable to IRLs under separate requirements set by Congress in 42 U.S.C. 6295(i)(3).

With regard to comments on the definition of GSLEDs, for consistency in this rule, DOE removes all supplemental definitions adopted in the January 2017 definition final rules, including the definition of GSLED. This rulemaking relates only to whether the 22 categories of lamps exempted from the definition of GSL should be maintained or discontinued per the requirements in 42 U.S.C. 6295(i)(6)(A)(i)(II).

4. T-Shape, B, BA, CA, F, G16–1/2, G25, G30, S, M–14 and Candelabra Base Lamps

EPCA defines the term GSL to include any other lamps that the Secretary determines are used to satisfy lighting applications traditionally served by GSILs. (42 U.S.C. 6291(30)(BB)(i)(IV)). In the 2017 GSL Rule, DOE determined that lamps that would satisfy the same applications as traditionally served by GSILs are ones that would provide overall illumination and can functionally be a ready substitute, or ''convenient unregulated alternative'' for lamps already covered as GSLs. 82 FR 7277. To inform its assessment as to which GSL exclusions should be maintained, DOE also used sales data, as the statute directs in 42 U.S.C. 6295(i)(6)(A)(i)(II). *Id.* Consequently, the definitions of GSL and GSIL adopted in the January 2017 definition final rules included a broad array of specialty incandescent lamps and candelabra base lamps, such as T-Shape, B, BA, CA, F, G16–1/2, G25, G30, S, and M–14 lamps. In the February 2019 NOPR, and in direct response to stakeholder comments, DOE proposed to withdraw the revised definitions of GSIL and GSL which added T-shape lamps and B, BA, CA, F, G16–1/2, G25, G30, S, and M–14 lamps to the definition of GSIL, agreeing with commenters that it may have overstepped its limited authority by relying on factors which Congress did not intend it to consider. 84 FR 3125. In the February 2019 NOPR, DOE further acknowledged it is unlikely Congress intended that DOE have broad discretion to regulate an incandescent lamp out of existence based on an assumption that manufacturers could make and sell an LED version of the lamp or that Congress authorized DOE to eliminate ''convenient unregulated alternatives'' that DOE concluded could undercut this unstated intent of Congress. *Id.* Along these lines, DOE also proposed to withdraw its revision to the GSL definition that included all lamps having an ANSI base, such as candelabra base lamps. DOE preliminarily determined that overbreadth in its January 2017 definition final rules had the consequence of including lamps such as candelabra base lamps as GSLs, even though such lamps could not meet the statutory definition of GSIL since such lamps do not have a medium screw base. New data submitted by NEMA also indicated that DOE's estimated shipment numbers for candelabra base incandescent lamps were potentially too high by a factor of more than two. *Id.*

NEMA, Westinghouse Lighting, Signify, GE Lighting, ALA and Lucidity Lights, dba/Finally Bulbs submitted comments in support of DOE's proposal to withdraw these lamp shapes from the definitions of GSL and GSIL, with NEMA stating that it avoided sweeping into a regulatory scheme special purpose bulbs that would be inappropriate, for both technical and economic reasons, to regulate in the same manner as the GSIL, the CFL or the general service LED lamp. (NEMA, No. 329 at p.31) These commenters agreed that DOE overstepped its authority by redefining GSLs as outlined in the 2007 EISA legislation. (*See* Finally Bulbs, No. 253 at p. 1; GE Lighting, No. 325 at p. 2, NEMA, No. 329 at p. 3) For example, GE Lighting commented that the intent of the 2007 EISA law, governing lightbulb regulation, was to regulate 40w, 60w, 75w, and 100w general service incandescent A-line lamps as well as lamps that can be used in applications traditionally served by general service incandescent A-line lamps. (GE Lighting, No. 325 at p. 2) NEMA pointed out that the statutory test of whether the Secretary can include other lamps in the definition of ''general service lamp'' beyond the three types of light bulbs specified in the statute is that the ''other lamps'' must be used to satisfy lighting applications traditionally served by general service incandescent lamps.'' 42

U.S.C. 6291(30)(BB)(i)(IV). (NEMA, No. 329 at p. 4) Thus, when Congress authorized DOE to determine whether the exemptions for certain incandescent lamps should be maintained or discontinued in 42 U.S.C. 6295(i)(6)(A)(i)(II), this authorization did not include applying energy conservation standards applicable to general service lamps to a broad array of light bulbs with odd bulb shapes and designs, limited light output, uncommon applications, and unusual lamp bases. (NEMA, No. 329 at p. 31) NEMA stated that these are not traditional applications of the general service incandescent lamp; DOE overstepped its limited authority by relying on factors which Congress did not intend it to consider such as whether a lamp is a ''convenient unregulated alternative.'' (NEMA, No. 329 at p. 4). Additionally, it was brought to the attention of DOE by representatives of the Federal Aviation Administration (FAA), that some of the lamps listed in the February 2019 NOPR are used in critical aviation applications, such as navigational aids, airfield lighting, and airfield signage and as yet the lamps used in those safety-critical applications do not have acceptable LED alternatives. Furthermore, according to the FAA, the nation's busiest passenger airports have been aggressively transitioning their lighting systems to LED technology over the past decade and by its estimation this conversion should reach its optimum penetration over the next 5 years.

In contrast, DOE received numerous comments from stakeholders asserting that DOE failed to provide an adequate reason for its departure from its previous interpretation of congressional intent. (*See* State Attorneys General, No. 350 at p. 12) For example, the Joint Commenters stated that, in basing its decision to discontinue exemptions for non-pear lamps on unit sales in combination with other factors, DOE was acting entirely within its discretion under EPCA. (Joint Commenters, No. 335 at p. 18) Similarly, the Joint Commenters noted that DOE lawfully invoked its authority under 42 U.S.C. 6291(30)(BB)(i)(IV) to include candelabra lamps within the definition of general service lamp. (Joint Commenters, No. 335 at p. 20) The Joint Commenters, as well as PG&E and SDG&E commented that this provision does not require that a bulb be able to fit within the definition of general service lamp; the provision simply requires that the bulb be able to serve the same lighting application. *Id.* (PG&E and SDG&E, No. 348 at 7) Similarly, the California Investor Owned Utilities (CA IOUs) commented at the public meeting for the February 2019 NOPR that, while GSILs typically have a medium screw base, GSLs are supposed to also capture CFLs, GSLEDs, and OLEDs, and those have more than just [medium screw] [8] base types. (CA IOUs, Public Meeting Transcript, No. 44 at p. 92) PG&E and SDG&E and the Joint Commenters also asserted that NEMA's updated shipment information for candelabra lamps does not support a repeal. The Joint Commenters stated that the February 2019 NOPR ignores the limited role of shipment information in deciding whether a lamp is ''used to satisfy lighting applications traditionally served by general service incandescent lamps.'' (Joint Commenters, No. 335 at p. 20) Similarly, PG&E and SDG&E commented that DOE's previous usage of the concept of ''lamp-switching potential'' to address non-sales-based considerations was supported by various stakeholders as a means for proactively addressing product loopholes that would otherwise proliferate. (PG&E and SDG&E, No. 348 at p. 6) DOE's assertion that it must depend only on sales for evidence of lamp switching to warrant the discontinuation of exemptions would remove DOE's discretion to maintain or discontinue exemptions, which is contrary to Congress's express intent in EISA. (PG&E and SDG&E, No. 348 at p. 6)

The definition of ''general service lamp'' includes specific categories of lamps, along with ''any other lamps that the Secretary determines are used to satisfy lighting applications traditionally served by general service incandescent lamps.'' 42 U.S.C. 6291(30)(BB)(i). DOE determines that its January 2017 definition final rules that treated specialty lamps such as T-Shape, B, BA, CA, F, G16–1/2, G25, G30, S, M–14 and candelabra base lamps as GSLs is not consistent with the best reading of the statute, because such lamps are not used in the same applications as the standard general service incandescent lamp. The exemptions from the GSIL definition for the specific shapes listed in the previous sentence generally apply to lamps of 40 watts or less. DOE agrees with NEMA that traditional general service incandescent lighting applications do not include light bulbs that provide only a limited range of light output, such as light bulbs with very dim light output because of their low wattage. (NEMA, No. 329 at pp. 4–5) Furthermore, as described by NEMA, decorative light bulbs such as those with a ''candle'' shape bulb (''B'' blunt tip; ''BA'' bent tip; ''C'' flame tip; ''CA'' bent tip; ''F'' flame shape) and small globe shape lamps (G16.5) have a form factor that is not as large as the general service incandescent lamp's pear shape bulb. These decorative light bulbs present a decorative aesthetic to the consumer that is not replicated in the general service incandescent lamp, which is not used in decorative applications. The decorative bulb serves a different application for the consumer than the GSIL. When these decorative bulbs are mounted on a medium screw base, they are by definition low wattage (≤ 40W) and therefore low lumen lamps and will not serve the broader range of light outputs sought by consumers for applications traditionally served by general service incandescent lamps. (NEMA, No. 329 at p. 24) Lamps with an S shape have a small form factor, low wattage, and low lumen output; they are used in marquee signs and sometimes in appliance applications, night lights, and lava lamps. Lamps with a T shape have a tubular form factor and are also low wattage and low lumen lamps; they are typically used in music stands and showcase displays. Neither S nor T shape lamps are used in applications traditionally served by GSILs. (NEMA, No. 329 at p. 25) With respect to candelabra base lamps, these lamps additionally could not meet the statutory definition of GSIL since such lamps do not have a medium screw base. This distinction is important, as the purpose of this rule is to determine whether the statutory exclusions from GSILs should be retained per 42 U.S.C. 6295(i)(6)(A)(i)(II). As a pure matter of law, a candelabra base lamp cannot be a GSIL because EPCA defines a GSIL, in part, as having a medium-screw base. Congress made plain in the statute the scope of lamps it authorized DOE to consider. To the extent there is any uncertainty on this point, DOE believes the best interpretation of the statute is to remain within bounds of the existing statutory definition. DOE is no longer using ''convenient unregulated alternatives'' as a basis upon which to discontinue exemptions for specialty lamp types. This type of consideration is never mentioned in the statute and DOE agrees with those commenters that assert it goes beyond the authority granted to it by Congress to use the potential that a lamp may be considered a loophole to GSL standards as the basis

[8] DOE's public meeting transcript was incomplete regarding this statement from the CA IOUs. DOE has added what it believes to be the missing language.

for discontinuing its exemption under the statute.

In response to commenters asserting otherwise, DOE believes it gave proper weight to its consideration of the sales information for candelabra base lamps provided by manufacturers. The data provided by NEMA indicated that shipments of candelabra base incandescent lamp have been in a continuous decline since 2011 and there is no evidence of increasing shipments. (NEMA, No. 329 at p. 41) As sales data is the only factor Congress specifically pointed to in determining whether exemptions for certain incandescent lamps should be maintained or discontinued in 42 U.S.C. 6295 (i)(6)(A)(i)(II), DOE finds it appropriate to give this manufacturer data considerable weight in determining whether to maintain the exemption for the regulation of candelabra base lamps as GSLs. In light of the declining shipments for candelabra base lamps and the fact that consumers use candelabra as well as T-shape, B, BA, CA, F, G16–1/2, G25, G30, S, M–14 lamps for different applications than a general service incandescent lamp, in this final rule, DOE withdraws the revised definitions of GSL and GSIL, and maintains the current exclusion of these lamp shapes from the definitions of GSL/GSIL.

5. Supplemental Definitions

In the February 2019 NOPR, DOE proposed to withdraw the revised definitions of GSL and GSIL established in the January 2017 definition final rules as well as the supplemental definitions established in those rules that would no longer be necessary in light of the proposed withdrawal of the revised definitions of GSL and GSIL. 84 FR 3122. NEMA, with the support of Westinghouse Lighting, Signify, GE Lighting, and ALA provided comments supporting the retention of certain supplemental definitions, stating that it would be beneficial to define statutory terms that are undefined in the statute or are found in the current DOE regulations where DOE has adopted the statutory term or are appropriate in connection with these definitions. (NEMA, No. 329 at p. 33) GE Lighting additionally commented that if DOE is reverting to the original definitions in the EISA 2007 law, this should include keeping definitions for excluded lamps. (GE Lighting, No. 325 at p. 3) NEMA also requested that DOE modify the definition of GSLEDs to be consistent with the February 2019 NOPR and the intent of Congress. (NEMA, No. 329 at p. 34) NEMA derived its proposed definition of GSLED from the congressional definition of the medium base compact fluorescent lamp. (NEMA, No. 329 at p. 34)

For consistency in this rule, DOE removes all supplemental definitions adopted in the January 2017 definition final rules, including the definition of GSLED. DOE anticipates addressing undefined statutory terms in a future GSL standards rulemaking in which it can consider these issues with the benefit of analysis and public comment.

C. Additional Issues

Commenters expressed concern over a number of additional issues arising out of the February 2019 NOPR, which are discussed below.

1. Preemption

Northwest Energy Efficiency Alliance (NEEA), the Emmett Institute, the New York Assembly Commission on Science and Technology, and the National Association of Statue Utility Consumer Advocates (NASUCA) provided comments generally that if DOE rescinds the revised definitions of GSL and GSIL established in the January 2017 definition final rules, states will resume regulation of these lamps, leaving a patchwork of state regulations for retailers to navigate. (NEEA, No. 358 at p. 2; Emmett Institute, No. 341 at pp. 6–7; New York Assembly Commission on Science and Technology, No. 321 at p. 2; NASUCA, No. 347 at p. 7; Green Energy Consumers Alliance, No. 322 at p. 1) Signify requested that DOE address directly the issue of preemption for states that have adopted, or are adopting a 45 lm/W GSL standard and the expanded definitions promulgated on January 19, 2017. (Signify, No. 354 at p. 2) Signify prefers a strong regulatory framework, noting that a patchwork of different State regulations is counter-productive, hurts manufacturers and ultimately increases costs for consumers and stymies market adoption and energy savings. (Signify, No. 354 at p. 2)

Federal energy conservation requirements generally supersede state laws or regulations concerning energy conservation standards. (42 U.S.C. 6297(a)–(c)) Absent limited exceptions, states generally are precluded from adopting energy conservation standards for covered products both before an energy conservation standard becomes effective, and after an energy conservation standard becomes effective. (42 U.S.C. 6297(b) and (c)) However, the statute contains three narrow exceptions to this general preemption provision specific to GSLs in 42 U.S.C. 6295(i)(6)(A)(vi). Under the limited exceptions from preemption specific to GSLs that Congress included in EPCA, only California and Nevada have authority to adopt, with an effective date beginning January 1, 2018 or after, either:

(1) A final rule adopted by the Secretary in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv);

(2) If a final rule has not been adopted in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv), the backstop requirement under 42 U.S.C. 6295(i)(6)(A)(v); or

(3) In the case of California, if a final rule has not been adopted in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv), any California regulations related to ''these covered products'' adopted pursuant to state statute in effect as of the date of enactment of EISA 2007.

DOE clarifies in this rule that none of these narrow exceptions from preemption are available to California or Nevada. The first exception applies if DOE determines that standards in effect for GSILs need to be amended and issues a final rule setting standards for these lamps in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv). In that event, California and Nevada would be allowed to adopt a rule identical to the Federal standards rule. This exception does not apply since DOE had not yet determined whether standards in effect for GSILs need to be amended and thus has not issued a final rule setting standards for these lamps in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv). The second exception allows California and Nevada to adopt the statutorily prescribed backstop of 45 lm/W if DOE determines standards in effect for GSILs need to be amended and fails to adopt a final rule for these lamps in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv). This exception does not apply because DOE has not yet made the determination on whether to amend standards for GSILs, and thus no obligation currently exists for DOE to issue a final rule setting standards for these lamps in accordance with the 42 U.S.C. 6295(i)(6)(A)(i)–(iv). The third exception does not apply since there are no California efficiency standards for GSLs in effect as of the date of enactment of EISA 2007. Therefore, all states, including California and Nevada, are prohibited from adopting energy conservation standards for GSLs.

2. Manufacture Date in Lieu of Sales Prohibition

Signify and Finally Bulbs requested that DOE's final GSL standard rulemaking should impose an effective date tied to a manufacturing date as opposed to a sales date. (Signify, No. 354 at p. 2) Finally Bulbs commented that a sales ban generates multiple

issues that would result in financial losses throughout distribution channels. (Finally Bulbs, No. 253 at p. 2)

DOE notes that the sales prohibition on GSLs that do not meet a minimum 45 lm/W standard beginning on January 1, 2020 would go into effect only if the backstop has been triggered. If the backstop requirement had been triggered the sales prohibition would be required by statute under 42 U.S.C. 6295(i)(6)(A)(v) and DOE has no discretion to change this requirement.

3. Consumer/Environmental Harm

DOE received many comments, including 64,145 bulk comments contained in batched form letters, two spreadsheets, and executive correspondence surrounding the alleged uncertainty introduced by the February 2019 NOPR and its potential to increase costs for retailers and consumers while damaging the environment. (See ASAP, No. 331 at p. 8; NEEA, No. 358 at p. 2; Ceres BICEP Network, No. 313 at p. 3; Green Mountain Power, No. 259 at p. 1; United States Climate Alliance, No. 270 at pp. 1–2) The Sierra Club and NRDC filed several comments from individuals through a form letter process. The Sierra Club submitted comments from 3,788 individuals strongly urging DOE to abandon its proposal stating that it would cost Americans billions in electricity bills and put millions of tons of greenhouse gases and pollutants in the atmosphere. These commenters also stated that application of more stringent requirements for recessed lighting, chandeliers, and other decorative fixtures beginning in 2020 will save consumers nearly $12 billion annually. Additionally, they noted that the adoption of lighting standards have already greatly increased the market for high-efficiency LED bulbs and the proposal was taking them in the wrong direction. (Sierra Club, No. 236, 238, 240, 244, 246, 390, 392, 395, 397, 399, 401, 403, 405, 407, 408, 410, 412, 414, 415, 417,421, 423, 424 at all pages) The NRDC submitted comments from 46,945 individuals stating strong opposition to DOE's proposal to narrow the scope of light bulbs covered by what commenters understood as the upcoming 2020 backstop. Further, these commenters stated that DOE's proposal would cost consumers billions of dollars in additional annual energy costs and increase carbon emissions by millions of tons. (NRDC, No. 343, 359 at spreadsheet attachment) NASUCA commented that consumers of essential utility service stand to lose environmental benefits and millions of dollars in energy efficiency savings if the DOE rolls back lighting standards. (NASUCA, No. 347 at p. 4) NEEA noted that the proposal, if finalized, will cause utilities in the Northwest region to replace the lost energy savings either by building more power plants or by creating more utility programs around other products to achieve the savings through much less cost-effective means. (NEEA, No. 358 at p. 1) The Energy Strategy Coalition [9] asserted that the February 2019 NOPR would hinder technological progress and make it harder for them to reduce their systems' emissions and provide cost-saving programs to customers (Energy Strategy Coalition, No. 324 at p. 3) The California Municipal Utilities Association, SMUD, CEC, PG&E and SDG&E, the Consumer Federation of America and the National Consumer Law Center (Consumer Groups), the United States Senate, and the Colorado Energy Office also generally noted that substantial consumer benefits are threatened by DOE's withdrawal of the definition final rules as, among other things, it will result in increased energy consumption and higher electricity bills. (SMUD, No. 312 at p. 2; CEC, No. 332 at p. 4; PG&E and SDG&E, No. 348 at pp. 1–2; Consumer Groups, No. 310 at p. 2; United States Senate, No. 377 at p.1 and Colorado Energy Office, No. 330 at p. 1) Joint commenters from utilities/energy associations (collectively, NorthWestern Energy),[10] as well as comments from the Sunrise Bay Area Hub, estimated that DOE's proposal to rescind the 2017 definition of GSL would reduce household energy savings by an average of $100 every year (as of 2025). (NorthWestern Energy, No. 327 at p. 1; Sunrise Bay Area Hub, No. 317 at p. 1) Many of these commenters, as well as the Green Energy Consumers Alliance, the American Chemical Society, the New York State Assembly Commission on Science and Technology, the Nevada Governor's Office of Energy, and the Connecticut Department of Energy and Environmental Protection also asserted that the February 2019 NOPR will release even more carbon emissions from the power sector. (Green Energy Consumers Alliance, No. 322 at p. 1; American Chemical Society, No. 298 at p. 1; the New York State Assembly Commission on Science and Technology, No. 321 at p. 1; the Nevada Governor's Office of Energy, No. 171 at p. 1; and the Connecticut Department of Energy and Environmental Protection, No. 261 at p.2) Further, the State Attorneys General, CEC and the Emmett Institute commented that DOE's proposed action has significant environmental effects which must be evaluated under NEPA. (State Attorneys General, No. 350 at p. 27; CEC, No. 332 at p. 5; and Emmett Institute, No. 341 at p. 7) Emmett Institute stated that the February 2019 NOPR would almost certainly result in a significant increase in energy consumption once numerous categories of lamps are no longer subject to EPCA standards. The State Attorneys General added that the proposed rule violates other environmental laws, including the Endangered Species Act, the Coastal Zone Management Act, and the National Historic Preservation Act. (State Attorneys General, No. 350 at p. 31)

As DOE has consistently stated throughout this rulemaking, this rule to withdraw the revised definitions of GSL and GSIL is not a standard. The January 2017 definition final rules likewise were emphatic in stating that they were not setting a standard. DOE has not applied the backstop requirement to the lamps that remain as GSL or to those that are being withdrawn from the definition. The obligation for DOE to consider energy conservation standards for lamps considered to be GSLs remains and DOE is working toward completing that task. More importantly for purposes of responding to these comments, this rule does not prevent consumers from buying the lamps they desire, including efficient options. NEMA's market and lamp shipment data analysis demonstrates that the average GSL product in the market already has an average efficacy greater than 45 lm/w. (NEMA, No. 329 at p. 49) Further, NEMA's confidential data provided to DOE, and the lamps consumers find currently offered for sale at retail establishments, shows that the market is successfully transitioning to LEDs regardless of government regulation. Consumers are clearly taking advantage of the energy savings provided by LEDs, and the data provided by NEMA gives

[9] These commenters include: Austin Energy, Con Edison, Exelon Corporation, Los Angeles Department of Water and Power, National Grid, New York Power Authority, Pacific Gas & Electric Corporation, Sacramento Municipal Utility District, and Seattle City Light.

[10] These commenters include: Ameren Missouri, American Electric Power, Arizona Public Service, Austin Energy, Avista, Berkshire Hathaway Energy, Chelan County PUD, California Municipal Utilities Association, Cedarburg Light & Water Utility, Consumers Energy, CPS Energy, Dominion Energy, DTE Energy Company, Entergy Corporation, Evergy, Eversource, Exelon Utilities, Hawaiian Electric, Idaho Power, Kerrville Public Utility Board (Texas), Lincoln Electric System (Nebraska), Long Island Power Authority, Los Angeles Department of Water and Power, New York Power Authority, NorthWestern Energy, PNM Resources, PSEG, Portland General Electric, Puget Sound Energy, Sacramento Municipal Utility District, San Diego Gas & Electric, Seattle City Light, Southern California Edison, Tacoma Public Utilities, Tucson Electric Power, Vistra Energy, and Xcel Energy.

no indication that the current market direction toward an increasing use of LED lamps will change as a result of this rule or any other factor. This final rule does not affect the availability of efficient LED lamp types, and DOE anticipates that consumers will continue to purchase and install highly efficient lighting options. As such, there is nothing about this rule that will lead to the need for more power generation, increased emissions, or lost consumer benefits. Consumers who already benefit from the wide availability of LEDs will continue to do so.

Lastly, in response to the concerns raised regarding the increase in energy consumption and environmental effects of this rule, DOE reiterates that this rulemaking addresses the scope of the definitions for GSL and GSIL and does not adopt an energy conservation standard for these products. DOE acknowledges that the February 2019 NOPR referenced an inapplicable categorical exclusion to meet its NEPA obligations to evaluate the environmental impact of the rulemaking. DOE recognizes that it can still comply with NEPA through the use of a different categorical exclusion. As this rulemaking changes the scope of an existing rule that does not alter the environmental effect of the rule being amended, DOE determined the categorical exclusion under 10 CFR part 1021, subpart D, appendix 5A, applies. (10 CFR 1021.410) [11] DOE now seeks to correct this oversight.

Further, although the February 2019 NOPR relied on the same categorical exclusion used in the January 2017 definition final rules that were met with no objections,[12] this rulemaking, as DOE has earlier explained, is not the adoption of an energy conservation standard, and is distinct from the types of rules that would accurately fall under Categorical Exclusion B5.1(b). Like the January 2017 definition final rules, this action does not establish an energy conservation standard, but rather only defines certain statutory terms (here, by adhering to the existing definitions in the statute). Moreover, as previously noted, the 2017 definition final rules are not yet in effect. Consequently, DOE's action in this rule does not result in a change to the environmental effect of the existing rule being amended. (10 CFR 1021.410) A change that would result in a measurable environmental impact would be the product of a separate regulatory action, such as setting energy conservation standards which this rule does not adopt. DOE's action here maintains the scope of the definitions of GSL and GSIL as that of the statute and withdraws a broader scope and supplemental definitions prior to their having taken effect. These actions are limited to identifying which lamps are defined as GSLs and GSILs and do not cause a change to the environmental effect of the existing rule. In fact, this action maintains the status quo. As such, this action, therefore, fits within this A5 categorical exclusion and its use meets DOE's obligations to evaluate the environmental impact of its proposed action under NEPA.

4. Data

The February 2019 NOPR, and this final rule, address two issues: (1) The scope of lamp types included in the definitions of GSL and GSIL; and (2) the applicability of the 2020 backstop requirement. Issue 1, because it relates to definitions and does not establish or materially change any standard, is not a subject of analysis under DOE's statutory requirements at 42 U.S.C. 6295(o)(2)(B). As a result, DOE did not draft an analysis of these definitional changes and did not seek comments on any analysis of these changes.

In contrast, Issue 2 reduces market uncertainty to a significant extent by clarifying the applicability of a 2020 backstop sales prohibition. DOE sought comment in its February 2019 NOPR on data that would enable it to better analyze this issue. Specifically, DOE sought comment on seven topics related to the distribution of relevant lamps throughout the retail cycle and the potential opportunity cost to retailers of transitioning lamp types into and out of stock. 84 FR 3127. DOE sought comment on these topics to enable an analysis of the second issue dealt with in this final rule—that is, the degree to which clarifying applicability of the 2020 backstop will reduce uncertainty in the market. This analysis is unrelated to Issue 1, which deals with the definitions that are changed by this final rule.

DOE received responses to these seven data questions from multiple commenters. In particular, NEMA, LEDVANCE, and ALA provided data dealing with the retail channel pipeline, travel time for wholesale goods, length of time lamps sit on a retail shelf, and the proportion of bays, sales, or inventory that constitutes lighting products. (NEMA, No. 329 at pp. 42–44; LEDVANCE, No. 326 at pp. 1–5; ALA, No. 308 at pp. 3–4)

Commenters provided information on procurement cycles for lamp retailers, including timeframes for procurement and transit. NEMA provided a high level generalization of the manufacturer experience in working with retail customers, indicating that the total time between the retailer's initial factory order and when a consumer can purchase a good can range from 4 weeks to 6 months or longer. (NEMA, No. 329 at p. 44) NEMA states that the purchase cycle begins when a purchase order is placed with the lamp factory, based on retailer demand. For lower to medium volume products, retailers typically place regular stocking orders based on a one to two week lead time for cartons and pallets. However, NEMA stated that a longer lead time (60 to 75 days) is needed for larger, full container orders to deliver directly to a retailer's distribution center. Once received, the goods remain in a retailer's distribution center between two and four weeks until the goods are shipped to individual store locations based on individual item/store demand. (NEMA, No. 329 at pp. 43–44) LEDVANCE further illustrated the upstream timing considerations and stated that it takes on average three months from the start of the process of procuring raw materials until the release of component shipment to the factory, although the time will vary depending on the source of the materials. This timeframe includes paperwork, placing binding orders, shipping components from remote sources, clearing customs (for international components), and transportation to the facility. After components arrive, production will take two or three months and once released from production it may take 5–14 more days to rout the final product from the distribution center to the retail customer. (LEDVANCE, No. 326 at pp. 2–3)

Other factors, such as retailer-specific contracts and ''safety stock'', may also affect how retailers stock lamps. For example, LEDVANCE stated that contract terms with certain retailers will mandate inventory levels. Such contracts specify that LEDVANCE provide multiple months of inventory, particularly for new items. In addition, LEDVANCE stated that it carries 2–3 months of component inventory in ''safety stock'' in order to meet all customer demands. (LEDVANCE, No. 326 at pp. 2–3) In total, LEDVANCE asserted that it takes between 5 and 12 months, including transit, for a lamp to move from source through a major retailer's distribution centers to the store. LEDVANCE stated that most

[11] 10 CFR part 1021, subpart D, appendix 5A Interpretative rulemakings with no change in environmental effect, (''Rulemakings interpreting or amending an existing rule or regulation that does not change the environmental effect of the rule or regulation being amended.'').

[12] 82 FR 7276, 7319; 82 FR 7322, 7331; 10 CFR part 1021, appendix B5.1(b).

retailers have on average three months of inventory between their story and distribution centers. (LEDVANCE, No. 326 at p. 2) NEMA asserted that individual stores will carry sufficient inventory to prevent having empty shelf space. (NEMA, No. 329 at pp. 43–44) LEDVANCE submitted confidential data on three years of total industry shipments of lamp types, showing that a significant number of units are in transit and/or in a distribution center or on shelf, awaiting order and/or purchase. (LEDVANCE, No. 326 at p. 3)

Once goods are at the retail site, NEMA estimated that lower to medium demand products and specialty seasonal demand products (*e.g.* colored lights) may sit on a store shelf between 30 and 90 days, while retailers prefer to maintain at least two weeks of inventory for high demand products. (NEMA, No. 329 at pp. 43–44) Commenters generally agreed that timeframes to sale vary by lamp type. ALA commented that specialty lamps, which are lower-volume products, spend significantly longer time on store shelves, while LED A lamps move through inventory systems at faster rates. Approximately 70 percent of sales in the specialty lamp category are incandescent lamps. (ALA, No. 308 at p. 3) NEMA agreed that high-volume lamps tend to through retail channels more quickly than lower-volume specialty lamps, including those at subject in the 2019 NOPR. NEMA asserted that because these specialty lamps have a longer shelf-life, they would entail greater exposure to risk from a sales prohibition order such as that contemplated by the ''backstop.'' (NEMA, No. 329 at p. 42)

Commenters generally agreed on the proportion of space at major retailers that is devoted to lighting products. LEDVANCE estimated that lighting and luminaires can occupy between 5% and 10% of a DIY retailer's floor space (LEDVANCE, No. 326 at p.3) and ALA retailers estimate about 6%–10% percent of showroom and warehouse space is used for lamps (ALA, No. 308 at p. 3).

Commenters provided different views on the scope of retailers affected by uncertainty. NEMA noted that large retail hardware stores and urban/suburban retail stores tend to move light bulbs through the distribution channel than specialty retail stores or rural retail stores. (NEMA, No. 329 at p. 42) LEDVANCE noted that all types of retailers, and other upstream stakeholders in the supply chain, are affected by uncertainty regarding the January 2020 date. (LEDVANCE, No. 326 at p. 5) Among the sources of uncertainty LEDVANCE listed that components could be stranded, packaging must be recycled/scrapped at cost, contracts with suppliers and customers that cannot be fulfilled may result in financial penalties, excess inventory must be scrapped, and that last minute product reset is challenging with possibly lower pricing requirements. *Id.* The California Municipal Utilities Association (CMUA) provided a different perspective and stated that retailers that have already adjusted their procurement activities to reflect the 2017 definitions will be harmed. (CMUA, No. 328 at p. 3)

Commenters presented differing views regarding the burden or benefits associated with open bays. LEDVANCE commented that open bays present significant problems in that customers are frustrated by a lack of products and choices and retailers lose sales opportunities as a result. (LEDVANCE, No. 326 at pp. 3–5) In the February 2019 NOPR public meeting, NRDC noted that freeing up space on retailers' shelves could be a benefit instead of a burden as there are other products that could also provide revenue. (NRDC, Public Meeting Transcript, No. 44 at p. 144) LEDVANCE agreed in part that open bays provide an opportunity for new product, but noted that filling the open bays takes time, and there may be added reset costs. (LEDVANCE, No. 326 at pp. 3–5) LEDVANCE elaborated that identifying and sourcing new products for an open retail bay can require 6–12 months, including identifying and qualifying the source, setting up the new vendor, product testing time, price negotiation, purchase orders, transit from the source, and initiating new data setup in store registers. (LEDVANCE, No. 326 at pp. 3–5) ALA stated that the typical supply chain for a traditional lighting retailer is roughly 30 days. (ALA, No. 308 at p. 4) LEDVANCE added that lamp sales are seasonal and affected by scheduled events, which requires manufacturers to prepare three months earlier to have adequate inventory to meet demand. (LEDVANCE, No. 326 at pp. 3–5) From the perspective of retailers, updating the layout and product offerings requires planning time, advanced scheduling, and execution time. Big box retailers schedule line reviews for lamps using fast changing technologies, such as LED lamps; these line review may take 4–6 months followed by a shelf reset 8–10 months after the start of the cycle. Convenience retailers are less likely to schedule line reviews, and may schedule shelf refreshes in the spring and the fall. *Id.*

The Colorado Office of Consumer Counsel (COCC) and the Colorado Energy Office (CEO) noted that uncertainty may be enhanced by DOE's rulemaking as a result of potential legal challenges. COCC and CEO stated that multiple organizations have indicated that they might pursue litigation, which would not be resolved until well into 2020. As a result, COCC and CEO stipulated that retailers, who will be responsible for compliance with a potential 45 lm/W backstop, will be uncertain whether lamps shipped in 2019 will be legal to sell when they arrive at the stores. (COCC, No. 319 at p. 3; CEO, No. 330 at p. 2)

DOE also received comments on its overall use of data in the rulemaking. Many commenters were confused as to which aspect of its rulemaking DOE intended to analyze, and did not distinguish between Issue 1 and Issue 2 of the February 2019 NOPR. For example, PG&E and SDG&E commented that DOE's use of data in the rulemaking does not justify its withdrawal of the exemption discontinuations from the 2017 definition final rules. (PG&E and SDG&E, No. 348 at p. 8) They commented that the February 2019 NOPR did not explain how submitted data helped to inform the proposal. They argued DOE claimed that the data serves to establish retailer burden but does not explain how the data that is provided is relevant. Nor does DOE address how retailer burden itself plays any role in DOE's proposal. PG&E and SDG&E also noted the proposal only focuses on burden of some retailers, while totally discounting burdens on retailers who are committed to selling LED lamps and have proactively based their business plans on the forthcoming standards. These commenters stated that DOE does not consider burdens on consumers, forward thinking manufacturers and retailers and utilities. (PG&E and SDG&E, No. 348 at p. 8) Ceres BICEP Network similarly commented, noting that DOE is putting extraordinary weight on sales data from NEMA to revisit a definition that is now two years old, a reversal that will only create more confusion in the marketplace. (Ceres BICEP Network, No. 313 at p. 3)

Historically, DOE has not conducted analysis of its definitional rules. In its January 2017 definition final rules, DOE explained that the analytical requirements to which DOE is subject apply, by their terms, only when DOE prescribes a new or amended standard. By contrast, a rule that alters definitions does not establish or materially change any standard, and the same analytical requirements do not apply. *See* 82 FR 7278; see also 84 FR 3125. As a result, this rule is not accompanied by a

technical support document or other analyses for the definition change.

As DOE noted in the previous section, this rule does not prevent consumers from buying the lamps they desire, including efficient options; the same is true for retailers. In response to CMUA, those retailers who prefer to stock only LEDs are in no way prohibited from doing so under this final rule. Per PG&E/SDG&E's comments, DOE takes this opportunity to clarify that retailer burden does not play a role in DOE's definition changes. Rather, DOE sought to clarify the applicability of the 2020 backstop, which involved a sales prohibition that, if it applied, would burden retailers who must transition their lighting stock. DOE only uses data and supporting analysis in this rule to illustrate the scope of uncertainty in the market regarding the applicability of the backstop sales prohibition. DOE agrees with NRDC that retailers may replace lighting products with higher-revenue products; however, this does not negate the very real transition costs to retailers who switch out their stock. In addition, due to the particulars of the retail supply chain, such a transition is likely to take a significant amount of time, and some retailers may forego revenue if they are unable to find a timely product replacement. The analysis that DOE provides in this final rule addresses those transition and opportunity costs.

In the February 2019 NOPR, DOE said that the agency would attempt to quantify the uncertainty created by its prior rulemakings in the proceeding. In particular, DOE noted that it had created substantial uncertainty by making apparently conflicting statements about the applicability of the backstop requirement. DOE anticipates that having clarified that the backstop does not apply has and will result in measurable effects on the markets for certain incandescent lamps, including rough-service, vibration service, 3-way, shatter resistant, high-lumen, candelabra, halogen, and globe lamps. Further, significant uncertainty existed in the retail market regarding the scope of lamps that may be available for sale, which DOE had failed to clarify in previous statements or rulemakings. As a result of this uncertainty, retail outlets had not been able to plan adequately for a potential change in stock, or lack thereof. This uncertainty creates cost for retailers, and this clarification is expected to reduce those uncertainty costs.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

This final rule constitutes a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was subject to review by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB).

B. Review Under Executive Order 13771

This final rule is considered an E.O. 13771 deregulatory action. Details on the estimated costs of this rule can be found below.

1. Analytical Approach

This rulemaking clarifies that DOE has not yet taken the predicate actions to trigger the 45 lm/W backstop. DOE must still make a determination regarding whether to amend standards for GSILs, which would affect whether the 45 lm/W backstop standard would apply to general service lamps. Clarifying this applicability removes any uncertainty that exempted lamps, such as those at subject in this rulemaking, would be subject to the 45 lm/W backstop requirement. Clarifying this point will result in measurable effects on the markets for certain incandescent lamps, including vibration service, 3-way, shatter resistant, high-lumen, candelabra, halogen, and globe lamps.

The analysis that follows quantifies the cost savings to the retail market associated with resolving uncertainties as to which lamps may be sold as of January 1, 2020 as a result of clarifying applicability of the 2020 backstop. The February 2019 NOPR requested information on the potential range of cost savings associated with the proposed action. The information received was used to quantify how many lamps were affected by uncertainty surrounding the 2020 backstop and the extent to which retailers would have borne costs associated with changes in inventory throughout the distribution chain.

As a result of prior confusion regarding whether the 45 lm/W backstop had been triggered, it is likely that there would be substantial variation in what retailers understand to be prohibited for sale after January 1, 2020. In the face of this uncertainty, retailers would be compelled to continue to order and stock the full suite of lamp offerings to avoid losing customers to a competitor that offers a more comprehensive lamp selection, with retailers risking stranded inventory. However, the retailer's financial risk of keeping the shelves well-stocked goes beyond the cost of the retailer inventory stranded on the retailer's shelves and warehouses. The retailer's financial liability starts from the moment a purchase order is placed in the supply chain. Under most conditions, once an order is placed the retailer cannot cancel or modify the order without penalty. (NEMA, No. 329 at p. 43; LEDVANCE, No. 326 at p. 5) Thus, the applicable inventory losses include all losses associated with product orders cancelled when a prohibition for which a retailer is not adequately able to anticipate and plan is effective. This inability to take appropriate action in advance of the prohibition on sales would create costs associated with potential stranded work in progress and inventory in manufacturer warehouses as well as the distribution channel. (NEMA, No. 329 at p. 42; LEDVANCE, No. 326 at p. 5) Contractually, the risks and costs could be shared between retailer and others in the supply chain, but in all likelihood, and for sake of simplicity, the analysis assumes that all inventory costs are entirely passed on to the retailer. The analysis does not include explicit financial penalties for cancelled orders because those values are captured in the analysis as opportunity costs to the retailer in the form of lost sales revenue for all lamps in the distribution chain.

Quantifying the inventory at risk requires that the analysis estimates the dollar value of lamps within the supply chain when the prohibition would be effective, in particular the dollar value of those lamps subject to the prohibition. From comments received, DOE estimates that lamp inventory turns over approximately 2 to 9 times per year, placing at risk as few as 6 weeks or as many as 6 months of lamp sales. (NEMA, No. 329 at p. 44; ALA, No. 308 at p. 3; LEDVANCE, No. 326 at p. 2) If the shelf space stays empty, the financial loss equals the entire lost revenue at the retail level. In theory, if the shelf space is gradually filled with other products the financial loss is reduced. But the loss is reduced by only a fraction of the replacement retail revenue since contrary to the stranded lamps inventory which has already been paid to suppliers, the replacement products to fill the vacated shelf space has not been paid. In previous rulemakings for GSLs DOE estimated that product costs represented approximately 66 percent of the retail price of GSLs (accounting for

replacement product costs). Furthermore, in practice, identifying, qualifying, and sourcing new products is a process requiring many months (LEDVANCE, No. 326 at pp. 3–4).

2. Cost Estimate

NEMA's confidential estimates of total domestic shipments for the years 2015 to 2018 were used to forecast future shipments. An exponential forecast was determined to be the best fit to the data provided. The analysis uses manufacturer shipments as a surrogate for unit sales because it is presumed that retailer inventories remain fairly constant from year to year such that annual shipments track closely with actual unit sales. Shipments were assumed to be equally spread among months of the year. Based on comments from industry, as few as 6 weeks or as many as 6 months of incandescent lamp sales may be at risk. Thus, a low-end and high-end estimate were calculated based on the two different time frames.

3. Results

DOE estimates that if retailers had on their shelves incandescent lamps and were prohibited from selling them, the lost revenue in 2020 would range from $64.3 million to $257 million (in 2016$). Sales of subject incandescent lamps over the analyzed time period (approximated by shipments) range from 37.8 million to 151 million lamps with an average lamp price of $1.70 (in 2016$).

TABLE 1—SUMMARY OF COST IMPACTS

Category	Present value (thousands 2016$)	Discount rate (percent)
Cost Savings		
Reduction in Uncertainty	$57,098–$228,393	3
	$49,027–$196,108	7
Total Net Cost Impact		
Total Net Cost Impact	($57,098)–($228,393)	3
	($49,027)–($196,108)	7

TABLE 2—SUMMARY OF ANNUALIZED COST IMPACTS

Category	Annualized value (thousands 2016$)	Discount rate (percent)
Annualized Cost Savings		
Reduction in Uncertainty	$1,713–$6,852	3
	$3,432–$13,728	7
Total Net Annualized Cost Impact		
Total Net Cost Impact	($1,713)–($6,852)	3
	($3,432)–($13,728)	7

The final rule yields annualized cost savings of between approximately $3.4 million and $13.7 million using a perpetual time horizon discounted to 2016 at a 7 percent discount rate.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IRFA) for any rule that by law must be proposed for public comment, and a final regulatory flexibility analysis (FRFA) for any such rule that an agency adopts as a final rule, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website (*http://energy.gov/gc/office-general-counsel*).

DOE reviewed the withdrawal of the revised definitions for GSL, GSIL and related terms under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. DOE certifies that this final rule does not have a significant economic impact on a substantial number of small entities. The factual basis for this certification is set forth in the following paragraphs.

For manufacturers of GSLs, the SBA has set a size threshold, which defines those entities classified as ''small businesses'' for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule See 13 CFR part 121. The size standards are listed by NAICS code and industry description and are available at *https://www.sba.gov/document/support-table-size-standards*. Manufacturing of GSLs is classified under NAICS 335110, ''Electric Lamp Bulb and Part Manufacturing.'' The SBA sets a threshold of 1,250 employees or less for an entity to be considered as a small business for this category.

To estimate the number of companies that could be small businesses that manufacture GSLs covered by this rulemaking, DOE conducted a market survey using publicly available information. DOE's research involved information provided by trade associations (*e.g.,* NEMA [13]) and information from DOE's Compliance Certification Database,[14] EPA's ENERGY

[13] National Electric Manufacturers Association | Member Products | Lighting Systems | Related Manufacturers, *http://www.nema.org/Products/Pages/Lighting-Systems.aspx* (last accessed September 26, 2018).

[14] DOE's Compliance Certification Database | Lamps—Bare or Covered (No Reflector) Medium Base Compact Fluorescent, *http://www.regulations.doe.gov/certification-data* (last accessed September 26, 2018).

STAR Certified Light Bulbs Database,[15] previous rulemakings, individual company websites, SBA's database, and market research tools (*e.g.,* D&B Hoover's reports [16]). DOE used information from these sources to create a list of companies that potentially manufacture or sell GSLs and would be impacted by this rulemaking. DOE screened out companies that do not offer products covered by this rulemaking, do not meet the definition of a ''small business,'' or are completely foreign owned and operated. DOE determined that eight companies are small businesses that maintain domestic production facilities for general service lamps.

DOE notes that this final rule withdraws the revised definitions of GSIL and GSL that are effective in 2020 in order to maintain the existing regulatory definitions of these terms, which is the same as the statutory definitions of these terms, including exclusions of certain lamp types. As a result, certain lamps will continue to be exempt from complying with current Federal test procedures and any applicable Federal energy conservation standards. For this reason, DOE concludes and certifies that the withdrawal of the definitions does not have a significant economic impact on a substantial number of small entities, and the preparation of a FRFA is not warranted.

D. Review Under the Paperwork Reduction Act of 1995

Manufacturers of GSLs must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for GSLs, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment. *See generally* 10 CFR part 429. The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 30 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

E. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act (NEPA) of 1969, DOE has analyzed this proposed action in accordance with NEPA and DOE's NEPA implementing regulations (10 CFR part 1021). DOE has determined that this rule qualifies for categorical exclusion under 10 CFR part 1021, subpart D, appendix A5 because it is a rulemaking that amends an existing rule that does not change the environmental effect of the rule and meets the requirements for application of a CX. See 10 CFR 1021.410. Therefore, DOE has determined that promulgation of this rule is not a major Federal action significantly affecting the quality of the human environment within the meaning of NEPA, and does not require an EA or EIS.

F. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt state law or that have federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the states and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this final rule and has determined that it does 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. EPCA governs and prescribes Federal preemption of state regulations as to energy conservation for the products that are the subject of this final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) Therefore, no further action is required by Executive Order 13132.

G. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

H. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on state, local, and tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action likely to result in a rule that may cause the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The

[15] ENERGY STAR Qualified Lamps Product List, *http://downloads.energystar.gov/bi/qplist/Lamps_Qualified_Product_List.xls?dee3-e997* (last accessed September 26, 2018).

[16] Hoovers | Company Information | Industry Information | Lists, *http://www.hoovers.com* (last accessed June 27, 2019).

UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of state, local, and tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *http://energy.gov/gc/office-general-counsel.* DOE examined this final rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

I. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Public Law 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This final rule does not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

J. Review Under Executive Order 12630

Pursuant to Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (March 15, 1988), DOE has determined that this final rule does not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

K. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

L. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

This regulatory action to withdraw the revised definitions of GSL, GSIL and supplemental definitions is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will submit to Congress a report regarding the issuance of this final rule prior to the effective date set forth at the outset of this rulemaking. The report will state that it has been determined that the rule is not a ''major rule'' as defined by 5 U.S.C. 801(2).

V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 10 CFR Part 430

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

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

Signed in Washington, DC, on: August 28, 2019.

Daniel R Simmons,

Assistant Secretary, Energy Efficiency and Renewable Energy.

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ Accordingly, the final rules published in the **Federal Register** on January 19, 2017 (82 FR 7276 and 82 FR 7322), amending 10 CFR 430.2, which were to become effective on January 1, 2020, are withdrawn effective October 7, 2019.

[FR Doc. 2019–18940 Filed 9–4–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Parts 12 and 141

[USCBP–2016–0075; CBP Dec. No. 19–11]

RIN 1651–AB02

Technical Correction to Centers of Excellence and Expertise Regulations

AGENCY: U.S. Customs and Border Protection, DHS.

ACTION: Final rule; technical correction.

SUMMARY: On December 20, 2016, U.S. Customs and Border Protection (CBP) published an interim final rule in the **Federal Register**, which established the Centers of Excellence and Expertise (Centers) as a permanent organizational component of the agency and transitioned certain operational trade functions to the Center directors that traditionally resided with the port directors. This technical correction clarifies two sections of CBP regulations that do not currently reflect CBP's operational structure or the objective of the ''Regulatory Implementation of the Centers of Excellence and Expertise'' interim final rule. This document amends CBP regulations to correct the discrepancies.

DATES: This final rule is effective on September 5, 2019.

FOR FURTHER INFORMATION CONTACT: Lori Whitehurst, CBP Office of Field Operations, by telephone at (202) 344–2536 or by email at *lori.j.whitehurst@cbp.dhs.gov;* or Susan S. Thomas, CBP Office of Field Operations, by telephone at (202) 344–2511 or by email at *susan.s.thomas@cbp.dhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On December 20, 2016, U.S. Customs and Border Protection (CBP) published the ''Regulatory Implementation of the Centers of Excellence and Expertise'' interim final rule (Centers IFR) in the **Federal Register** (81 FR 92978), which established the Centers of Excellence and Expertise (Centers) as a permanent organizational component of CBP and transitioned certain trade functions to the Centers. As part of this transition, the Centers IFR amended certain regulations to provide Center directors with the authority to make decisions normally reserved for port directors. However, two of the regulations in title 19 of the Code of Federal Regulations (CFR), 19 CFR 12.73(j) and 141.113(b), do not currently reflect the Center directors' authority provided in the Centers IFR as discussed further below. This document amends these sections to correct the discrepancies. CBP will publish a final rule addressing the public comments received for the Centers IFR at a later date.

II. Amendatory Changes

Section 12.73(j)

Section 12.73(j) was amended in the Centers IFR to provide that, if good cause is shown, the Center director, rather than the port director, has the authority to extend the period of time that the importer has to submit the necessary U.S. Environmental Protection Agency (EPA) declaration providing that a vehicle or engine being imported conforms to Federal emission requirements. Additionally, the Centers IFR specified that the EPA declaration must be delivered by the importer to CBP, either to the port of entry or electronically. This extended the authority to collect the document to either the Center director or port director.

On December 27, 2016, seven days after publication of the Centers IFR, 19 CFR 12.73(j) was amended by the ''Importations of Certain Vehicles and Engines Subject to Federal Antipollution Emission Standards'' final rule publication in the **Federal Register** (81 FR 94974) as part of a substantial revision of part 12. This final rule resulted in contradictory regulatory text in 19 CFR 12.73(j) that only partially reflected the authority of the Center directors. As a result, the current regulation only partially accounts for the edits made by the Centers IFR and two discrepancies regarding the Center directors' authority must be addressed in this document.

Currently, § 12.73(j) contains an inconsistency. It states that the importer or consignee must deliver documentation of EPA approval to CBP, either at the port of entry or electronically, but later requires that EPA approval must be delivered to the port director. Pursuant to the Centers IFR, the EPA document must be delivered to CBP, either to the port of entry or electronically, to extend the authority to collect the document to either the Center director or port director. This document corrects § 12.73(j) accordingly. It is noted that if the EPA approval is not delivered to CBP within the specified period, § 12.73(j) remains unchanged in that the importer or consignee must deliver or cause to be delivered to the port director those vehicles that were released under a bond.

Additionally, § 12.73(j) currently states that the Center director may set a later deadline for submission based on good cause; yet subsequently, the paragraph states that the port director sets the later deadline. To reconcile these contradictions in the current regulatory text and to reflect the changes made in the Centers IFR, CBP is correcting the text in § 12.73(j) to provide that, if good cause is shown, the Center director, rather than the port director, has the authority to extend the period of time for submission of the EPA approval.

Section 141.113(b)

Due to an accidental omission in the amendatory instructions in the Centers IFR, 19 CFR 141.113(b) was not revised as CBP intended. As described in the preamble to the Centers IFR, CBP intended to amend § 141.113(b) to provide that if the Center director, rather than the port director, finds during the conditional release period of an imported textile or textile product, that the textile or textile product is not entitled to admission into the commerce of the United States because the country of origin of the textile or textile product was not accurately represented to CBP, he or she shall promptly demand its return to CBP custody. Although this amendment was described in the preamble of the Centers IFR, due to an inadvertent error, the instruction to amend § 141.113(b) by replacing 'port director' with 'Center director' was omitted in the Centers IFR. Thus, this document amends § 141.113(b) accordingly.

III. Signing Authority

This document is being issued in accordance with 19 CFR 0.2(a), which provides that the authority of the Secretary of the Treasury with respect to CBP regulations that are not related to customs revenue functions was transferred to the Secretary of Homeland Security pursuant to section 403(1) of the Homeland Security Act of 2002. Accordingly, this final rule to amend such regulations may be signed by the Secretary of Homeland Security (or his delegate).

List of Subjects in 19 CFR Parts 12 and 141

Reporting and recordkeeping requirements.

Amendments to the Regulations

For the reasons given above, parts 12 and 141 of title 19 of the Code of Federal Regulations (19 CFR parts 12 and 141) are amended as set forth below.

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for §§ 12.73 and 12.74 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

* * * * *

Sections 12.73 and 12.74 also issued under 19 U.S.C. 1484, 42 U.S.C. 7522, 7601;

* * * * *

■ 2. The third and fourth sentences of § 12.73(j) are revised to read as follows:

§ 12.73 Importation of motor vehicles and motor vehicle engines.

* * * * *

(j) * * * If the EPA approval is not delivered to CBP, either to the port of entry or electronically, within the specified period, the importer or consignee must deliver or cause to be delivered to the port director those vehicles which were released under a bond required by this paragraph (j). In the event that the vehicle or engine is not redelivered within five (5) days following the date the exemption or exclusion indicated on the EPA declaration form expires, or any later deadline specified by the Center director, whichever is later, liquidated damages will be assessed in the full amount of the bond, if it is a single entry bond, or if a continuous bond is used, in the amount that would have been assessed under a single entry bond.

* * * * *

PART 141—ENTRY OF MERCHANDISE

■ 3. The general authority citation for part 141 and the specific authority citation for

§ 141.113 continues to read as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1498, 1624.

* * * * *

Section 141.113 also issued under 19 U.S.C. 1499, 1623.

§ 141.113 [Amended]

■ 4. Section 141.113(b) is amended by removing the words ''port director'' and adding in their place the words ''Center director''.

Dated: August 30, 2019.

Robert E. Perez,

Deputy Commissioner, U.S. Customs and Border Protection.

[FR Doc. 2019–19129 Filed 9–4–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 24

[USCBP–2019–0032; CBP Dec. No. 19–10]

RIN 1515–AE47

Amendment to Statement Processing and Automated Clearinghouse (ACH)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Interim final rule; solicitation of comments.

SUMMARY: This document amends the U.S. Customs and Border Protection (CBP) regulations regarding statement processing and Automated Clearinghouse (ACH) to reflect that CBP will identify final statements as paid upon the completion of the funds transfer. Additionally, this document makes certain technical corrections to the CBP regulations on statement processing and ACH.

DATES: This interim final rule is effective September 7, 2019; comments must be received by November 4, 2019.

ADDRESSES: You may submit comments, identified by *docket number* USCBP–2019–0032, by *one* of the following methods:

- *Federal eRulemaking Portal* at *http://www.regulations.gov.* Follow the instructions for submitting comments via Docket No. USCBP–2019–0032.
- *Mail:* Trade and Commercial Regulations Branch, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection, 90 K Street NE, 10th Floor, Washington, DC 20229–1177.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Submitted comments may be inspected during regular business days between the hours of 9 a.m. and 4:30 p.m. at the Trade and Commercial Regulations Branch, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection, 90 K Street NE, 10th Floor, Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at 202–325–0118.

FOR FURTHER INFORMATION CONTACT: Kara Welty, Debt Management Branch, Revenue Division, Office of Finance, (866) 530–4172, *collectionscapabilityowners@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of this interim final rule. See **ADDRESSES** above for information on how to submit comments. CBP also invites comments that relate to the economic, environmental, or federalism effects that might result from this regulatory change. Comments that will provide the most assistance to CBP will reference a specific portion of the rule, explain the reason for any recommended change, and include data, information or authority that support such recommended change.

II. Background on Statement Processing

Upon importation, the importer becomes liable to CBP for the amount of duties, taxes, and fees estimated to be payable on the merchandise. *See* 19 U.S.C. 1505(a) and sections 141.1(a), (b) and 141.3 of title 19 of the Code of Federal Regulations (19 CFR 141.1(a), 141.1(b), and 141.3). One way in which estimated duties, taxes, and fees can be deposited with CBP is by transmitting the estimated duties, taxes, and fees to CBP pursuant to statement processing, as described in 19 CFR 24.25. *See* 19 CFR 141.101.

Statement processing is a voluntary automated program for participants in the Automated Broker Interface (ABI), allowing the grouping of entry/entry summaries and entry summaries, by either importer or by filer, on a daily basis. *See* 19 CFR 24.1(a)(8) and 24.25(a). Any duties, taxes, and fees (as well as interest, if applicable) that are related to the grouped entry/entry summaries and entry summaries may be paid with a single payment, rather than by individual checks for each entry. *See* 19 CFR 24.25(a) and 143.32(p).

The ABI filer must elect whether payment for a particular entry summary will be by individual check or by statement processing upon the transmission of entry/entry summary and entry summary data to CBP through ABI. *See* 19 CFR 24.25(c)(1). The election of statement processing for a particular entry summary also requires the ABI filer to elect (1) whether the entry summary is to be grouped by the importer or broker, and (2) a valid scheduled statement date, which shall be within ten (10) days of entry, but not on a Saturday, Sunday, or holiday. *See* 19 CFR 24.25(c)(1) and (e).

On the scheduled statement date, CBP provides the ABI filer with a preliminary statement that is transmitted electronically to the filer using a CBP-authorized Electronic Data Interchange (EDI) system. 19 CFR 24.25(c)(2) and 143.32(p). The preliminary statement contains all entry/entry summaries and entry summaries scheduled for that statement date and the amount of duties, taxes, and fees due for payment. *See* 19 CFR 24.1(a)(8), 24.25(c)(2), and 143.32(p). The ABI filer is required to ensure that payment is made on each preliminary statement within ten (10) working days of the entry of the related merchandise. *See* 19 CFR 24.25(c)(2), (c)(3), and (e).

The preferred method of payment for ABI users of statement processing is by ACH, except where the importer has provided a separate check payable to ''U.S. Customs and Border Protection'' for customs charges (mixing of payment methods for a single statement is prohibited). *See* 19 CFR 24.1(a)(8) and 24.25(a). There are two (2) ACH payment processes—the ACH debit process and the ACH credit process, each of which is explained below with respect to its current state and how that will change under the amended regulations.

III. ACH Payment Processes

A. ACH Debit Process

The ACH debit process is an arrangement in which the filer electronically provides payment authorization for the Department of the Treasury (Treasury)-designated ACH processor bank to perform an electronic debit to the payor's bank account. *See* 19 CFR 24.25(a). ABI filers using this process are required to provide CBP with the bank account and routing number for each account from which ACH payments are to be electronically debited. *See* 19 CFR 24.25(b)(2). The ABI filer initiates the payment process by transmitting one ACH debit authorization per preliminary statement to CBP through ABI. *See* 19 CFR 24.25(a) and (c). If the ACH debit authorization is error-free, then CBP will accept the ACH debit authorization and provide the ABI filer with a message confirming CBP's acceptance of the ACH debit authorization. *See* 19 CFR 24.25(c)(4).

Currently, upon CBP's acceptance of the ACH debit authorization, CBP identifies the preliminary statement as paid and posts the appropriate amounts to the related entries. CBP then initiates the funds transfer by sending an electronic message to the Treasury-designated ACH processor bank instructing the Treasury-designated ACH processor bank to perform an electronic debit to the payor's bank account. *See* 19 CFR 24.25(a) and (c)(4). CBP generally makes the final statement available to the ABI filer the day following the acceptance of the ACH payment. *See* 19 CFR 24.25(c)(4). A final statement serves as evidence of the payment of a preliminary statement through an ACH transaction. *See* 19 CFR 24.25(c)(4).

Even though the preliminary statement is currently identified as paid upon acceptance of the ACH debit authorization, the funds transfer is usually not completed until two (2) business days after CBP's acceptance of the ACH debit authorization. To more accurately reflect the status of the funds transfer, CBP is amending its regulations to remove the requirement to identify the preliminary statement as paid. The preliminary statement will still be issued; but, instead, the amended regulations will require CBP to identify the final statement as paid and post the appropriate amounts to the related entries upon receiving confirmation from Treasury that the funds are available and transferred to CBP (which marks the completion of the funds transfer).

The amendments to the CBP regulations do not affect the timeliness of the payment, which remains based upon the date of CBP's acceptance of the ACH debit authorization. Once CBP receives confirmation from Treasury that the funds are available and transferred to CBP, then CBP will treat the date of CBP's acceptance of the ACH debit authorization as the effective payment date for purposes of determining the timeliness of the payment. The date of CBP's acceptance of the ACH debit authorization also remains the date for the calculation of interest and/or liquidated damages, if applicable; the calculation is unaffected by this amendment to the CBP regulations pertaining to ACH debit payments.

B. ACH Credit Process

Pursuant to 19 CFR 24.26(a), ACH credit is an optional payment method that allows a payor to electronically transmit statement processing payments under 19 CFR 24.25, deferred tax payments under 19 CFR 24.4, or bill payments under 19 CFR 24.3, through its financial institution, directly to the CBP account maintained by Treasury. Currently, when an importer uses the ACH credit process, CBP will, upon the acceptance of the credit payment, identify the preliminary statement as paid and post the appropriate amounts to the related entries. *See* 19 CFR 24.25(c)(4).

In order to promote consistency with the amendments to the ACH debit process, CBP is also amending 19 CFR 24.25(c)(4) to reflect that CBP will identify final statements, as opposed to preliminary statements, as paid for the ACH credit process. As explained above for the ACH debit process, these changes do not affect either the timeliness of the payment or the date for the calculation of interest and/or liquidated damages, if applicable, for the ACH credit process.

C. Implementation of Changes

In order to provide for the changes to the ACH payment processes discussed above, and to provide clarity regarding which aspects of the payment processes are not affected, this document amends § 24.25(c)(4) by revising this provision and by splitting this provision into three (3) subparagraphs—paragraphs (c)(4)(i) through (iii).

Paragraph (c)(4)(i) of § 24.25 reflects that, for purposes of determining the timeliness of the statement payment (as well as the calculation of any interest and/or liquidated damages, if applicable), CBP will continue to use the date of acceptance of the ACH debit payment authorization or ACH credit payment as the payment date once CBP receives confirmation from Treasury that the funds are available and transferred to CBP.

Paragraph (c)(4)(ii) of § 24.25 reflects the changes to CBP's internal accounting procedures; particularly, that CBP will, upon receiving confirmation from Treasury that the funds are available and transferred to CBP, identify the final statement as paid and post the appropriate amounts to the related entries.

Paragraph (c)(4)(iii) of § 24.25 reflects that CBP will continue to generally make available to the filer the final statement on the day following the receipt of the ACH payment by CBP. This paragraph also clarifies that CBP continues to accept final statements (for ACH transactions) and cancelled checks as evidence that can be used to prove that statement payment has occurred.

IV. Nomenclature Updates

This document also proposes to update the nomenclature in § 24.25, due to the renaming of the U.S. Customs Service to U.S. Customs and Border Protection. Specifically, this document is amending paragraph (a) of § 24.25, by replacing the reference to ''U.S. Customs Service'' with ''U.S. Customs and Border Protection'', as well as making a grammatical change to the phrase ''Customs charges'' to be in the lower case. Second, due to the renaming of the U.S. Customs Service to U.S. Customs and Border Protection, this document proposes to replace references to ''Customs'' with ''CBP'' in § 24.25.

V. Statutory and Regulatory Requirements

A. Inapplicability of Notice and Delayed Effective Date

The Administrative Procedure Act (APA) requirements in 5 U.S.C. 553 govern agency rulemaking procedures. Section 553(b) of the APA generally requires notice and public comment before issuance of a final rule. In addition, section 553(d) of the APA requires that a final rule have a 30-day delayed effective date. The APA, however, provides exceptions from the prior notice and public comment requirement and the delayed effective date requirements, when an agency for good cause finds that such procedures are impracticable, unnecessary, or contrary to the public interest. CBP finds that prior notice and comment are unnecessary and that good cause exists to issue this rule effective upon publication.

Prior notice and comment are unnecessary because the rule does not substantively alter the underlying rights or interests of importers or filers. Instead, the rule is essentially technical by merely modifying the regulations to reflect the marking of a statement as paid to coincide with the completion of the funds transfer for the ACH debit and credit payment processes. CBP will continue to treat the date of CBP's acceptance of the ACH debit authorization and the ACH credit payment as the effective payment date for purposes of determining the timeliness of the statement payment (as well as for the calculation of any interest and/or liquidated damages, if applicable) once CBP receives confirmation from Treasury that the funds are available and transferred to CBP. Accordingly, the trade community will experience no delays, interruptions or process changes associated with this change to the regulations. This change only affects CBP's internal accounting procedures and does not alter the substantive rights of the members of the trade community.

B. Executive Orders 13563, 12866 and 13771

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

This interim final rule is not a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has not reviewed this regulation. As this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771. *See* OMB's Memorandum titled ''Guidance Implementing Executive Order 13771, Titled 'Reducing Regulation and Controlling Regulatory Costs' '' (April 5, 2017).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions) when the agency is required to publish a general notice of proposed rulemaking for a rule. Since a general notice of proposed rulemaking is not necessary for this rule, CBP is not required to prepare a regulatory flexibility analysis for this rule.

D. Paperwork Reduction Act

This interim final rule does not impose an additional information collection burden under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) and does not involve any material change to the existing approved information collection by the Office of Management and Budget (OMB) under assigned OMB control number 1651–0078.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB.

E. Signing Authority

This document is being issued by CBP in accordance with § 0.1(a)(1) of the CBP Regulations (19 CFR 0.1(a)(1)) pertaining to the authority of the Secretary of the Treasury (or his/her delegate) to approve regulations related to certain customs revenue functions.

List of Subjects in 19 CFR Part 24

Accounting, Claims, Harbors, Reporting and recordkeeping requirements, Taxes.

Amendments to the Regulations

For the reasons stated above, part 24 of title 19 of the Code of Federal Regulations (19 CFR part 24) is amended as set forth below:

PART 24—CUSTOMS FINANCIAL AND ACCOUNTING PROCEDURE

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

Authority: 5 U.S.C. 301; 19 U.S.C. 58a–58c, 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1505, 1520, 1624; 26 U.S.C. 4461, 4462; 31 U.S.C. 3717, 9701; Pub. L. 107–296, 116 Stat. 2135 (6 U.S.C. 1 *et seq.*).

* * * * *

■ 2. In § 24.25:

■ a. Paragraph (a), third sentence, is amended by:

■ 1. Removing the phrase '' ''U.S. Customs Service'' '' and adding the phrase '' ''U.S. Customs and Border Protection'' '' in its place;

■ 2. Removing the phrase ''Customs charges'' and adding the phrase ''customs charges'' in its place; and

■ 3. Removing the word ''Customs'' before the phrase ''(see § 111.29(b) of this chapter)'' and adding the word ''CBP'' in its place.

■ b. Paragraph (a), seventh sentence is amended by removing the word ''Customs'' and adding the word ''CBP'' in its place;

■ c. Paragraph (b) is amended by removing the word ''Customs'' in each place that it appears and adding in each place the word ''CBP'';

■ d. Paragraph (c)(2) is amended by removing the word ''Customs'' in each place that it appears and adding in each place the word ''CBP'';

■ e. Paragraph (c)(4) is revised;

■ f. Paragraph (d) is amended by removing the word ''Customs'' in each place that it appears and adding in each place the word ''CBP''; and

■ g. Paragraph (e) is amended in the last sentence by removing the word ''Customs'' and adding in its place the word ''CBP''.

The revision reads as follows:

§ 24.25 Statement processing and Automated Clearinghouse.

* * * * *

(c) * * *

(4) Payments made through ACH are processed as follows:

(i) *Payment date; interest and liquidated damages.* The date of acceptance of the ACH debit payment authorization or ACH credit payment for the preliminary statement is the payment date when determining compliance with the due date for scheduled statements and for purposes of § 24.3a of this part, and subject to the provisions of § 113.62(a)(1)(i) and (m)(4) of this chapter.

(ii) *Issuance of final statement.* CBP shall, upon confirmation from the Department of the Treasury that funds are available and transferred to CBP, identify the final statement as paid and post the appropriate amounts to the related entries.

(iii) *Evidence of payment.* The final statement generally shall be available to the filer the day following the receipt of the ACH payment by CBP. The final statement may be utilized as evidence that statement payment has occurred through an ACH transaction. In other

instances, a cancelled check may serve as evidence of payment.

* * * * *

Robert E. Perez,

Deputy Commissioner, U.S. Customs and Border Protection.

Approved: August 29, 2019.

Timothy E. Skud,

Deputy Assistant Secretary, Department of the Treasury.

[FR Doc. 2019–19149 Filed 9–4–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9839]

RIN 1545–BN41

Partnership Representative Under the Centralized Partnership Audit Regime and Election To Apply the Centralized Partnership Audit Regime; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final rule; correction.

SUMMARY: This document contains a correction to a Treasury Decision 9839, which was published in the **Federal Register** on Thursday, August 9, 2018. Treasury Decision 9839 contains final regulations regarding the designation and authority of the partnership representative under the centralized partnership audit regime, which was enacted into law on November 2, 2015 by section 1101 of the Bipartisan Budget Act of 2015 (BBA).

DATES: This correction is effective September 5, 2019 and applicable August 9, 2018.

FOR FURTHER INFORMATION CONTACT: Joy E. Gerdy Zogby of the Office of Associate Chief Counsel (Procedure and Administration), (202) 317–4927 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9839) that are the subject of this correction are issued under section 1101.

Need for Correction

As published, the final regulations (TD 9839), contains errors that may prove to be misleading and are in need of clarification.

Correction to Publication

Accordingly, the final regulations (TD 9839), that are the subject of FR Doc. 2018–17002, in the issue of August 9, 2018 (83 FR 39331), are corrected as follows:

■ 1. On page 39331, in the third column, ''RIN 1545–BN41'' is corrected to read ''RIN 1545–BN33''.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2019–19126 Filed 9–4–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 318

[Docket ID: DOD–2019–OS–0057]

RIN 0790–AK64

Defense Threat Reduction Agency Privacy Program

AGENCY: Defense Threat Reduction Agency, DoD.

ACTION: Final rule.

SUMMARY: This final rule removes the Department of Defense (DoD) regulation concerning the Defense Threat Reduction Agency (DTRA) Privacy Program. On April 11, 2019, DoD published a revised DoD-level Privacy Program rule, which contains the necessary information for an agency-wide privacy program regulation under the Privacy Act and now serves as the single Privacy Program rule for the Department. That revised Privacy Program rule also includes all DoD component exemption rules. Therefore, this part is now unnecessary and may be removed from the CFR.

DATES: This rule is effective on September 5, 2019.

FOR FURTHER INFORMATION CONTACT: Pamela Andrews, 703–767–1792.

SUPPLEMENTARY INFORMATION: DoD now has a single DoD-level Privacy Program rule at 32 CFR part 310 (84 FR 14728) that contains all the codified information required for the Department. The DTRA Program regulation at 32 CFR part 318, last updated on April 10, 2000 (65 FR 18894), is no longer required and can be removed.

It has been determined that publication of this CFR part removal for public comment is impracticable, unnecessary, and contrary to public interest since it is based on the removal of policies and procedures that are either now reflected in another CFR part, 32 CFR part 310, or are publicly available on the Department's website. To the extent that the DTRA internal guidance concerning the implementation of the Privacy Act within DTRA is necessary, it will continue to be published in DTRA Instruction 5400.11, ''Defense Threat Reduction Agency (DTRA) Instruction Privacy Program,'' available at *https://www.dtra.mil/Portals/61/DTRA%20Instruction%205400_11.pdf* (November 13, 2007).

This rule is one of 20 separate component Privacy rules. With the finalization of the DoD-level Privacy rule at 32 CFR part 310, the Department eliminated the need for this component Privacy rule, thereby reducing costs to the public as explained in the preamble of the DoD-level Privacy rule published on April 11, 2019, at 84 FR 14728–14811.

This rule is not significant under Executive Order (E.O.) 12866, ''Regulatory Planning and Review.'' Therefore, E.O. 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' does not apply.

List of Subjects in 32 CFR Part 318

Privacy.

PART 318—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 318 is removed.

Dated: August 30, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–19168 Filed 9–4–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 505

[Docket ID: USA–2019–HQ–0021]

RIN 0702–AB03

The Army Privacy Program

AGENCY: Department of the Army, DoD.

ACTION: Final rule.

SUMMARY: This final rule removes DoD's regulation concerning the Department of the Army's Privacy Program. On April 11, 2019, DoD published a revised DoD-level Privacy Program rule, which contains the necessary information for an agency-wide Privacy Program regulation under the Privacy Act and now serves as the single Privacy Program rule for the Department. That revised Privacy Program rule also

includes all DoD component exemption rules. Therefore, the regulation is now unnecessary and may be removed from the CFR.

DATES: This rule is effective on September 5, 2019.

FOR FURTHER INFORMATION CONTACT: Tracy Rogers at 571–515–0248.

SUPPLEMENTARY INFORMATION: DoD now has a single DoD-level Privacy Program rule at 32 CFR part 310 (84 FR 14728) that contains all the codified information required for the Department. The Department of the Army Privacy Act Program regulation at 32 CFR part 505 is no longer required and may be removed.

It has been determined that publication of this CFR part removal for public comment is impracticable, unnecessary, and contrary to public interest since it is based on the removal of policies and procedures that are either now reflected in another CFR part, 32 CFR part 310, or are publically available on the Army's website. To the extent that Army internal guidance concerning the implementation of the Privacy Act within the Army is necessary, it will continue to be published in Army Regulation 25–22 (available at *https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN13587_R25_22_FINAL.pdf*).

This rule is one of 20 separate component privacy rules. With the finalization of the DoD-level Privacy rule at 32 CFR part 310, the Department eliminated the need for this component Privacy rule, thereby reducing costs to the public as explained in the preamble of the DoD-level Privacy rule published on April 11, 2019, at 84 FR 14728–14811.

This rule is not significant under Executive Order (E.O.) 12866, ''Regulatory Planning and Review,'' therefore, E.O. 13771, ''Reducing Regulation and Controlling Regulatory Costs'' does not apply.

List of Subjects in 32 CFR Part 505

Administrative practice and procedure, Privacy program.

PART 505—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 505 is removed.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2019–19148 Filed 9–4–19; 8:45 am]

BILLING CODE 5001–03–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2019–0568]

RIN 1625–AA08

Special Local Regulation; Lake Havasu City, AZ

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation for the Havapalooza 2019 marine event that will be held on the navigable waters of Lake Havasu, Lake Havasu City, AZ. This action is necessary to provide for the safety of life on these navigable waters on Thompson Bay in Lake Havasu during a waterside concert on September 14, 2019. This rule prohibits spectators from anchoring, blocking, loitering or transiting through in the event area unless authorized by the Captain of the Port Sector San Diego or a designated representative.

DATES: This rule is effective from 10 a.m. to 8 p.m. on September 14, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0568 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Briana Biagas, Coast Guard; telephone 619–278–7656, email *D11MarineEventsSD@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard was not notified of this event's date until June 4, 2019. It is impracticable to publish an NPRM because we must establish regulated area by September 14, 2019 and lack sufficient time to provide a reasonable comment period and consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register.** Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to ensure the safety of life on Lake Havasu.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041 (previously 33 U.S.C. 1236). The Captain of the Port Sector San Diego (COTP) has determined that a large congregation of vessels in Thompson Bay associated with the Havapalooza 2019 marine event on September 14, 2019, poses a potential safety concern. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within Thompson Bay while the event is occurring.

IV. Discussion of the Rule

This rule establishes a temporary special local regulation from 10 a.m. to 8 p.m. on September 14, 2019. This special local regulation establishes a spectator area covering all navigable waters of Thompson Bay shoreward of a line connected by the following points: Beginning at 34°27′55″ N, 114°20′48″ W (Point A); thence running southerly to 34°27′52″ N, 114°20′49″ W (Point B); thence running southeasterly to 34°27′49″ N, 114°20′47″ W (Point C); thence running southeasterly to 34°27′45″ N, 114°20′43″ W (Point D); thence running southeasterly to 34°27′40″ N, 114°20′34″ W (Point E) thence running southeasterly and ending at 34°27′37″ N, 114°20′27″ W (Point F). The duration of the regulated area is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled marine event. All non-event participants would be permitted to enter the regulated area without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-day of the regulated area. Vessel traffic can safely transit around this regulated which would impact a an approximately 17,000 square yard area of Thompson Bay from 8 a.m. to 10 p.m. Moreover, the Coast Guard would make a post in the Local Notice to Mariners with details on the regulated area.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary regulated area that would limit access to an approximately 17,000 square yard area of Thompson bay from 10 a.m. to 8 p.m. It is categorically excluded from further review under paragraph L61 in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON THE NAVIGABLE WATERS

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

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.1102T11–0568 to read as follows

§ 100.1102T11–0568 Special Local Regulation; Lake Havasu City, AZ

(a) *Location:* The following area is a special local regulation: all navigable waters of Thompson Bay shoreward of

a line connected by the following points: Beginning at 34°27′55″ N, 114°20′48″ W (Point A); thence running southerly to 34°27′52″ N, 114°20′49″ W (Point B); thence running southeasterly to 34°27′49″ N, 114°20′47″ W (Point C); thence running southeasterly to 34°27′45″ N, 114°20′43″ W (Point D); thence running southeasterly to 34°27′40″ N, 114°20′34″ W (Point E) thence running southeasterly and ending at 34°27′37″ N, 114°20′27″ W (Point F).

(b) *Effective period.* This section is effective from 10 a.m. to 8 p.m. on September 14, 2019.

(c) *Regulations.* (1) In accordance with the general regulations in § 100.35 of this part, entry into or remaining within this regulated area is prohibited unless authorized by the Captain of the Port Sector San Diego (COTP) or a designated representative.

(2) Vessels requiring entry into this regulated area must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 69 or by telephone at 562–447–0940.

(3) Persons and vessels permitted to enter this area must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this regulated area through Local Notice to Mariners.

Dated: August 21, 2019.

D.P. Montoro,

Captain, U.S. Coast Guard, Alternate, Captain of the Port Sector San Diego.

[FR Doc. 2019–19119 Filed 9–4–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

EPA–HQ–SFUND–1989–0008; FRL–9999–36–Region 3]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Strasburg Landfill Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 3 announces the deletion of the Strasburg Landfill Superfund Site (Site) located south and slightly east of Strasburg Road in Newlin Township, Chester County, Pennsylvania from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the Commonwealth of Pennsylvania, through the Pennsylvania Department of Environment (PADEP, Southeast Region), have determined that all appropriate response actions under CERCLA, other than operation and maintenance (O&M), monitoring, and Five-Year Reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: This action is effective September 5, 2019.

ADDRESSES:

Docket: EPA has established a docket for this action under Docket Identification No. EPA–HQ–SFUND–1989–0008. 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.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *https://www.regulations.gov* or in hard copy at the site information repositories. Locations, contacts, phone numbers and viewing hours are:

USEPA Region III Administrative Records Room, 1650 Arch Street—6th Floor, Philadelphia, PA 19103–2029, 215–814–3157, Business Hours: Monday through Friday, 8:00 a.m.–4:30 p.m.; by appointment only.

Local Repository, Bayard Taylor Memorial Library, 216 East State Street, Kennett Square, PA. 19358, Business Hours: Monday through Friday, 9:00 a.m.–8:00 p.m.

FOR FURTHER INFORMATION CONTACT: David Greaves, Remedial Project Manager, U.S. Environmental Protection Agency, Region III, 3HS21 1650 Arch St. Philadelphia, PA. 19103, 215–814–5729, email *greaves.david@epa.gov.*

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is: Strasburg Landfill Superfund Site, Strasburg Road, Newlin Township, Chester County, Pennsylvania. A Notice of Intent to Delete for this Site was published in the **Federal Register** (84 FR 31826) on July 3, 2019.

The closing date for comments on the Notice of Intent to Delete was August 2, 2019. One public comment was received. The comment received was a request for EPA to make publicly available information on Site cleanup activities, estimates of future costs related to Site cleanup, and the actual costs when cleanup activities are completed. Since the comment is an informational request and is not an adverse comment regarding the deletion of this Site, EPA still believes this deletion action is appropriate. A responsiveness summary was prepared and placed in both the docket, EPA–HQ–SFUND–1989–0008, on *www.regulations.gov,* and in the local repositories listed above.

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion from the NPL does not preclude further remedial action. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system. Deletion of a site from the NPL does not affect responsible party liability in the unlikely event that future conditions warrant further actions.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: August 13, 2019.

Cosmo Servidio,

Regional Administrator, Region III.

For reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B to Part 300—[Amended]

■ 2. Table 1 of appendix B to part 300 is amended by removing ''PA'',

''Strasburg Landfill'', ''Newlin Township''.

[FR Doc. 2019–19175 Filed 9–4–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2019–0003; Internal Agency Docket No. FEMA–8595]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *https://www.fema.gov/national-flood-insurance-program-community-status-book.*

DATES: The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Adrienne L. Sheldon, PE, CFM, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 212–3966.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.,* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region VI				
Oklahoma:				
Afton, Town of, Ottawa County	400155	March 30, 1976, Emerg; January 3, 1986, Reg; September 13, 2019, Susp.	September 13, 2019 ..	September 13, 2019.
Bernice, Town of, Delaware County.	400559	N/A, Emerg; December 22, 2003, Reg; September 13, 2019, Susp.	.....do	Do.
Bluejacket, Town of, Craig County	400262	November 3, 1976, Emerg; October 24, 1978, Reg; September 13, 2019, Susp.	.....do	Do.
Craig County, Unincorporated Areas.	400540	May 3, 1993, Emerg; April 17, 1996, Reg; September 13, 2019, Susp.	.....do	Do.
Disney, Town of, Mayes County ..	400554	N/A, Emerg; February 29, 2012, Reg; September 13, 2019, Susp.	.....do	Do.
Jay, City of, Delaware County	400057	August 5, 1976, Emerg; July 5, 1978, Reg; September 13, 2019, Susp.	.....do	Do.
Mayes County, Unincorporated Areas.	400458	April 8, 1987, Emerg; December 1, 1989, Reg; September 13, 2019, Susp.	.....do	Do.
Miami, City of, Ottawa County	400157	November 29, 1974, Emerg; December 16, 1980, Reg; September 13, 2019, Susp.	.....do	Do.
Vinita, City of, Craig County	400050	June 18, 1975, Emerg; June 1, 1981, Reg; September 13, 2019, Susp.	.....do	Do.

* do = Ditto.
Code for reading third column: Emerg. —Emergency; Reg. —Regular; Susp. —Suspension.

Dated: August 29, 2019.

Eric Letvin,

Deputy Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration—FEMA Resilience, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2019–19190 Filed 9–4–19; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 180713633–9174–02]

RIN 0648–XY019

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod in the Aleutian Islands Subarea of the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod, except for the Community Development Quota program (CDQ), in the Aleutian Islands subarea of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the non-CDQ allocation of the 2019 Pacific cod total allowable catch (TAC) in the Aleutian Islands subarea of the BSAI.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), September 4, 2019, through 2400 hrs, A.l.t., December 31, 2019.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

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

The non-CDQ allocation of the 2019 Pacific cod TAC in the Aleutian Islands subarea of the BSAI is 12,693 metric tons (mt) as established by the final 2019 and 2020 harvest specifications for groundfish in the BSAI (84 FR 9000, March 13, 2019). In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS, has determined that the non-CDQ allocation of the 2019 Pacific cod TAC in the Aleutian Islands subarea of the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 11,393 mt, and is setting aside the remaining 1,300 mt as incidental catch in directed fishing for other species. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod in the Aleutian Islands subarea of the BSAI.

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

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishing closure of non-CDQ Pacific cod in the Aleutian Islands subarea of the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of August 29, 2019.

The AA also finds good cause to waive the 30-day delay in the effective

date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: August 30, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–19167 Filed 8–30–19; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 84, No. 172
Thursday, September 5, 2019

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 HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. FDA–2018–N–4845]

RIN 0910–AH81

Amendments to the List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) has issued a regulation creating a list of bulk drug substances (active pharmaceutical ingredients) that can be used to compound drug products in accordance with certain compounding provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drugs. This proposed rule would amend that list by placing five additional bulk drug substances on the list. This proposed rule also identifies 26 bulk drug substances that FDA has considered and proposes not to include on the list. Additional substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of a future rulemaking.

DATES: Submit either electronic or written comments on the proposed rule by December 4, 2019. See section VI for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on the comment due date provided in the **DATES** section. 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–2018–N–4845 for ''Amendments to the List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act.'' 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.

- 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Rosilend Lawson, Center for Drug Evaluation and Research, Office of Unapproved Drugs and Labeling Compliance, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20993, 240–402–6223, *Rosilend.Lawson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary
A. Purpose of the Proposed Rule
B. Summary of the Major Provisions of the Proposed Rule
C. Legal Authority
D. Costs and Benefits
II. Table of Abbreviations/Commonly Used Acronyms in This Document
III. Background
IV. Legal Authority
V. Description of the Proposed Rule
A. Criteria for Evaluating Bulk Drug Substances for the 503A Bulks List
B. Methodology for Developing the 503A Bulks List
C. Substances Proposed for Inclusion on the 503A Bulks List
D. Substances Considered and Not Proposed for Inclusion on the 503A Bulks List
VI. Proposed Effective Date
VII. Preliminary Economic Analysis of Impacts
VIII. Analysis of Environmental Impact
IX. Paperwork Reduction Act of 1995
X. Federalism
XI. Consultation and Coordination With Indian Tribal Governments
XII. References

I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing to amend its regulations to add substances to the list of bulk drug substances that can be used in compounding under section 503A of the FD&C Act (21 U.S.C. 353a) (referred to as ''the 503A Bulks List''). Bulk drug substances that appear on the 503A Bulks List can be used to compound drug products subject to the conditions of section 503A, even though those substances are not the subject of an applicable USP or NF monograph or components of approved drug products.

B. Summary of the Major Provisions of the Proposed Rule

Based on the results of its evaluation of nominated bulk drug substances to date, as well as consultation with the Pharmacy Compounding Advisory Committee (PCAC), and the United States Pharmacopoeia Convention, Incorporated, FDA is proposing to amend the 503A Bulks List to include five additional bulk drug substances: Glutaraldehyde, glycolic acid, L-citrulline, pyruvic acid, and trichloroacetic acid (TCA). FDA is also proposing that 26 other substances not be included on the list: 7-keto dehydroepiandrosterone (DHEA), acetyl-L-carnitine (ALC), alanyl-L-glutamine, Aloe vera 200:1 freeze dried, artemisinin, astragalus extract 10:1, *boswellia serrata* extract (BWSE), cesium chloride, chondroitin sulfate, chrysin, curcumin, D-ribose, deoxy-D-glucose, diindolylmethane, domperidone, epigallocatechin gallate (EGCG), germanium sesquioxide, glycyrrhizin, kojic acid, nettle, nicotinamide adenine dinucleotide (NAD), nicotinamide adenine dinucleotide disodium reduced (NADH), rubidium chloride, sodium dichloroacetate, vanadyl sulfate, and vasoactive intestinal peptide (VIP).

C. Legal Authority

Section 503A of the FD&C Act, in conjunction with our general rulemaking authority in section 701(a) of the FD&C Act (21 U.S.C. 371(a)), serves as our principal legal authority for this proposed rule.

D. Costs and Benefits

FDA evaluated 31 bulk drug substances for this proposed rule, proposing to place 5 bulk drug substances on the 503A Bulks List, and not to place 26 substances on the 503A Bulks List. The primary estimate of the present value of the costs over 10 years is $1.03 million. The primary estimate of the annualized costs is $0.15 million at a 7 percent discount rate and $0.12 million at a 3 percent discount rate. Because we lack sufficient information to quantify most of the costs and benefits of this proposed rule, we also include a qualitative description of potential benefits and potential costs. We expect that the rule will affect compounding pharmacies and other producers that market the affected substances or drug products made from the affected substances, consumers of drug products containing the affected substances, and payers that cover these drug products or alternative treatments.

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

Abbreviation/acronym	What it means
ALC	Acetyl-L-carnitine.
BWSE	*Boswellia serrata* extract.
CFR	Code of Federal Regulations.
CFS	Chronic fatigue syndrome.
CIRS	Chronic inflammatory response syndrome.
DHEA	Dehydroepiandrosterone.
EGCG	Epigallocatechin gallate.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	Food and Drug Administration.
GAIT	Glucosamine/Chondroitin Arthritis Intervention Trial.
GRAS	Generally recognized as safe.
HSV	Herpes simplex virus.
IND	Investigational new drug.
IV	Intravenous.
MS	Multiple sclerosis.
NAICS	North American Industry Classification System.
NAD	Nicotinamide adenine dinucleotide.
NADH	Nicotinamide adenine dinucleotide disodium reduced.
NF	National Formulary.
NPRM	Notice of proposed rulemaking.
OA	Osteoarthritis.
PCAC	Pharmacy Compounding Advisory Committee.
RA	Rheumatoid arthritis.
RFA	Regulatory Flexibility Analysis.
SBA	Small Business Administration.
TCA	Trichloroacetic acid.
UCD	Urea cycle disorder.
USP	United States Pharmacopeia.

II. TABLE OF ABBREVIATIONS/COMMONLY USED ACRONYMS IN THIS DOCUMENT—Continued

Abbreviation/acronym	What it means
VIP	Vasoactive intestinal peptide.

III. Background

Section 503A of the FD&C Act describes the conditions under which a compounded drug product may qualify for an exemption from certain sections of the FD&C Act. Those conditions include that a licensed pharmacist in a State-licensed pharmacy or Federal facility or a licensed physician compounds the drug product using bulk drug substances that: (1) Comply with the standards of an applicable USP or NF monograph,[1] if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary of the Department of Health and Human Services (Secretary); or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appear on the 503A Bulks List. (See section 503A(b)(1)(A)(i) of the FD&C Act.)

On February 19, 2019, FDA published a final rule establishing the criteria for evaluating substances for inclusion on the 503A Bulks List, placing six substances on the list, and identifying four other substances that were evaluated and not included on the 503A Bulks List (84 FR 4696). That final rule noted that additional substances were under evaluation, and that new substances may be added to the list through subsequent rulemaking. This proposed rule would amend that list by adding five additional substances. It also identifies 26 other substances that FDA has evaluated and proposes not to include on the list.

Section 503A of the FD&C Act adopts the definition of ''bulk drug substance'' in FDA's drug establishment registration and listing regulations, which was codified at § 207.3(a)(4) (21 CFR 207.3(a)(4)) at the time section 503A was enacted. (See section 503A(b)(1)(A) of the FD&C Act.) Under the definition, bulk drug substance means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

On August 31, 2016, FDA published a final rule in the **Federal Register** to update its registration and listing regulations in part 207 (21 CFR part 207), which included minor changes to the definition of bulk drug substance and moved the definition to § 207.3 (see 81 FR 60170 at 60175). This definition became effective on November 29, 2016. As set forth in § 207.3, ''bulk drug substance,'' as referenced in section 503A(b)(1)(A) of the FD&C Act, means the same as ''active pharmaceutical ingredient'' as defined in § 207.1 (21 CFR 207.1). An ''active pharmaceutical ingredient'' is any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. The term ''active pharmaceutical ingredient'' does not include intermediates used in the synthesis of the substance (§ 207.1).

Inactive ingredients used in compounded drug products, such as flavorings, dyes, or diluents, need not appear on the 503A Bulks List to be eligible for use in compounding drug products and will not be included on the list.

For regulatory history of the 503A Bulks List, see 81 FR 91071 (December 16, 2016).

IV. Legal Authority

As described in Section III. Background, section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act (sections 501(a)(2)(B), 502(f)(1), and 505 (21 U.S.C. 351(a)(2)(B), 352(f)(1), and 355)). One of the conditions that must be satisfied for a compounded drug to qualify for the exemptions under section 503A of the FD&C Act is that a licensed pharmacist in a State-licensed pharmacy or Federal facility or a licensed physician compounds the drug product using bulk drug substances that: (1) Comply with the standards of an applicable USP or NF monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appear on the 503A Bulks List. (See section 503A(b)(1)(A)(i) of the FD&C Act.) Section 503A(c)(1) of the FD&C Act also states that the Secretary shall issue regulations to implement section 503A, and that before issuing regulations to implement section 503A(b)(1)(A)(i)(III) pertaining to the 503A bulks list, among other sections, the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. Section 503A(c)(2) of the FD&C Act requires the Secretary to issue the regulations in consultation with the USP, and to include in the regulation the criteria for such substances that shall include historical use, reports in peer-reviewed journals, or other criteria the Secretary identifies. Thus, section 503A of the FD&C Act, in conjunction with our general rulemaking authority in section 701(a) of the FD&C Act, serves as our principal legal authority for this proposed rule.

V. Description of the Proposed Rule

FDA proposes to amend § 216.23 (21 CFR 216.23) to include 5 of the bulk drug substances that were considered on the 503A Bulks List and to identify 26 substances that were considered and would not be included on the list. The criteria and methodology for evaluating bulk drug substances for inclusion on the list, and FDA's proposals regarding the substances addressed in this notice of proposed rulemaking (NPRM) are described in the paragraphs that follow.

A. Criteria for Evaluating Bulk Drug Substances for the 503A Bulks List

Section 503A(c)(2) of the FD&C Act provides that the criteria for determining which substances should appear on the 503A Bulks List shall include historical use, reports in peer-reviewed medical literature, or other

[1] FDA has interpreted the statutory language ''applicable United States Pharmacopoeia or National Formulary monograph'' to refer only to official USP or NF monographs for drug substances. Therefore, a substance that is the subject of a dietary supplement monograph, but not a USP or NF drug substance monograph, does not satisfy the condition regarding bulk drug substances in section 503A(b)(1)(A)(i)(I) of the FD&C Act. Such a substance may only be used as a bulk drug substance under section 503A of the FD&C Act if it is a component of an FDA-approved drug product or is on the 503A Bulks List.

criteria the Secretary may identify. Under § 216.23, the following criteria are used to evaluate the nominated substances:

- The physical and chemical characterization of the substance;
- Any safety issues raised by the use of the substance in compounded drug products;
- The available evidence of effectiveness or lack of effectiveness of a drug product compounded with the substance, if any such evidence exists; and
- Historical use of the substance in compounded drug products, including information about the medical condition(s) the substance has been used to treat and any references in peer-reviewed medical literature.

In evaluating candidates for the 503A Bulks List under these criteria, the Agency uses a balancing test. Specifically, the Agency considers each criterion in the context of the others and balance them, on a substance-by-substance basis, to decide whether a particular substance is appropriate for inclusion on the 503A Bulks List. The criteria are discussed in further detail in the Agency's previous rulemaking on the 503A Bulks List (81 FR 91071; 84 FR 4696).

B. Methodology for Developing the 503A Bulks List

FDA reviewed the substances addressed in this proposed rule in the context of adequately supported uses that were proposed with the nomination. In certain circumstances, FDA also reviewed substances in the context of uses that were not proposed with the nomination or proposed uses that were inadequately supported because, for example, such uses appear to be widespread, are intended to treat serious conditions, or pose serious risks to patients. The information that FDA assessed to evaluate the substances addressed in this proposed rule under each of the evaluation criteria was obtained from publicly available sources, including peer-reviewed medical literature. Some of this information was referenced in the nominations, and the remainder FDA gathered through independent searches of medical and pharmaceutical databases. FDA did not review raw data. The nature, quantity, and quality of the information FDA assessed varied considerably from substance to substance. In some cases, there were very little data. For other substances, reports in the literature were more plentiful and sometimes comprised hundreds or thousands of articles. In those cases, generally the Agency limited its review to a sample of the best literature sources available (*e.g.,* review articles in widely known, peer-reviewed journals; meta-analyses; reports of randomized controlled trials).

FDA's evaluation of the nominated substances was, necessarily, far less rigorous and less comprehensive than the Agency's review of drugs as part of the new drug approval process. The new drug approval process is conducted based on extensive data compiled and submitted with new drug and abbreviated new drug applications, which are not available for the nominated substances. Additionally, the Agency's review during the drug approval process includes premarket evaluation of a specific drug formulation, the applicant's chemistry and manufacturing controls, and inspection of the establishments where approved drugs will be manufactured. In contrast, these bulk drug substances will be evaluated only for possible use in compounded drugs.

Therefore, the proposed inclusion of a drug substance on the 503A Bulks List should not, in any way, be equated with or considered an FDA approval, endorsement, or recommendation of any drug compounded using the substance. Nor should it be assumed that a drug compounded using the substances on the proposed list has been proven to be safe and effective under the standards required for Agency approval. Any person who represents that a compounded drug made with a bulk drug substance that appears on this list is approved by FDA, or otherwise endorsed by FDA generally, or for a particular indication, will cause the drug to be misbranded under section 502(a) (labeling) and/or 502(bb) (advertising or promotion) of the FD&C Act.

On October 27 and 28, 2015, March 8, 2016, June 23, 2016, November 3, 2016, May 8 and 9, 2017, and November 20, 2017, FDA consulted with the PCAC created under section 503A(c)(1) of the FD&C Act about the 31 substances that are addressed in this proposed rule (Refs. 1 to 11). The Agency considered the PCAC's recommendations in developing this proposed rule, and the Agency intends to continue to consult with the PCAC in evaluating future candidates for the 503A Bulks List. Going forward, FDA intends to publish NPRMs proposing additional substances be included on the list or not included on the list on a rolling basis as evaluations are completed. Depending on the length of time it takes to complete a rulemaking, multiple rulemakings may be ongoing simultaneously.

Section 503A of the FD&C Act also requires that FDA create the 503A Bulks List in consultation with the USP. (See section 503A(c)(2) of the FD&C Act.) To this end, FDA has consulted with USP about the substances that are the subject of this proposed rule (Refs. 12 to 16). After publication of this NPRM, the public will have an opportunity to submit comments on the proposed rule to the docket. After considering those comments, FDA will publish a final rule amending the 503A Bulks List codified at § 216.23. The final version of the rule may include all, none, or only some of the substances proposed here for inclusion on the 503A Bulks List, based upon the Agency's consideration of the comments received, and will also identify those substances the Agency has determined should not be included on the list. The Agency may amend the 503A Bulks List to add or delete substances after further notice and comment rulemaking.

With respect to any substance already addressed in a final rule, individuals and organizations may petition FDA to amend the 503A Bulks List (to add or delete those bulk drug substances or to consider information about those bulk drug substances that is different from that which FDA presented to the PCAC) (see 21 CFR 10.30). With respect to substances that have not been addressed in rulemaking, individuals and organizations may submit nominations of new substances or comments on nominated substances to Docket No. FDA–2015–N–3534.

C. Substances Proposed for Inclusion on the 503A Bulks List

Under section 503A(c)(2) of the FD&C Act, FDA is proposing that the following five bulk drug substances, which are neither the subject of an applicable USP or NF monograph nor components of FDA-approved drugs, be included on the 503A Bulks List, and the drug products compounded with those substances may qualify for the exemptions provided for in section 503A of the FD&C Act (*i.e.,* from sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act). When a salt or ester of an active moiety is listed, only that particular salt or ester may be used for compounding under section 503A of the FD&C Act. The base compound and other salts or esters of the same active moiety must be evaluated separately for inclusion on the 503A Bulks List. Additionally, when a bulk drug substance is included on the 503A Bulks List subject to certain restrictions (for example, for a particular route of administration (*e.g.,* topical)), only drug

products that conform to that restriction may qualify for the 503A exemptions.

The following bulk drug substances are being proposed for placement on the 503A Bulks List, to appear in § 216.23(a) of title 21 of the CFR:

(1) *Glutaraldehyde.* Glutaraldehyde [2] was evaluated for topical use in the treatment of warts. Glutaraldehyde is well characterized physically and chemically. Glutaraldehyde is reasonably safe to use topically in 0.1 percent to 10 percent solutions for the treatment of warts. Nonclinical studies do not show safety issues in vivo other than irritation and skin sensitization. Skin discoloration has been observed with the use of glutaraldehyde in the treatment of warts, which eventually subsides after treatment. Other risks, such as allergic contact dermatitis, skin ulceration, and necrosis, were observed when high strengths of glutaraldehyde were used. These risks should be managed by the use of glutaraldehyde in strengths of 10 percent or lower.

Although there is no standard regimen for its use, there is available evidence from uncontrolled clinical studies and one randomized controlled trial demonstrating the effectiveness of glutaraldehyde in nongenital cutaneous wart treatment. There are no approved prescription therapies for warts outside of the genital area. Glutaraldehyde has been used in compounded drug products for over 40 years, primarily in the treatment of nongenital warts.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of glutaraldehyde weigh in favor of inclusion of this substance on the list. FDA recommended to the PCAC that this substance be included on the 503A Bulks List for topical use, at concentrations of 10 percent or lower (Ref. 17). At its meeting on October 28, 2015, the PCAC voted to include glutaraldehyde on the list (Ref. 3). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). This proposed rule would place glutaraldehyde on the 503A Bulks List for topical use at concentrations of 10 percent or lower.

(2) *Glycolic Acid.* Glycolic acid for topical use was evaluated for use in the treatment of hyperpigmentation and photodamaged skin. Glycolic acid, also known as hydroxyacetic acid, is physically and chemically well characterized. When used in high concentrations, glycolic acid causes local effects that are typical of a strong acid, such as dermal and eye irritation. Reported adverse reactions were generally limited in duration and readily manageable. There is no information available on long-term outcomes. The available data on short-term outcomes do not raise major safety concerns associated with the topical use of glycolic acid.

Data from controlled clinical trials have shown consistently positive results in the treatment of epidermal melasma or other forms of hyperpigmentation. The available evidence suggests that there is a role for glycolic acid in the treatment of melasma, typically as a second line treatment. There is also some evidence indicating that glycolic acid may be effective for the mitigation of manifestations of photodamaged skin. Historically, glycolic acid has been used in compounded drug products for several decades.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of glycolic acid weigh in favor of inclusion of this substance on the list. FDA recommended to the PCAC that this substance be included on the 503A Bulks List, for topical use in concentrations up to 70 percent (Ref. 18). At its meeting on November 3, 2016, the PCAC voted to include glycolic acid for topical use on the list (Ref. 8). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). This proposed rule would place glycolic acid for topical use, in concentrations up to 70 percent, on the 503A Bulks List.

(3) *L-citrulline.* L-citrulline for oral use was evaluated for use in the treatment of certain urea cycle disorders (UCDs). L-citrulline, a non-essential amino acid, is well characterized physically and chemically. The available nonclinical and clinical data are inadequate to evaluate the safety of L-citrulline for oral use, but no serious adverse events have been linked to its use.

Regarding effectiveness, we found no clinical trials supporting the effectiveness of the use of L-citrulline for UCDs. This lack of data is expected given the small number of patients with UCDs. However, there is a strong mechanistic rationale supporting the use of L-citrulline for UCDs, based on the pathophysiology of the disorder and the goals of treatment. There have also been anecdotal reports of successful treatment of certain UCDs with L-citrulline. Historically, the duration of use of L-citrulline in compounded drug products is not clear. L-citrulline has been used clinically in the treatment of certain UCDs for approximately 30 to 40 years. Oral L-citrulline is part of the standard of care for certain UCDs.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of L-citrulline weigh in favor of inclusion of this substance on the list. FDA recommended to the PCAC that this substance, for oral use, be included on the 503A Bulks List (Ref. 19). At its meeting on November 20, 2017, the PCAC voted to include L-citrulline for oral use on the list (Ref. 10). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). This proposed rule would place L-citrulline for oral use on the 503A Bulks List.

(4) *Pyruvic Acid.* Pyruvic acid for topical use was evaluated for use in the treatment of acne, melasma, and warts. It is physically and chemically well characterized, but it is unlikely to be stable in ambient conditions. Stability concerns can be addressed by carefully sealing the drug product and isolating it from moisture and light. Regarding safety, we identified no significant safety concerns related to the topical use of pyruvic acid in compounded drug products. The available data indicate that the topical use of pyruvic acid is associated with local irritancy, but reported adverse reactions were generally limited in duration and readily manageable. The most serious risk reported was upper respiratory tract irritation due to inhaled vapors, which can be avoided when patients and healthcare providers take appropriate precautionary measures (*e.g.,* ensuring the product is administered in a room with adequate ventilation) to protect against inhalation.

Regarding effectiveness, limited data derived from small, open-label trials indicate that the topical use of pyruvic acid might be somewhat effective in the treatment of acne, melasma, and warts,

[2] Note that there is a USP monograph for glutaral concentrate (glutaraldehyde in a 50 percent aqueous solution), which is a different concentration than that proposed in the nominations. USP Guidelines state that ''[s]ome drug substances are available as concentrated solutions . . . and are intended to be used as intermediates for final formulations.'' USP Nomenclature Guideline Outline, available at *https://www.usp.org/sites/default/files/usp/document/about/expert-volunteers/expert-committees/nomenclature-guideline.pdf.* The glutaral concentrate that is the subject of the USP monograph is intended to be used as an intermediate for a final formulation; the USP monograph for glutaral concentrate states that it should be labeled with the statement that it is not intended for direct administration to humans or animals. Under § 207.3(a)(4), the definition of ''bulk drug substance'' excludes intermediates used in the synthesis of the bulk drug substance. Therefore, we are proposing glutaraldehyde for inclusion on the list in forms or concentrations other than those provided in the USP monograph.

which are not serious or life-threatening conditions. There are no approved prescription therapies for warts outside of the genital area. Pyruvic acid has been used in compounded drug products for approximately 30 years.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of pyruvic acid weigh in favor of inclusion of this substance on the list. FDA recommended to the PCAC that this substance be included on the 503A Bulks List for topical administration (Ref. 20). At its meeting on June 23, 2016, the PCAC voted to include pyruvic acid for topical use on the list (Ref. 7). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). This proposed rule would place pyruvic acid for topical use on the 503A Bulks List.

(5) *TCA.* TCA for topical use was evaluated for the treatment of warts and as a chemical peeling agent. TCA is well characterized physically and chemically and is likely to be stable when refrigerated. The safety profile shows that TCA commonly causes erythema, crusting, hyperpigmentation and hypopigmentation, burning, and pain at the application site. The reported incidents of adverse effects have increased in correlation with the concentration of TCA used (*e.g.,* adverse reactions were observed more frequently with a 95 percent TCA solution as compared with 85 percent or 50 percent solutions), and more adverse effects have been reported when TCA was used in the facial and genital areas. At higher concentrations, the potential for ulceration and subsequent absorption through open wounds increases. Ulcerations have been reported in most studies of TCA in the treatment of genital warts.

Regarding effectiveness, the available information suggests that TCA may have some effectiveness for the treatment of warts when used at higher concentrations (*e.g.,* in one comparative study, more subjects had a ''good'' response with an 80 percent TCA solution as compared with a 35 percent solution) or in conjunction with an additional wart treatment, and thus may have a role in treating refractory warts or patients intolerant of other therapies. Warts generally are not a serious or life-threatening condition. There are no approved prescription therapies for warts outside of the genital area. Historically, TCA has been used in compounded drug products for at least 20 years.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of TCA weigh in favor of inclusion of this substance on the list. FDA recommended to the PCAC that this substance be included on the 503A Bulks List for topical use (Ref. 18). At its meeting on November 3, 2016, the PCAC voted to include TCA on the list for topical use (Ref. 8). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). This proposed rule would place TCA on the 503A Bulks List for topical use.

D. Substances Considered and Not Proposed for Inclusion on the 503A Bulks List

FDA is proposing that 26 of the bulk drug substances that it has evaluated not be included on the 503A Bulks List. Bulk drug substances that are considered for the 503A Bulks list, but not placed on the list, cannot be used to compound drug products that would qualify for the exemptions in section 503A.[3]

The 26 bulk drug substances that have been evaluated and that FDA is proposing not be placed on the list, and the reasons for that proposal, are as follows:

(1) *7-keto DHEA.* 7-keto DHEA was evaluated for use in the treatment of Raynaud's phenomena and weight loss. 7-keto DHEA is physically and chemically well characterized. Although we did not identify a safety signal from available information, there are minimal data available, and we could not adequately assess whether it is safe to use 7-keto DHEA in compounded drug products. Similarly, there are insufficient data to establish whether 7-keto DHEA would be effective in the treatment of Raynaud's phenomena or obesity. Historically, it appears that 7-keto DHEA has been used in compounded drug products for approximately 7 years.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of 7-keto DHEA weigh against inclusion of this substance on the 503A Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 19). At its meeting on November 20, 2017, the PCAC voted not to include 7-keto DHEA on the list (Ref. 11). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). The proposed rule would not place 7-keto DHEA on the 503A Bulks List.

(2) *ALC.* ALC was evaluated for use in the treatment of Alzheimer's disease, chemotherapy-induced peripheral neuropathy, and hepatic encephalopathy. ALC is well characterized physically and chemically but given that hydrolysis may occur on its ester group in aqueous solutions, it is unlikely to be stable when formulated as an aqueous solution. But it is likely to be stable in solid dosage forms. Regarding safety, the available information, which is limited, did not indicate toxicity, and it appears to be well-tolerated when given orally up to 3 grams daily. However, the labeling of FDA-approved products that contain L-carnitine, a closely related drug substance, indicates that those products may affect blood clotting and pose a risk for seizures. There may be similar risks with the use of ALC.

There is insufficient evidence to indicate that ALC is effective for the treatment of the evaluated conditions. FDA-approved drug products have been demonstrated to be safe and effective under the conditions of use set forth in their labeling for the treatment of Alzheimer's disease, chemotherapy-induced peripheral neuropathy, and hepatic encephalopathy, which are serious conditions. The history of ALC use in compounded drug products is unknown.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of ALC weigh against inclusion of this substance on the list. FDA recommended to the PCAC that this substance not be included on the 503A Bulks List (Ref. 21), and at its meeting on March 8, 2016, the PCAC voted not to include ALC on the list (Ref. 6). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). This proposed rule would not place ALC on the 503A Bulks List.

(3) *Alanyl-L-Glutamine.* Alanyl-L-glutamine was evaluated for use in nutritional support and reducing rates of infectious complications in critically ill and surgical patients. Alanyl-L-glutamine is well characterized

[3] If a prescribing practitioner nevertheless believes that a patient should be treated with a drug product compounded from such a bulk drug substance, it may be possible to obtain the drug under an investigational new drug (IND) application. For information about the requirements for proceeding under an IND application, visit FDA's website at *https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm.*

physically and chemically, but there are toxicity concerns with potential impurities, specifically, solvents, endotoxins, bioburden, and heavy metal impurities linked to the source of the starting material and the reagents used in processing. Exposure to elemental impurities such as heavy metals has been associated with proven toxicities, such as irreversible neurological impairment and hepatotoxicity. We could not adequately assess whether the substance would be sufficiently free of such impurities to be suitable for compounding into parenteral solutions for intravenous (IV) administration, which would result in 100 percent bioavailability of impurities. Additionally, safety concerns were observed in a large, randomized controlled trial of critically ill patients who received glutamine supplementation, the results of which demonstrated the potential toxicity of alanyl-L-glutamine, including increased frequency of increased serum urea levels and an increase of in-hospital, 28-day, and 6-month mortality rates.

Regarding effectiveness, a meta-analysis published in the literature suggests that parenteral supplementation with alanyl-L-glutamine may benefit certain populations, including through potential decrease in rates of infection or infectious complications; however, the available data are limited, and some other analyses indicated unfavorable outcomes. Alanyl-L-glutamine has been used in compounded drug products for approximately 15 years.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of alanyl-L-glutamine weigh against inclusion of this substance on the list. FDA recommended to the PCAC that this substance not be included on the 503A Bulks List (Ref. 17), and at its meeting on October 27, 2015, the PCAC voted not to include alanyl-L-glutamine on the list (Ref. 2). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). This proposed rule would not place alanyl-L-glutamine on the 503A Bulks List.

(4) *Aloe Vera 200:1 Freeze Dried.* Aloe vera 200:1 freeze dried [4] was evaluated as treatment for burns, cuts, and wounds. We found no information to differentiate ''Aloe vera 200:1 freeze dried'' from other Aloe vera extracts. Aloe vera extract is not well characterized physically and chemically. Rather, it is a complex mixture that may contain various classes of chemical compounds, such as polysaccharides, organic acids, and anthraquinones.

Regarding safety, nonclinical data show that Aloe vera has abortifacient activity when taken orally and induced skeletal malformations in an oral embryofetal toxicity study in rats. Clinical data indicate that the topical use of Aloe vera gel can be tolerated for short durations without serious toxicity, although it is unclear whether those data are based on 200:1 freeze dried Aloe vera. The anthraquinone derivative in Aloe vera latex can pose safety concerns, including potential carcinogenicity, particularly when used repeatedly at high doses. We found no data on the safety of the long-term use of Aloe vera.

Regarding effectiveness, there is limited and conflicting information from controlled clinical trials regarding the effectiveness of Aloe vera topical products in the treatment of cuts, burns, and wounds. It is not clear whether these trials used 200: 1 freeze dried Aloe vera. Historically, Aloe vera has been used in herbal remedies in many parts of the world. However, we do not have sufficient information to evaluate the historical use of compounded drug products that include 200:1 freeze dried Aloe vera.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of 200:1 freeze dried Aloe vera weigh against inclusion of this substance on the list. FDA recommended to the PCAC that this substance not be included on the 503A Bulks List (Ref. 21), and at its meeting on March 8, 2016, the PCAC voted not to include 200:1 freeze dried Aloe vera on the list (Ref. 6). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). This proposed rule proposes not to include Aloe vera 200:1 freeze dried on the 503A Bulks List.

(5) *Artemisinin.* Artemisinin was evaluated for use in the treatment of malaria, helminthic infections, protozoal (particularly toxoplasmosis) infections, stomach ulcers, and cancer. Artemisinin is well characterized physically and chemically. However, it has a short half-life and poor oral bioavailability due to excess first pass metabolism and is poorly soluble in water and oil. Regarding safety, artemisinin has clinically significant effects on different cytochrome P450 enzymes. It is possible that artemisinin acts as a perpetrator to change the exposure of other concomitantly administered drug products that are substrates of these cytochrome P450 isoforms in patients. These effects may lead to significant drug-drug interactions when artemisinin is used with other concomitant medications that are substrates of these cytochrome P450 isoforms on a daily basis. For use in the treatment of malaria, when dosing is limited to 1 or 2 days, we did not identify significant safety concerns associated with the use of artemisinin in compounded drug products. However, with repeat dosing (as would be used in the treatment of the other conditions evaluated), there is evidence of serious adverse events, the most concerning being drug-induced hepatitis. There are numerous reports in the literature of elevations of transaminases and bilirubin in patients taking repetitive doses of artemisinin leading to hospitalization.

Regarding effectiveness, there is evidence indicating that artemisinin is likely an effective therapy for the treatment of malaria. However, there are numerous FDA-approved drug products that have been demonstrated to be safe and effective under the conditions of use set forth in their labeling for the treatment of malaria. Additionally, because of concerns about resistance, artemisinin is not appropriate for use for prophylaxis of malaria when traveling to countries where malaria is endemic. For the other uses evaluated, there is insufficient information to evaluate the effectiveness of artemisinin. We found no information regarding the historical use of artemisinin in compounded drug products. It does not appear to be currently used in compounding in the United States.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of artemisinin weigh against inclusion of this substance on the 503A Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 22). At its meeting on May 9, 2017, the PCAC voted not to include artemisinin on the list (Ref. 9). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). The proposed rule would not place artemisinin on the 503A Bulks List.

(6) *Astragalus Extract 10:1.* Astragalus Extract 10:1 (astragalus) was evaluated for use in the treatment of diabetes

[4] A USP dietary supplement monograph exists for Aloe (USP 38–NF33, Aloe). However, no USP or NF monograph exist for Aloe vera *200:1 freeze-dried* or Aloe vera *gel 200:1 freeze-dried.* See Ref. 21 for additional information.

mellitus, allergic rhinitis, wound healing, asthma, and herpes simplex keratitis. It is not physically or chemically well characterized. Rather, it contains hundreds of known and unknown chemical entities, particularly polysaccharides, most of which would be difficult to characterize and quantify. Nonclinical data regarding the safety of astragalus are limited, and the significance of the available data is unknown given the variability between astragalus compounds. Based on limited clinical data, it appears that astragalus may be well-tolerated; however, the limited data are insufficient to allow evaluation of potential adverse outcomes associated with the use of astragalus.

Regarding effectiveness, there have been numerous investigations of astragalus extracts in the treatment of diabetes. Some of these studies indicate that some formulations of astragalus extracts reduced plasma glucose and insulin sensitivity. However, as noted above, the significance of the data from these studies is unknown given the variability between astragalus compounds. Studies in allergic rhinitis, wound healing, and asthma were inadequate to assess effectiveness, and no studies in herpes simplex keratitis were found that assessed clinically meaningful endpoints. Historically, astragalus has been used as an herbal treatment for a variety of conditions, but there is insufficient information to determine whether astragalus has been used in compounded drug products.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of astragalus weigh against inclusion of this substance on the 503A Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 19). At its meeting on November 20, 2017, the PCAC voted not to include astragalus on the list (Ref. 11). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). The proposed rule would not place astragalus on the 503A Bulks List.

(7) *BWSE.* BWSE was evaluated as treatment for rheumatoid arthritis (RA) and osteoarthritis (OA). BWSE is not physically or chemically well characterized. Rather, because it is a naturally derived, botanical substance, BWSE's physical and chemical characteristics can vary according to the source and extraction method and cannot adequately be controlled to ensure a consistent composition absent proper controls of the botanical raw materials and manufacturing processes. Regarding safety, there are reports that resin from *Boswellia* may be an emmenagogue and induce abortion. BWSE has also been associated with gastrointestinal adverse events, including diarrhea, abdominal pain, and nausea. There are reports of an increase in anticoagulant effect when BWSE interacts with oral anticoagulants.

There is some evidence that BWSE might improve symptoms of OA in some patients, but BWSE has not been shown to be effective in inhibiting radiographic progression of RA. There are numerous FDA-approved drug products that have been demonstrated to be safe and effective under the conditions of use set forth in their labeling for both RA and OA. Regarding its historical use, *Boswellia* has been used for millennia, particularly in Ayurvedic and traditional Chinese medicine, for a variety of uses, including wound care, pain, and arthritis, although we don't know how long it has been used in compounded drug products.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of BWSE weigh against inclusion of this substance on the list. FDA recommended to the PCAC that this substance not be included on the 503A Bulks List (Ref. 21), and at its meeting on March 8, 2016, the PCAC voted not to include BWSE on the list (Ref. 6). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). This proposed rule would not place BWSE on the 503A Bulks List.

(8) *Cesium Chloride.* Cesium chloride, an inorganic chloride salt, was evaluated for use in the treatment of cancer. It is well characterized physically and chemically. Both nonclinical and clinical studies give rise to significant safety concerns related to the use of cesium chloride in compounded drug products. Those concerns include links between cesium chloride use and hypokalemia, seizures, QT prolongation, and cardiac arrhythmias. There is no evidence that cesium chloride would be effective in the prevention or treatment of cancer. In contrast, there are numerous FDA-approved drug products that have been demonstrated to be safe and effective under the conditions of use set forth in their labeling for the treatment of cancer. We found no evidence regarding the historical use of cesium chloride in compounded drug products, although it appears to have been used for the treatment of cancer. Literature discussing studies of the substance date back to the 1980s

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of cesium chloride weigh against inclusion of this substance on the 503A Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 20). At its meeting on June 23, 2016, the PCAC voted not to include cesium chloride on the list (Ref. 7). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). The proposed rule would not place cesium chloride on the 503A Bulks List.

(9) *Chondroitin Sulfate.* Chondroitin sulfate was evaluated for use in the treatment of OA. Chondroitin sulfate is an unspecified mixture, composed mainly of chondroitin 4-sulfate and chondroitin 6-sulfate in varying percentages. The relative amounts of chondroitin sulfate A and chondroitin sulfate C in the mixture are not well defined and can vary.

The data available are inadequate to evaluate the safety of the use of chondroitin sulfate in compounded drug products, although there have been no significant safety signals associated with the use of topical chondroitin sulfate. While most adverse events reported in the literature with the use of chondroitin sulfate orally have not been serious in nature, there have been adverse event reports of concern, including reports of increased effectiveness of anticoagulants (leading to a risk of bleeding) when given in combination with chondroitin sulfate and reports of abnormal liver function. Regarding effectiveness, a large, well-controlled trial, the NIH-sponsored ''Glucosamine/chondroitin Arthritis Intervention Trial (GAIT)'' (Ref. 21), showed that, whether alone or in combination with glucosamine, the oral use of chondroitin sulfate appears to be ineffective for the treatment of pain associated with OA. Other trials reported positive results, including with the topical use of chondroitin sulfate, but those trials were generally smaller and of shorter duration, and suggest that, at best, any effect may be transient. As noted above, there are numerous FDA-approved drug products that have been demonstrated to be safe and effective under the conditions of use set forth in their labeling for the treatment of OA.

Regarding historical use, the use of chondroitin sulfate has been reported in medical literature dating back to the 1980s, but that discussion was not

specific to its use in compounded drug products. We found no information regarding how long chondroitin sulfate has been used in compounded drug products.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of chondroitin sulfate weigh against inclusion of this substance on the list. FDA recommended to the PCAC that this substance not be included on the 503A Bulks List (Ref. 21), and at its meeting on March 8, 2016, the PCAC voted not to include chondroitin sulfate on the list (Ref. 6). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). This proposed rule would not place chondroitin sulfate on the 503A Bulks List.

(10) *Chrysin.* Chrysin was evaluated for use as an aromatase inhibitor.[5] Chrysin is well characterized physically and chemically. Regarding safety, limited nonclinical studies show chrysin has the potential for mutagenicity and neurotoxicity. Clinically, systemic exposure to chrysin is low due to poor oral bioavailability and rapid metabolism and elimination. We found insufficient information about the topical or oral use of chrysin to evaluate its safety.

Regarding effectiveness, in vitro data shows that chrysin inhibits aromatase at high concentrations, but we found no clinical data indicating that chrysin would be effective in the treatment of cancer, which is the use for which FDA-approved aromatase inhibitors are indicated, specifically, for the treatment of breast cancer in women. There are also FDA-approved products indicated for testosterone replacement, another common use of compounded chrysin products. We found insufficient information to evaluate the historical use of chrysin in compounded drug products. It is currently being compounded for use in drug products promoted for bodybuilding and ''men's health.''

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of chrysin weigh against inclusion of this substance on the 503A Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 20). At its meeting on June 23, 2016, the PCAC voted not to include chrysin on the list (Ref. 7). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). The proposed rule would not place chrysin on the 503A Bulks List.

(11) *Curcumin.* Curcumin, a dye obtained from turmeric, was evaluated as treatment for familial adenomatous polyposis, gastric metaplasia, and oral leukoplakia. Although curcumin and its major components are well characterized physically and chemically, the term ''curcumin'' is used to refer to a wide range of substances comprised of different amounts of different curcuminoids, which might have different physical and chemical characteristics.

Curcumin appears to be mostly well tolerated for short durations, and the most common adverse events were mild. However, the evaluated conditions can be chronic, requiring treatment for years. There are limited data about the safety of curcumin in compounded drug products given its poor bioavailability, lack of exposure-response for safety, lack of uniformity of the curcumin used, and lack of information from well-designed clinical trials. Although preliminary signs of activity related to curcumin (generally related to biomarkers or effects on disease processes) have been reported in small and uncontrolled studies, there is insufficient evidence that it would be effective for the proposed conditions. Further, there is a risk that patients might use curcumin to treat the conditions reviewed in lieu of FDA-approved products that have been demonstrated to be safe and effective under the conditions of use set forth in their labeling, or that they might delay the use of such products. Familial adenomatous polyposis in particular is a serious condition; virtually all patients will develop colon cancer if it is left untreated. Turmeric has historically been used in traditional Indian medicine, but we found no information on the length of time curcumin has been used in compounded drug products. It has been used in an IV dosage form to treat eczema and thrombocytopenia (Ref. 23).

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of curcumin weigh against inclusion of this substance on the list. FDA recommended to the PCAC that this substance not be included on the 503A Bulks List (Ref. 17), and at its meeting on October 27, 2015, the PCAC voted not to include curcumin on the list (Ref. 2). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). This proposed rule would not place curcumin on the 503A Bulks List.

(12) *D-Ribose.* D-Ribose was evaluated as treatment for heart disease and chronic fatigue syndrome (CFS).[6] D-ribose is well characterized physically and chemically. It is commercially available for use as a food additive and has been designated as Generally Recognized as Safe (GRAS). However, a substance that is safe when used as a food might not be safe as an active ingredient in a drug product, for example, when used for a route of administration other than oral. In addition, a GRAS determination does not indicate that a substance would have any effectiveness for a proposed use when used in a compounded drug product. When used as a drug product D-ribose may cause a false hypoglycemia if the dose constitutes a substantial fraction of total daily caloric intake.[7] The use of D-ribose in compounded drug products poses a particular safety concern to patients with diabetes mellitus, since they often have concomitant coronary artery disease or ischemic cardiac myopathy/ischemic heart failure. Hypoglycemia, detected with glucose monitoring, could complicate the titration of insulin in patients with diabetes, particularly when high pharmacologic doses of D-ribose and insulin are administered close in time.

Regarding effectiveness, there is a lack of proven benefit associated with D-ribose for the treatment of either heart disease or CFS. The reported studies of the utility of D-ribose for the treatment of cardiovascular disease provide no convincing evidence of a meaningful clinical benefit. There are many FDA-approved drug products that have been demonstrated to be safe and effective under the conditions of use set forth in their labeling for the treatment of heart disease, which is a serious condition. While we recognize that there are no FDA-approved therapies indicated for CFS, the treatment of CFS with D-ribose has been evaluated in only a single

[5] Chrysin was proposed for use ''as an aromatase inhibitor which prevents the conversion of testosterone to estrogen'' for the treatment of ''high estrogen and low testosterone.'' (Ref. 20).

[6] Currently, FDA does not recognize a particular definition or name as appropriate for use in clinical trials of drug products for CFS, which is also referred to as myalgic encephalomyelitis or systemic exertion intolerance disease. CFS is used in this NPRM because it was the term used in the nomination for D-ribose.

[7] Food products that contain D-ribose as a food additive at ≥1 percent per volume or weight also contain other sources of carbohydrates (and thus glucose), and thus might not pose the same risk of false hypoglycemia.

small uncontrolled, unblinded study (Ref. 24). We do not believe that this study demonstrates that there is a benefit to CFS patients that would outweigh the risks of using D-ribose outlined above.

Regarding the historical use of D-ribose, we do not know how long it has been used as a compounded drug product. It first appeared in the medical literature in 1946.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of D-ribose weigh against inclusion of this substance on the list. FDA recommended to the PCAC that this substance not be included on the 503A Bulks List (Ref. 21), and at its meeting on March 8, 2016, the PCAC voted not to include D-ribose on the list (Ref. 6). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). This proposed rule would not place D-ribose on the 503A Bulks List.

(13) *Deoxy-D-Glucose.* Deoxy-D-glucose, also known as 2-deoxy-D-glucose, was evaluated for use in the treatment of cancer and herpes simplex virus (HSV). Deoxy-D-glucose is physically and chemically well characterized. Regarding safety, in rats, dietary supplementation with deoxy-D-glucose showed cardiac toxicity, developmental and reproductive toxicity, carcinogenicity, and decreased median survival. In humans, the safety profile of deoxy-D-glucose was only manageable at lower doses used with combination treatments; when used as a single agent, based on limited clinical evidence, the high dose of deoxy-D-glucose required was unacceptably toxic.

Regarding effectiveness, we found no evidence indicating that deoxy-D-glucose would be effective as a treatment for cancer or HSV. In the reported clinical trials that studied the use of deoxy-D-glucose for the treatment of cancer, toxicity was reached before there was evidence of effectiveness. We located only one clinical trial that studied deoxy-D-glucose in the treatment of HSV, from which no conclusions regarding efficacy could be drawn due to the quality of the study. Each of these serious conditions has a number of FDA-approved drug products that have been demonstrated to be safe and effective under the conditions of use set forth in their labeling. We found insufficient evidence to evaluate the historical use of deoxy-D-glucose in compounded drug products.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of deoxy-D-glucose weigh against inclusion of this substance on the list. FDA recommended to the PCAC that this substance not be included on the 503A Bulks List (Ref. 17), and at its meeting on October 27, 2015, the PCAC voted not to include deoxy-D-glucose on the list (Ref. 2). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). This proposed rule would not place deoxy-D-glucose on the 503A Bulks List.

(14) *Diindolylmethane.* Diindolylmethane was evaluated for use in the treatment of cancer. It is well characterized physically and chemically. Oral administration of diindolylmethane caused white pulp atrophy and decreased immune cell counts in the spleen of neonatal mice and increased serum cytokines in adult mice. Diindolylmethane induced hepatic CYP1A1, CYP1A2, and CYP3A2 in rats, suggesting that drug-drug interactions might occur with its use in patients. While the nonclinical data are limited, the available data suggest that there may be a safety concern with the use of diindolylmethane in compounded drug products. Although we identified no serious adverse events reports related to the use of diindolylmethane in humans, the available clinical data are too limited to draw conclusions regarding the safety of diindolylmethane.

Clinical studies published to date show changes in biomarkers, but no clinical publication to date describes an effect of diindolylmethane on any endpoint generally accepted in clinical oncology as being of clinical benefit. There is no evidence that diindolylmethane would be effective in the treatment of cancer. In contrast, there are numerous FDA-approved drug products that have been demonstrated to be safe and effective under the conditions of use set forth in their labeling for the treatment of cancer. We found no evidence regarding the historical use of diindolylmethane in compounded drug products.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of diindolylmethane weigh against inclusion of this substance on the 503A Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 18). At its meeting on November 3, 2016, the PCAC voted not to include diindolylmethane on the list (Ref. 8). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). The proposed rule would not place diindolylmethane on the 503A Bulks List.

(15) *Domperidone.* Domperidone was evaluated as treatment for gastroparesis, nausea and vomiting, and to enhance lactation. Domperidone is well characterized physically and chemically. Serious concerns about the safety of domperidone are raised by both clinical and nonclinical studies. At therapeutic doses approved outside the United States, domperidone carries a serious risk of life-threatening cardiac arrhythmias and sudden cardiac death in all populations, including healthy lactating women, and potentially, their infants. Domperidone has known risks of QT interval prolongation, and the dose and exposure at which domperidone can cause serious cardiac arrhythmias are not well characterized in patients.

The effectiveness of domperidone as a galactagogue is unknown given the limited evidence available, and evidence suggesting that domperidone may be beneficial for nausea and vomiting and gastroparesis is limited due to the small size of the clinical trials that have been conducted for these uses or design flaws with those trials. Domperidone has been compounded in the United States for at least a decade and has been used in other jurisdictions since at least the 1970s.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of domperidone weigh against inclusion of this substance on the list. FDA recommended to the PCAC that this substance not be included on the 503A Bulks List (Ref. 17), and at its meeting on October 28, 2015, the PCAC voted not to include domperidone on the list (Ref. 4). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 16). This proposed rule would not place domperidone on the 503A Bulks List.

(16) *EGCG.* EGCG, or (-)-epigallocatechin-3-gallate, was evaluated for use in the treatment of obesity, type 1 and type 2 diabetes, cardiac hypertrophy, corneal neovascularization, non-alcoholic fatty liver disease, Parkinson's disease, and wound healing. EGCG is the most abundant type of catechin in green tea. It is well characterized physically and chemically, but degrades significantly within 1 month. It was nominated for

use in capsules, topical gels, and ophthalmic solutions, but it is not expected to be stable in formulations other than solid oral dosage forms. Regarding safety, in several nonclinical models, liver and gastrointestinal toxicities were noted. In humans, there are numerous case reports of hepatotoxicity, including fulminant hepatic failure, the need for liver transplantation, or death associated with products that contain EGCG, which is typically administered as one component of a multicomponent dietary supplement/botanical product. Establishing whether EGCG has a causal link with these existing cases is not feasible, and additional data are needed to evaluate the safety of the use of EGCG in compounded drug products. A review by Health Canada published in December 2017 concluded that there may be a link between the use of green tea extract and a risk of rare and unpredictable liver injury (Ref. 25).

Regarding effectiveness, there are hypotheses regarding the potential therapeutic utility of EGCG, as well as nonclinical and clinical pharmacologic data identifying potential mechanisms of action in various disease states. However, clinical data for EGCG have not been identified to support the effectiveness of EGCG for any of the uses evaluated. We found insufficient information to determine how long EGCG has been used in compounded drug products.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of EGCG weigh against inclusion of this substance on the 503A Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 19). At its meeting on November 20, 2017, the PCAC voted not to include EGCG on the list (Ref. 11). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). The proposed rule would not place EGCG on the 503A Bulks List.

(17) *Germanium Sesquioxide.* Germanium sesquioxide was evaluated as treatment for cancer. It is physically and chemically well characterized. It can, however, include impurities with significant toxicities, specifically, potentially dangerous levels of inorganic germanium salts (*e.g.,* GeO2, germanium lactate citrate, Ge-lac-cit), which can accumulate in the body. The limited information available about the safety of germanium sesquioxide gives rise to significant concerns about its use in compounded drug products, particularly given the risk of contamination with highly toxic inorganic forms of germanium salts. The nephrotoxicity of inorganic forms of germanium, such as germanium dioxide or germanium citrate lactate, is well established, and prolonged use of germanium products has been associated with cases of renal failure and death. There is currently a restriction on the importation of all germanium compounds, except those used for semiconductors (Ref. 26).

There are very little clinical data regarding the effectiveness of germanium sesquioxide in the treatment of cancer. We located only a single case report, from which no conclusions regarding the effectiveness of germanium sesquioxide could be drawn. In contrast, there are numerous FDA-approved drug products that have been demonstrated to be safe and effective under the conditions of use set forth in their labeling for the treatment of various types of cancer. We found little information regarding the history of the use of germanium sesquioxide in compounded drug products and could not determine whether or how long it has been used in compounded drug products.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of germanium sesquioxide weigh against inclusion of this substance on the list. FDA recommended to the PCAC that this substance not be included on the 503A Bulks List (Ref. 17), and at its meeting on October 27, 2015, the PCAC voted not to include germanium sesquioxide on the list (Ref. 2). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). This proposed rule would not place germanium sesquioxide on the 503A Bulks List.

(18) *Glycyrrhizin.* Glycyrrhizin, also known as glycyrrhizic acid or glycyrihizinic acid, is a triterpene saponin extracted from licorice. It was evaluated for use in the treatment of hepatitis C by intravenous administration. Although glycyrrhizin's molecular structure can be characterized, the term ''glycyrrhizin'' is used to refer to a variety of licorice extracts, which are often complex mixtures that are not well characterized physically or chemically. Glycyrrhizin also poses safety concerns. The association between glycyrrhizin use and serious pseudo-hyperaldosterone effects is well established and has been noted in over 100 case reports. Regarding effectiveness, clinical studies of IV administration of glycyrrhizin in patients with chronic hepatitis C have shown no demonstrable antiviral effect.

Regarding its historical use, *Glycyrrhiza* (licorice) has been used for curative and flavoring purposes for 4,000 years, and glycyrrhizin has been used to treat chronic hepatitis in Japan for over 30 years. However, we found no evidence of the use of glycyrrhizin in IV compounded drugs products in the United States.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of glycyrrhizin weigh against inclusion of this substance on the list. FDA recommended to the PCAC that this substance not be included on the 503A Bulks List (Ref. 17), and at its meeting on October 28, 2015, the PCAC voted not to include glycyrrhizin on the list (Ref. 3). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). This proposed rule would not place glycyrrhizin on the 503A Bulks List.

(19) *Kojic Acid.* Kojic acid was evaluated for use in the treatment of melasma and as an iron chelator in wound healing and photodamage prevention. Kojic acid is well characterized physically and chemically, but it is a very reactive and unstable compound. Nonclinical data suggest that kojic acid is potentially genotoxic, and data about its carcinogenicity are equivocal. Data suggest that the use of kojic acid may be associated with local irritancy, but reported adverse reactions appear to have been transient and manageable. There have been no reports of systemic adverse reactions. We identified no major safety concerns related to the use of kojic acid to treat melasma, but we found no data evaluating the safety of the use of kojic acid in open wounds or the prevention of photodamage.

Regarding effectiveness, there is insufficient evidence to show that kojic acid would be an effective treatment for any of the evaluated uses. Most trials evaluating the use of kojic acid for melasma or hyperpigmentation disorders used kojic acid in combination with other topical therapies, and often flaws in trial design prevented the data from being sufficiently reliable. Historically, kojic acid has been used in compounded drug products for decades, often in combination with other substances.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of kojic acid weigh against inclusion of this substance on the 503A

Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 18). At its meeting on November 3, 2016, the PCAC voted not to include kojic acid on the list (Ref. 8). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). The proposed rule would not place kojic acid on the 503A Bulks List.

(20) *Nettle.* Nettle (*Urtica dioica L.*), a botanical substance, was evaluated for use in glycemic control. Nettle is not physically or chemically well characterized. The major and/or active components of nettle are unknown. There is a dearth of reliable information regarding the safety of the use of nettle in compounded drug products. The most frequent adverse effects appear to be mild gastrointestinal irritation and allergic reactions; however, the available information is based on formulations with poorly characterized compositions. It is unclear how the formulations employed in the existing literature might compare qualitatively or quantitatively to a bulk drug substance used in compounded drug products.

The effectiveness of nettle has not been adequately assessed with well-characterized formulations. A small number of clinical effectiveness investigations of nettle and some nonclinical data in animal models for diabetes suggest that nettle may have some effect in reducing fasting blood sugar and other parameters related to diabetes. However, they do not provide sufficient evidence that nettle would be effective in providing glycemic control. Historically, nettle has been used for centuries as an herbal treatment for a variety of conditions. It has been used in compounded drug products for at least 7 years.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of nettle weigh against inclusion of this substance on the 503A Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 22). At its meeting on May 8, 2017, the PCAC voted not to include nettle on the list (Ref. 9). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). The proposed rule would not place nettle on the 503A Bulks List.

(21) *NAD.* NAD was evaluated for use in the treatment of fatigue in patients with multiple sclerosis (MS). It is well characterized physically and chemically, but it degrades substantially when exposed to light, moisture, alkaline pH, or standard room temperatures and would not be stable under ordinary storage conditions absent multiple compensatory measures. Nonclinical data found in the literature are inadequate to characterize the potential toxicity profile for NAD, particularly for use in a chronic disease such as MS. Similarly, we did not find sufficient clinical data about NAD to evaluate whether it is safe for use in compounded drug products.

We identified no published studies that support the use of NAD for the treatment of fatigue in patients with multiple sclerosis. Therefore, we have insufficient information on which to evaluate the effectiveness for NAD for its proposed use. There are FDA-approved drug products that have been demonstrated to be safe and effective under the conditions of use set forth in their labeling for the treatment of MS. We do not have enough information to determine how long NAD has been used in compounded drug products.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of NAD weigh against inclusion of this substance on the 503A Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 22). At its meeting on May 8, 2017, the PCAC voted not to include NAD on the list (Ref. 9). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). The proposed rule would not place NAD on the 503A Bulks List.

(22) *NADH.* NADH was evaluated for use in the treatment of CFS.[8] It is well characterized physically and chemically, but degrades substantially when exposed to light, moisture, alkaline pH, or standard room temperatures and would not be stable under ordinary storage conditions absent multiple compensatory measures. We found no reports of serious adverse events; however, the clinical safety data available for review were minimal. Nonclinical data reported in the literature suggest that NADH is not stable in an acid medium and is likely to be degraded before absorption after oral dosing. Nonclinical safety data are insufficient to characterize the potential toxicity profile for NADH, particularly for use in a chronic disease such as CFS.

Regarding effectiveness, there is insufficient information to indicate that NADH would be effective for the evaluated use. The available clinical effectiveness data regarding administration of NADH to patients with CFS failed to provide an assessment of fatigue specifically, and it also failed to show statistically significant improvement on assessment scales of multiple other symptoms. We do not have enough information to determine how long NAD has been used in compounded drug products.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of NADH weigh against inclusion of this substance on the 503A Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 22). At its meeting on May 8, 2017, the PCAC voted not to include NADH on the list (Ref. 9). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). The proposed rule would not place NADH on the 503A Bulks List.

(23) *Rubidium Chloride.* Rubidium chloride, also known as rubidium monochloride or rubinorm, was evaluated for use in the treatment of cancer. Rubidium chloride is physically and chemically well characterized. We found insufficient information to determine whether the use of rubidium chloride in compounded drug products would be safe or effective. Non-clinical studies showed that the administration of rubidium in rats affected their growth, survival times, and behavior. Rubidium chloride in the treatment of cancer appears to have only been studied in clinical trials by one individual in the 1960s and 1970s, but the role of rubidium in the results of those studies is uncertain since data were reported in the aggregate. Since that time, there have been no documented studies of the safety or effectiveness of rubidium chloride in the treatment of cancer. In contrast, there are numerous FDA-approved drug products that have been demonstrated to be safe and effective under the conditions of use set forth in their labeling in the treatment of various types of cancer. Although rubidium chloride was first discussed in medical literature in the 1960s, we did not find information regarding the history of use of rubidium chloride in compounded drug products.

[8] See footnote 5, above, regarding use of the term ''CFS.''

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of rubidium chloride weigh against inclusion of this substance on the list. FDA recommended to the PCAC that this substance not be included on the 503A Bulks List (Ref. 17), and at its meeting on October 27, 2015, the PCAC voted not to include rubidium chloride on the list (Ref. 2). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). This proposed rule would not place rubidium chloride on the 503A Bulks List.

(24) *Sodium Dichloroacetate.* Sodium dichloroacetate, also known as dichloroacetate sodium, was evaluated for use in the treatment of cancer. It is well characterized physically and chemically, but unlikely to be stable when formulated as a solution for injection. There are significant safety concerns related to the use of sodium dichloroacetate in compounded drug products, primarily related to its toxicity profile, as observed in both nonclinical and clinical studies. One study of sodium dichloroacetate identified in the literature was closed due to patient deaths and safety concerns (Ref. 27). There is no evidence that sodium dichloroacetate would be effective in the prevention or treatment of cancer. In contrast, there are numerous FDA-approved drug products that have been demonstrated to be safe and effective under the conditions of use set forth in their labeling for the treatment of cancer. We found no evidence regarding the historical use of sodium dichloroacetate in compounded drug products.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of sodium dichloroacetate weigh against inclusion of this substance on the 503A Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 20). At its meeting on June 23, 2016, the PCAC voted not to include sodium dichloroacetate on the list (Ref. 7). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 14). The proposed rule would not place sodium dichloroacetate on the 503A Bulks List.

(25) *Vanadyl Sulfate.* Vanadyl sulfate was evaluated for use in the treatment of diabetes, hyperlipidemia, and heart disease, and for the prevention of cancer. Vanadyl sulfate, an inorganic vanadium salt, is well characterized physically and chemically. Regarding the safety of vanadyl sulfate in compounded drug products, nonclinical safety data, including toxicokinetic data, chronic toxicity data, reproductive data, and carcinogenicity data, found in the literature suggest the potential for a high toxicity profile. Administration by injection, the proposed dosage form, appears to be associated with greater toxicity than the oral route of administration. Human safety data are limited and do not reveal the same types or degrees of toxicity that are shown in nonclinical testing. The differences between nonclinical and clinical safety findings may be explained by shortcomings in the available clinical data and limited duration of treatment.

Regarding effectiveness, limited clinical effectiveness data provide preliminary evidence that vanadyl sulfate or other vanadium containing compounds could have an effect in treating diabetes or hyperlipidemia. We identified no clinical effectiveness data for the treatment of cancer or heart disease with vanadyl sulfate. There is insufficient evidence to indicate that vanadyl sulfate has any effectiveness in treating any of the evaluated conditions. Cancer and heart disease are serious conditions for which there are FDA approved drugs that have been found to be safe and effective under the conditions of use set forth in their labeling. We do not have enough information to determine how long vanadyl sulfate has been used in compounded drug products.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of vanadyl sulfate weigh against inclusion of this substance on the 503A Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 22). At its meeting on May 8, 2017, the PCAC voted not to include vanadyl sulfate on the list (Ref. 9). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). The proposed rule would not place vanadyl sulfate on the 503A Bulks List.

(26) *VIP.* VIP, a 28-amino acid peptide, was evaluated for use in the treatment of a condition described as ''chronic inflammatory response syndrome'' (CIRS).[9] VIP is well characterized physically and chemically, but absent sufficient controls on its production, synthesis is likely to result in peptides of different lengths or different amino acid sequencing. Although most adverse reactions observed related to the use of VIP appear to be relatively mild, it has been associated with severe immunologic reactions. Regarding effectiveness, we located only one published study of VIP in a condition that appears to be related to CIRS (Ref. 28), which failed to clearly establish benefits of the administration of VIP. We did not find sufficient information to determine the historical use of VIP in compounded drug products. However, it appears that VIP is currently used in compounded nasal sprays.

On balance, the physiochemical characteristics, safety, effectiveness, and historical use of VIP weigh against inclusion of this substance on the 503A Bulks List. FDA proposed to the PCAC that this substance not be included on the 503A Bulks List (Ref. 18). At its meeting on November 3, 2016, the PCAC voted not to include VIP on the list (Ref. 8). We have also consulted with USP regarding placement of this substance on the 503A Bulks List, and USP did not identify any additional quality concerns related to this substance (Ref. 15). The proposed rule would not place VIP on the 503A Bulks List.

VI. Proposed Effective Date

The Agency proposes that any final rule based on this proposed rule will become effective 30 days after the date of publication of the final rule in the **Federal Register**.

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset

[9] CIRS is a term we located in three publications. It appears to be the subject of research. It is not listed in the International Statistical Classification of Diseases and Related Health Problems (ICD–10), a medical classification list by the World Health Organization (Ref. 18). Further, CIRS is not listed in the Medical Dictionary for Regulatory Activities (MedDRA) (id.).

by the elimination of existing costs associated with at least two prior regulations.'' We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we do not have enough information about the effect of the proposed rule on small entities, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

We evaluated 31 bulk drug substances for this proposed rule. We propose to place 5 bulk drug substances on the 503A Bulks List, and we propose not to place 26 substances on the 503A Bulks List. We expect that the rule will affect compounding pharmacies and other producers that market the affected substances or drug products made from the affected substances, consumers of drug products containing the affected substances, and payers that cover these drug products or alternative treatments. Because we lack sufficient information to quantify most of the costs and benefits of this proposed rule, we also include a qualitative description of potential benefits and potential costs.

In table 1, we summarize the impacts of the proposed rule. The estimated costs are derived from administrative costs related to reading the rule. The primary estimate of the present value of the costs over 10 years is $1.03 million. The primary estimate of the annualized costs is $0.15 million at a 7 percent discount rate and $0.12 million at a 3 percent discount rate.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate	Period covered	
Benefits:							
Annualized Monetized ($m/year).							
Annualized Quantified.							
Qualitative	Potential gains or losses in consumer surplus, depending on consumer preferences for compounded drugs. Potential public health benefits from increased use of other drug products that may be more effective.						
Costs:							
Annualized Monetized ($m/year)	$0.15 $0.12	$0.10 $0.08	$0.20 $0.16	2017 2017	7% 3%	10 years. 10 years.	
Annualized Quantified.							
Qualitative	Costs to submit investigational new drug applications (INDs) for some compounded drug products.						
Transfers:							
Federal Annualized Monetized ($m/year).							
	From:			To:			
Other Annualized Monetized ($m/year).							
	From:			To:			
Effects:	State, Local, or Tribal Government: None. Small Business: None. Wages: None. Growth: None.						

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 29) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we

conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. *FDA, Transcript of the October 27, 2015, Meeting of the Pharmacy Compounding Advisory Committee (Morning Session), 2015. Available at *https://wayback.archive-it.org/7993/20170404155219/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM484905.pdf.*
2. *FDA, Transcript of the October 27, 2015, Meeting of the Pharmacy Compounding Advisory Committee (Afternoon Session), 2015. Available at *https://wayback.archive-it.org/7993/20170404155220/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM484906.pdf.*
3. *FDA, Transcript of the October 28, 2015, Meeting of the Pharmacy Compounding Advisory Committee (Morning Session), 2015. Available at *https://wayback.archive-it.org/7993/20170404155221/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM484907.pdf.*
4. *FDA, Transcript of the October 28, 2015, Meeting of the Pharmacy Compounding Advisory Committee (Afternoon Session), 2015. Available at *https://wayback.archive-it.org/7993/20170404155222/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM484908.pdf.*
5. *FDA, Transcript of the March 8, 2016, Meeting of the Pharmacy Compounding Advisory Committee (Morning Session), 2016. Available at *https://wayback.archive-it.org/7993/20170403224125/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM507771.pdf.*
6. *FDA, Transcript of the March 8, 2016, Meeting of the Pharmacy Compounding Advisory Committee (Afternoon Session), 2016. Available at *https://wayback.archive-it.org/7993/20170404155209/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM507772.pdf.*
7. *FDA, Transcript of the June 23, 2016, Meeting of the Pharmacy Compounding Advisory Committee (Morning Session), 2016. Available at *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM563843.pdf.*
8. *FDA, Transcript of the November 3, 2016, Meeting of the Pharmacy Compounding Advisory Committee (Morning Session), 2016. Available at *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM563842.pdf.*
9. *FDA, Transcript of the May 8–9, 2017, Meeting of the Pharmacy Compounding Advisory Committee, 2017. Available at *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM565933.pdf.*
10. *FDA, Transcript of the November 20, 2017, Meeting of the Pharmacy Compounding Advisory Committee (Morning Session), 2017. Available at *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM604328.pdf.*
11. *FDA, Transcript of the November 20, 2017, Meeting of the Pharmacy Compounding Advisory Committee (Afternoon Session), 2017. Available at *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM604329.pdf.*
12. *Memorandum to File on FDA Consultations with United States Pharmacopeia, September 26, 2016.
13. *Letter from the United States Pharmacopeia to FDA, October 7, 2016.
14. *Letter I from the United States Pharmacopeia to FDA, August 17, 2018.
15. *Letter II from the United States Pharmacopeia to FDA, August 17, 2018.
16. *Letter III from the United States Pharmacopeia to FDA, August 17, 2018.
17. *FDA Briefing Document for the October 27–28, 2015, Meeting of the Pharmacy Compounding Advisory Committee, 2015. Available at *https://wayback.archive-it.org/7993/20170405230355/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM466380.pdf.*
18. *FDA Briefing Document for the November 3, 2016, Meeting of the Pharmacy Compounding Advisory Committee, 2016. Available at *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM524613.pdf.*
19. *FDA Briefing Document for the November 20, 2017, Meeting of the Pharmacy Compounding Advisory Committee, 2017. Available at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/ucm582868.htm.*
20. *FDA Briefing Document for the June 23, 2016, Meeting of the Pharmacy Compounding Advisory Committee, 2016. Available at *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM505041.pdf.*
21. *FDA Briefing Document for the March 8–9, 2016, Meeting of the Pharmacy Compounding Advisory Committee, 2016. Available at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/ucm486144.htm.*
22. *FDA Briefing Document for the May 8–9, 2017, Meeting of the Pharmacy Compounding Advisory Committee, 2017. Available at *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM553368.pdf.*
23. *FDA, August 4, 2017, Statement, ''FDA investigates two serious adverse events associated with ImprimisRx's compounded curcumin emulsion product for injection.'' Available at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm570192.htm.*
24. Teitelbaum, J.E., et al. ''The Use of D-Ribose in Chronic Fatigue Syndrome and Fibromyalgia: A Pilot Study,'' *Journal of Alternative and Complementary Medicine,* 12:857–862, 2006.
25. *Government of Canada, ''Summary Safety Review-Green Tea Extract-

Containing Natural Health Products-Assessing the Potential Risk of Liver Injury (Hepatotoxicity),'' December 12, 2017. Available at *https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/green-tea-extract-containing-natural-health-products-assessing-potential-risk-liver-injury.html.*

26. *FDA Import Alert 54–07. Available at *https://www.accessdata.fda.gov/cms_ia/importalert_139.html.*
27. Garon, E.B., et al. ''Dichloroacetate Should be Considered with Platinum-based Chemotherapy in Hypoxic Tumors Rather Than as a Single Agent in Advanced Non-small Cell Lung Cancer,'' *Journal of Cancer Research and Clinical Oncology,* 140:443, 2014.
28. Shoemaker, R.C., et al. ''Vasoactive Intestinal Polypeptide (VIP) Corrects Chronic Inflammatory Response Syndrome (CIRS) Acquired Following Exposure to Water-Damaged Buildings,'' *Health,* 5:396–401, 2013. Available at *https://www.scirp.org/journal/health/.* (Open Access)
29. *Amendments to the List of Bulk Drug Substances that Can be Used to Compound Drug Products in Accordance with Section 503A of the Federal Food, Drug, and Cosmetic Act, Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, 2018. Available at *https://www.fda.gov/AboutFDA/Reports ManualsForms/Reports/Economic Analyses/default.htm.*

List of Subjects in 21 CFR Part 216

Drugs, Prescription drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 216 be amended as follows:

PART 216—HUMAN DRUG COMPOUNDING

■ 1. The authority citation for part 216 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353a, 353b, 355, and 371.

■ 2. In § 216.23, revise paragraphs (a) and (b) to read as follows:

§ 216.23 Bulk drug substances that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act.

(a) The following bulk drug substances, which are neither the subject of a current applicable United States Pharmacopeia or National Formulary monograph nor components of FDA-approved drugs, can be used in compounding under section 503A(b)(1)(A)(i)(III) of the Federal Food, Drug, and Cosmetic Act.

(1) Brilliant Blue G, also known as Coomassie Brilliant Blue G–250.

(2) Cantharidin (for topical use only).

(3) Diphenylcyclopropenone (for topical use only).

(4) Glutaraldehyde (for topical use only, in concentrations of 10 percent or lower).

(5) Glycolic acid (for topical use only, in concentrations of 70 percent or lower).

(6) L-citrulline (for oral administration only).

(7) N-acetyl-D-glucosamine (for topical use only).

(8) Pyruvic acid (for topical use only).

(9) Squaric acid dibutyl ester (for topical use only).

(10) Thymol iodide (for topical use only).

(11) Trichloroacetic acid (for topical use only).

(b) The following bulk drug substances have been nominated and evaluated for inclusion on the list of substance that can be used in compounding set forth in paragraph (a) of this section, and FDA has determined that they do not meet the criteria for inclusion set forth in paragraph (c) of this section:

(1) 7-keto dehydroepiandrosterone (DHEA).

(2) Acetyl L Carnitine.

(3) Alanyl L Glutamine.

(4) Aloe Vera 200:1 Freeze Dried.

(5) Artemisinin.

(6) Astragalus extract 10:1.

(7) *Boswellia.*

(8) Cesium Chloride.

(9) Chondroitin Sulfate.

(10) Chrysin.

(11) Curcumin.

(12) D-Ribose.

(13) Deoxy-D-Glucose.

(14) Diindolylmethane.

(15) Domperidone.

(16) Epigallocatechin gallate (EGCG).

(17) Germanium Sesquioxide.

(18) Glycyrrhizin.

(19) Kojic acid.

(20) Nettle.

(21) Nicotinamide adenine dinucleotide (NAD).

(22) Nicotinamide adenine dinucleotide disodium reduced (NADH).

(23) Oxitriptan.

(24) Piracetam.

(25) Rubidium Chloride.

(26) Silver Protein Mild.

(27) Sodium dichloroacetate.

(28) Tranilast.

(29) Vanadyl sulfate.

(30) Vasoactive intestinal peptide.

* * * * *

Dated: July 16, 2019.

Norman E. Sharpless,

Acting Commissioner of Food and Drugs.

Dated: August 13, 2019.

Eric D. Hargan,

Deputy Secretary, Department of Health and Human Services.

[FR Doc. 2019–18951 Filed 9–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

[OH–262–FOR; Docket ID: OSM–2019–0006 S1D1S SS08011000 SX064A000 190S180110; S2D2S SS08011000 SX064A000 19XS501520]

Ohio Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Ohio regulatory program, hereinafter the Ohio program, under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Ohio seeks to amend its program by revising a definition involving the transfer, assignment, or sale of permit rights. This document gives the times and locations that the Ohio program and this proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments, on the amendment and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this request until 4:00 p.m., Eastern Standard Time (e.s.t.), October 7, 2019. If requested, we will hold a public hearing on the request on September 30, 2019. We will accept requests to speak at a hearing until 4:00 p.m., e.s.t. on September 20, 2019.

ADDRESSES: You may submit comments, identified by SATS No. OH–262–FOR, Docket ID: OSM–2019–0006, by any of the following methods:

- *Mail/Hand Delivery:* Mr. Ben Owens, Chief, Pittsburgh Field Division Office of Surface Mining Reclamation and Enforcement 3 Parkway Center, Pittsburgh, Pa 15220.

• *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Ohio program, this request, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the request by contacting OSMRE's Pittsburgh Field Division or the full text of the request is available for you to read at *www.regulations.gov*.

Mr. Ben Owens, Chief, Pittsburgh Field Division, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937–2827, Email: *bowens@osmre.gov*.

In addition, you may review a copy of the request during regular business hours at the following location:

Mr. Larry E. Erdos, Chief, Division of Mineral Resources Management, Ohio Department of Natural Resources, 2045 Morse Rd., Building H–2, Columbus, OH 43229–6693, Telephone: (614) 265–6633, Email: *lanny.erdos@dnr.state.oh.us*.

FOR FURTHER INFORMATION CONTACT: Mr. Ben Owens, Chief, Pittsburgh Field Division, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937–2827, *Email: bowens@osmre.gov*.

SUPPLEMENTARY INFORMATION:

I. Background on the Ohio Program
II. Description of the Request
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the Ohio Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Ohio program on August 16, 1982. You can find additional background information on the Ohio program, including the Secretary's findings, the disposition of comments, and conditions of approval in the August 10, 1982, **Federal Register**, 47 FR 34688. You can also find later actions concerning Ohio's program and program amendments at 30 CFR 935.11 and 935.15.

II. Description of the Request

By letter dated April 11, 2019, Ohio sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*) that involves the regulatory definition of ''transfer, assignment, or sale of permit rights'' related to coal mining operations (Administrative Record No. OH–2198). Ohio seeks to add regulatory language at Chapter 1501:13–1–02, *Definitions,* section (VVVVVV) of the Ohio Administrative Code, which currently defines the term as ''a change of a permittee, including, but not limited to, any fundamental legal change in the structure or nature of a permittee, or a name change.'' With this amendment, Ohio seeks to expand the definition to include a change in the ownership and operational control of a permittee to a person who has not held a permit issued under Chapter 1513, *Coal Surface Mining,* of the Ohio Revised Code (ORC) for a period of not less than five years where the existence and name of the permittee remain the same. Ohio states that this change is intended to prevent a person who is not eligible to participate in the bond pool under section 1513.08(C)(2) of the ORC from gaining access to the bond pool through a change of ownership and operational control that does not change the existence and name of the permittee. Ohio states that requiring such a person to apply for a transfer, assignment, or sale of permit rights will assure that all performance security requirements are met.

The full text of the amendment is available for you to read at the locations listed above under **ADDRESSES** or at *www.regulations.gov*.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether this amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the State program.

Electronic or Written Comments

If you submit written or electronic comments on the request during the 30-day comment period, they should be specific, confined to issues pertinent to the request, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence our decision will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., e.s.t. on September 20, 2019. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak, and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB) will review all significant rules. Pursuant to OMB guidance, dated October 12, 1993, the approval of State program amendments is exempted from OMB review under Executive Order 12866. Executive Order 13563, which reaffirms and supplements Executive Order 12866, retains this exemption.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSMRE for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment. We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: June 4, 2019.

Thomas D. Shope,

Regional Director, Appalachian Region.

[FR Doc. 2019–19163 Filed 9–4–19; 8:45 am]

BILLING CODE 4310–05–P

Notices

Federal Register

Vol. 84, No. 172

Thursday, September 5, 2019

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Nez Perce—Clearwater National Forests; Idaho; Forest Plan Revision for the Nez Perce-Clearwater National Forests

AGENCY: Forest Service, USDA.

ACTION: Revised notice of intent to prepare an environmental impact statement.

SUMMARY: The USDA Forest Service published a notice of intent (NOI) to prepare an environmental impact statement (EIS) in the **Federal Register** on July 15, 2014. The NOI served as the scoping document for the Forest Plan Revision for the Nez Perce—Clearwater National Forests, and solicited comments have been used in the preparation of a proposed Nez Perce—Clearwater National Forests Land Management Plan (Forest Plan) and draft EIS. Due to ongoing work on this planning effort since 2014, the Nez Perce-Clearwater National Forests (Forest) is updating the information in the original NOI. These updates identify new addresses and contact information, update where information on the project can be found, update the responsible official, and update the nature of the decision to be made.

DATES: Comments concerning the updated information in this notice will be most useful in the continued development of the proposed Forest Plan and draft EIS if received by October 7, 2019. The draft EIS is expected by late fall 2019 and a final EIS is expected by winter 2020/2021.

ADDRESSES: Comments concerning the updated information in this notice may be sent via email to: *fpr_npclw@fs.fed.us.* Written comments may also be sent via mail or hand-delivered to: Nez Perce-Clearwater National Forest Supervisor's Office, Attn: Forest Plan Revision, 903 3rd Street, Kamiah, ID 83536.

FOR FURTHER INFORMATION CONTACT: Zach Peterson, Forest Planner, Nez Perce—Clearwater National Forests, 903 3rd Street, Kamiah, ID 83536, 208–935–4239.

SUPPLEMENTARY INFORMATION: Since the publication of the original NOI in 2014 (79 FR 41252), there have been updates to the Responsible Official, Nature of the Decision to be Made, and the website for where updated information can be accessed. These updates are described below.

Responsible Official

The responsible official who will approve the Record of Decision is the Forest Supervisor for the Nez Perce—)Clearwater National Forests.

Nature of Decision To Be Made

The EIS process is meant to inform the Forest Supervisor in order to decide which alternative best maintains and restores National Forest System terrestrial and aquatic resources while providing ecosystem services and multiple uses, as required by the National Forest Management Act and the Multiple Use Sustained Yield Act. The revised Forest Plan will identify delineation of new management areas across the Forest, identify the potential timber sale quantity, make recommendations to Congress for Wilderness designation, and list the rivers and streams eligible and suitable for inclusion in the National Wild and Scenic Rivers System.

Proposed Action

For updates to the Proposed Action, refer to ''Alternative Development'' on the Forest's website at: *http://bit.ly/NezClearFPR.*

Public Involvement

The Forest is using information received during the comment period associated with the 2014 NOI; public information workshops and meetings with community groups throughout 2015; alternative development workshops, webinars, and open houses in 2018; and ongoing engagement with state, county, and tribal governments to inform the development of the draft EIS and draft revised Forest Plan. Comments submitted in response to the original 2014 NOI and throughout the continuing engagement do not need to be resubmitted. Comments submitted in response to the updated information in this notice will also be considered. Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered, however, anonymous comments will not provide the Agency with the ability to provide the respondent with subsequent environmental documents.

The decision to approve the revised Forest Plan for the Nez Perce—Clearwater National Forests will be subject to the objection process identified in 36 CFR part 219 subpart B (219.50 to 219.62). According to 36 CFR 219.53(a), those who may file an objection are individuals and entities who have submitted substantive formal comments related to plan revision during the opportunities provided for public comment during the planning process; this includes comments submitted in response to the 2014 NOI and comments submitted in response to the updated information in this notice.

The website location for information on this project has been updated. For updates, refer to the Quick Link: ''Get Involved in Forest Planning! Collaboration and Participation Information'' on the Forest's website at: *http://bit.ly/NezClearFPR.*

Dated: August 6, 2019.

Frank R. Beum,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2019–19089 Filed 9–4–19; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Recreation Special Uses and Trail Program Administration

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the addition of two optional appendices and one clause to

the information collection: FS–2700–4i—Special Use Permit for Outfitting and Guiding.

DATES: Comments must be received in writing on or before November 4, 2019 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Ben Johnson, National Recreation Special Uses Program Lead, USDA Forest Service, USDA Forest Service, 201 14th Street SW, Washington, DC 20250.

Comments also may be submitted to Ben Johnson at 971–284–1941 or by email at *benjamin.c.johnson@usda.gov.*

The public may inspect comments received at the USDA Forest Service, 201 14th Street SW, Washington, DC 20250 during normal business hours.

FOR FURTHER INFORMATION CONTACT: Ben Johnson, National Recreation Special Uses Program Lead, at 971–284–1941 OR, or via email at *benjamin.c.johnson@usda.gov.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Title: Special Use Permit for Outfitting and Guiding Optional Clause and Appendices.

OMB Number: 0596–0082.

Type of Request: Renewal to a currently approved information collection with changes.

Abstract: The change to an approved information collection supports implementation of the National Forest System Trails Stewardship Act of 2016 (the Act) (16 U.S.C. 583k–5). The Act directs the Forest Service to establish a pilot program on not less than 20 forest units to offset all or part of the land use fee for an outfitting and guiding permit by the cost of the work performed by the permit holder to construct, improve, or maintain National Forest System trails, trailheads, or developed sites that support public use. The amended information collection and optional appendices will be the official permit that documents the relationship between the Forest Service and the permit holder.

Forms

FS–2700–4i, *Special Use Permit for Outfitting and Guiding.* This permit will be amended to include clause A–23. National Forest System Trails Stewardship Act—Fee Offset for Holder-Performed Work. Major headings in the clause are definitions, land use fee offset, and the holder maintenance plan. No new information will be collected.

FS–2700–4i, Appendix H, *Annual Stewardship Act Fee Offset Agreement,* is a new optional information collection that serves as an amendment to FS–2700–4i. The amendment will only be used if the permit is subject to the National Forest System Trails Stewardship Act fee offset agreement. This information collection asks for the name of the permit holder, the date of the permit, and the total estimated annual land use fee amount. The form also collects information about the agreed upon project/s (including whether the project is construction, improvement, or maintenance), the project completion due date, estimated cost, actual completion date, and actual cost.

FS–2700–4i, Appendix I, *Stewardship Act Fee Offset Claim Certification.* Information collected includes the National Forest and Ranger District location of the project, the project name, the fiscal year of the planned work, the name of the holder, and the date of the annual Stewardship Act fee offset agreement. Additionally collected, is the itemized costs of the project.

This information is used to manage permits applicable to the National Forest System Trails Stewardship Act fee offset. The information will be collected by Federal employees authorized to issue recreation special use permits for outfitters and guides. The name and contact information of the permit holder will be used to track which holders are participating in the fee offset program. The description of the agreed upon project and the estimated and actual cost of the project will be used to assure compliance with the fee offset program and to track trends and the amount of trail care completed by partners.

Estimate of Annual Burden: 30 minutes.

Type of Respondents: Permit Holders.

Estimated Annual Number of Respondents: 20.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 50 hours.

Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the Agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the request for Office of Management and Budget approval.

Dated: August 15, 2019.

Richard A. Cooksey,

Acting Associate Deputy Chief, National Forest Systems.

[FR Doc. 2019–19162 Filed 9–4–19; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Black Hills National Forest Advisory Board

AGENCY: Forest Service, USDA.

ACTION: Announcement of meetings.

SUMMARY: The Black Hills National Forest Advisory Board (Board) will meet in Rapid City, South Dakota. The Board is established consistent with the Federal Advisory Committee Act of 1972, the Forest and Rangeland Renewable Resources Planning Act of 1974, the National Forest Management Act of 1976, and the Federal Public Lands Recreation Enhancement Act. Additional information concerning the Board, including the meeting summary/minutes, can be found by visiting the Board's website at: *http://www.fs.usda.gov/main/blackhills/workingtogether/advisorycommittees.*

DATES: The meetings will be held on the following dates:

- Wednesday, September 18, 2019, from 1 p.m.–4:30 p.m.
- Wednesday, October 20, 2019, from 1 p.m.–4:30 p.m.
- Wednesday, November 20, 2019, from 1 p.m.–4:30

All meetings are subject to cancellation. For updated status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meeting will be held at the Forest Service Center, 8221 Mount Rushmore Road, Rapid City, South Dakota.

Written comments may be submitted as described under **SUPPLEMENTARY**

INFORMATION. All comments, including names and addresses, when provided, are placed in the record and available for public inspection and copying. The public may inspect comments received at the Black Hills National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Scott Jacobson, Committee Coordinator, by phone at 605–440–1409 or by email at *sjjacobson@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to provide:

(1) Orientation Topic: Timber Sale Program;

(2) District Updates;

(3) Mineral Withdrawal Botanical Area and Research Natural Area Working Group update;

(4) Motorized Trail Strategy Working Group update;

(5) Recreation Site Analysis (RSA) Working Group update; and

(6) August Field Trip.

The meeting is open to the public. If time allows, the public may make oral statements of three minutes or less. Individuals wishing to make an oral statement should submit a request in writing by September 13, 2019, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the Board may file written statements with the Board's staff before or after the meeting. Written comments and time requests for oral comments must be sent to Scott Jacobson, Black Hills National Forest Supervisor's Office, 1019 North Fifth Street, Custer, South Dakota 57730; by email to *sjjacobson@fs.fed.us,* or via facsimile to 605–673–9208.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: August 26, 2019.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2019–19158 Filed 9–4–19; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

First Responder Network Authority

First Responder Network Authority Combined Committee and Board Meeting

AGENCY: First Responder Network Authority (FirstNet Authority), U.S. Department of Commerce.

ACTION: Notice of public meeting of the FirstNet Authority Board.

SUMMARY: The Board of the FirstNet Authority (Board) will convene an open public meeting of the Board and the Board Committees on September 18, 2019.

DATES: A joint meeting of the four FirstNet Authority Board Committees and the FirstNet Authority Board will be held on September 18, 2019, between 11:00 a.m. and 1:00 p.m. (EDT). The meeting of the FirstNet Authority Board and the Governance and Personnel, Technology, Public Safety Advocacy, and Finance Committees will be open to the public from 11:00 a.m. to 1:00 p.m. (EDT).

ADDRESSES: The meeting on September 18, 2019 will be held at the Park Hyatt Washington, 1201 24th Street NW, Washington, DC 20037. Members of the public may listen to the meeting by dialing toll free 1–888–324–6860 and entering participant code 2951211#. The meeting will also be webcast. Please refer to the FirstNet Authority's website at *www.firstnet.gov* for webcast instructions and other information.

FOR FURTHER INFORMATION CONTACT: Karen Miller-Kuwana, Board Secretary, FirstNet Authority, 12201 Sunrise Valley Drive, M/S 243, Reston, VA 20192; telephone: (571) 665–6177; email: *Karen.Miller-Kuwana@firstnet.gov.* Please direct media inquiries to Ryan Oremland at (571) 665–6186.

SUPPLEMENTARY INFORMATION: This notice informs the public that the FirstNet Authority Board and the Board Committees will convene an open public meeting on September 18, 2019.

Background: The Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96, Title VI, 126 Stat. 256 (codified at 47 U.S.C. 1401 *et seq.*)) (Act) established the FirstNet Authority as an independent authority within the National Telecommunications and Information Administration that is headed by a Board. The Act directs the FirstNet Authority to ensure the building, deployment, and operation of a nationwide, interoperable public safety broadband network. The FirstNet Authority Board is responsible for making strategic decisions regarding the FirstNet Authority's operations. The FirstNet Authority Board held its first public meeting on September 25, 2012.

Matters to be Considered: The FirstNet Authority will post a detailed agenda for the Combined Board Committees and Board Meeting on its website, *www.firstnet.gov,* prior to the meetings. The agenda topics are subject to change. Please note that the subjects that will be discussed by the Committees and the Board may involve commercial or financial information that is privileged or confidential or other legal matters affecting the FirstNet Authority. As such, the Committee Chairs and Board Chair may call for a vote to close the meetings only for the time necessary to preserve the confidentiality of such information, pursuant to 47 U.S.C. 1424(e)(2).

Times and Dates of Meeting: A combined meeting of the FirstNet Authority Board and FirstNet Authority Board Committees will be held on September 18, 2019 between 11:00 a.m. and 1:00 p.m. (EDT). The meeting of the FirstNet Authority Board and the Governance and Personnel, Technology, Public Safety Advocacy, and Finance Committees will be open to the public from 11:00 a.m. to 1:00 p.m. (EDT). The times listed above are subject to change. Please refer to the FirstNet Authority's website at *www.firstnet.gov* for the most up-to-date information.

Place: The meetings on September 18, 2019 will be held at the Park Hyatt Washington, 1201 24th Street NW, Washington, DC 20037. Members of the public may listen to the meeting by dialing toll free 1–888–324–6860 and entering participant code 2951211#. The meeting will also be webcast. Please refer to the FirstNet Authority's website at *www.firstnet.gov* for webcast instructions and other information.

Other Information: These meetings are open to the public and press on a first-come, first-served basis. Space is limited. To ensure an accurate headcount, all expected attendees are asked to provide notice of intent to attend by sending an email to *BoardRSVP@firstnet.gov.* If the number of RSVPs indicates that expected attendance has reached its capacity, the FirstNet Authority will respond to all subsequent notices indicating that capacity has been reached and that in-person viewing may no longer be available but that the meeting may still be viewed by webcast as detailed below. For access to the meetings, valid

government issued photo identification may be requested for security reasons.

The Combined Committee and Board Meetings are accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Ms. Miller-Kuwana by telephone at (571) 665–6177 or email at *Karen.Miller-Kuwana@firstnet.gov* at least five (5) business days before the applicable meeting.

The meeting will also be webcast. Please refer to the FirstNet Authority's website at *www.firstnet.gov* for webcast instructions and other information. Viewers experiencing any issues with the live webcast may email *support@sparkstreetdigital.com* or call (202) 684–3361 x3 for support. A variety of automated troubleshooting tests are also available via the ''Troubleshooting Tips'' button on the webcast player. The meetings will also be available to interested parties by phone. To be connected to the meetings in listen-only mode by telephone, please dial toll free 1–888–324–6860 and enter participant code 2951211#. If you experience technical difficulty, please contact the Conferencing Center customer service at 1–866–900–1011.

Records: The FirstNet Authority maintains records of all Board proceedings. Minutes of the Board Meeting and the Committee meetings will be available at *www.firstnet.gov.*

Dated: August 30, 2019.

Karen Miller-Kuwana,

Board Secretary, FirstNet Authority.

[FR Doc. 2019–19182 Filed 9–4–19; 8:45 am]

BILLING CODE 3510–TL–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–52–2019]

Foreign-Trade Zone (FTZ) 168—Dallas/Fort Worth, Texas; Notification of Proposed Production Activity; Gulfstream Aerospace Corporation (Disassembly of Aircraft), Dallas, Texas

The Metroplex International Trade Development Corporation, grantee of FTZ 168, submitted a notification of proposed production activity to the FTZ Board on behalf of Gulfstream Aerospace Corporation (Gulfstream), located in Dallas, Texas. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on August 26, 2019.

Gulfstream already has authority to produce and disassemble passenger jet aircraft within Subzone 168E. The current request would add finished products to the scope of authority related to the disassembly of aircraft. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Gulfstream from customs duty payments on the foreign-status materials/components used in export production. On its domestic sales, for the foreign-status materials/components in the existing scope of authority, Gulfstream would be able to choose the duty rates during customs entry procedures that apply to: Jet fuel; aircraft door locks; and, lubricating oil—waste (duty rates: 52.5¢/bbl, 5.7%, 84¢/bbl). Gulfstream would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is October 15, 2019.

A copy of the notification will be available for public inspection in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: August 28, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–19184 Filed 9–4–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–32–2019]

Foreign-Trade Zone (FTZ) 84—Harris County, Texas; Authorization of Production Activity; Coreworks, LLC; (Brazed Aluminum Heat Exchangers and Cryogenic Equipment); Katy, Texas

On April 30, 2019, Coreworks, LLC submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 84, in Katy, Texas.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (84 FR 20090, May 8, 2019). On August 28, 2019, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including § 400.14.

Dated: August 28, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–19177 Filed 9–4–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–30–2019]

Foreign-Trade Zone (FTZ) 20—Norfolk, Virginia; Authorization of Production Activity STIHL, Incorporated (Outdoor Power Equipment), Virginia Beach, Virginia

On May 1, 2019, STIHL, Incorporated submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 20 in Virginia, Virginia.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (84 FR 20090, May 8, 2019). On August 29, 2019, the applicant was notified of the FTZ Board's decision that no further review of the proposed activity is warranted at this time. The FTZ Board authorized the production activity described in the notification, subject to the FTZ Act and the Board's regulations, including Section 400.14. Given the applicant's commitment in its notification, lithium battery primary cells must be admitted to the zone in privileged foreign status (19 CFR 146.41).

Dated: August 29, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–19183 Filed 9–4–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–34–2019]

Foreign-Trade Zone (FTZ) 29—Louisville, Kentucky; Authorization of Production Activity; LLFlex, LLC; (Aluminum and Steel Cable Wraps); Louisville, Kentucky

On May 1, 2019, LLFlex, LLC submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 29, in Louisville, Kentucky.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (84 FR 21326, May 14, 2019). On August 29, 2019, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including § 400.14.

Dated: August 29, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–19176 Filed 9–4–19; 8:45 am]

BILLING CODE 3510–DS–P

INTERNATIONAL TRADE ADMINISTRATION

Meeting of the United States Investment Advisory Council

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

ACTION: Notice of an open meeting.

SUMMARY: The United States Investment Advisory Council (Council) will hold a meeting on Tuesday, September 17, 2019. The Council advises the Secretary of Commerce on matters relating to the promotion and retention of foreign direct investment in the United States. At the meeting, members will identify and begin to deliberate policy priorities regarding the facilitation of foreign direct investment into the United States, including deregulation and the streamlining of processes that affect business investment opportunities across U.S. regions, the facilitation of infrastructure investment, workforce development, and mechanisms to increase investment competitiveness for domestic manufacturing companies, in addition to other topics. The agenda may change to accommodate Council business. The final agenda will be posted on the Department of Commerce website for the Council at: *http://trade.gov/IAC,* at least one week in advance of the meeting.

DATES: Tuesday, September 17, 2019, 8:00–11:00 a.m. EDT. The deadline for members of the public to register, including requests to make comments during the meeting and for auxiliary aids, or to submit written comments for dissemination prior to the meeting is 5:00 p.m. EDT on September 10, 2019. Due to late scheduling changes this notice was not able to be published in the **Federal Register** within the 15 day announcement window.

ADDRESSES: The meeting will be held at the Eisenhower Executive Office Building, 1600 Pennsylvania Avenue NW, Washington, DC. Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted to: United States Investment Advisory Council, U.S. Department of Commerce, 1401 Constitution Avenue NW, Room 30011, Washington, DC 20230, and to *IAC@trade.gov*. Members of the public are encouraged to submit registration requests and written comments via email to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Steve Meyers, United States Investment Advisory Council, Room 30011, 1401 Constitution Avenue NW, Washington, DC 20230, telephone 202–482–2612.

SUPPLEMENTARY INFORMATION:

Background

The Council advises the Secretary of Commerce on matters relating to the promotion and retention of foreign direct investment in the United States, and domestic manufacturing companies considering overseas expansions.

Public Participation

The meeting will be open to the public and will be accessible to people with disabilities. All guests are required to register in advance by the deadline identified under the **DATES** caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted but may be impossible to fill. There will be fifteen (15) minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for public comments may be limited to three (3) minutes per person. Individuals wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name and address of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers.

Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. EDT on September 10, 2019, for inclusion in the meeting records and for circulation to the Members of the Council.

In addition, any member of the public may submit pertinent written comments concerning the Council's affairs at any time before or after the meeting. Comments may be submitted to Steve Meyers at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EDT on September 10, 2019, to ensure transmission to the Council members prior to the meeting. Comments received after that date and time will be distributed to the members but may not be considered during the meeting. Comments and statements will be posted on the United States Investment Advisory Council website (*http://trade.gov/IAC*) without change, including any business or personal information provided such as it includes names, addresses, email addresses, or telephone numbers.

All comments and statements received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should submit only information that you wish to make publicly available.

Copies of Council meeting minutes will be available within 90 days of the meeting.

Anthony Diaz,

Executive Secretary, United States Investment Advisory Council.

[FR Doc. 2019–19161 Filed 8–30–19; 4:15 pm]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 99–13A05]

Export Trade Certificate of Review

ACTION: Notice of application to amend the Export Trade Certificate of Review issued to California Almond Export Association, LLC (''CAEA''), Application No. 99–13A05.

SUMMARY: The Office of Trade and Economic Analysis (''OTEA'') of the International Trade Administration, Department of Commerce, received an

application for an amended Export Trade Certificate of Review (''Certificate''). This notice summarizes the proposed amendment and requests comments relevant to whether the amended Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, OTEA, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001–21) (''the Act'') authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing Title III are found at 15 CFR part 325. OTEA is issuing this notice pursuant to 15 CFR 325.6(a), which requires the Secretary of Commerce to publish a summary of the application in the **Federal Register**, identifying the applicant and each member and summarizing the proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether an amended Certificate should be issued. If the comments include any privileged or confidential business information, it must be clearly marked and a nonconfidential version of the comments (identified as such) should be included. Any comments not marked as privileged or confidential business information will be deemed to be nonconfidential.

An original and five (5) copies, plus two (2) copies of the nonconfidential version, should be submitted no later than 20 days after the date of this notice to: Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce, Room 21028, Washington, DC 20230.

Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). However, nonconfidential versions of the comments will be made available to the applicant if necessary for determining whether or not to issue the amended Certificate. Comments should refer to this application as ''Export Trade Certificate of Review, application number 99–13A05.''

Summary of the Application

Applicant: CAEA.

Contact: Michael Coe, (916) 446–8686.

Application No.: 99–13A05.

Date Deemed Submitted: August 29, 2019.

Proposed Amendment: CAEA seeks to amend its Certificate by adding Pearl Crop, Inc. as a Member of the Certificate within the meaning of § 325.2(1) of the Regulations (15 CFR 325.2(1)).

CAEA's proposed amendment of its Certificate would result in the following Members list:

Almonds California Pride, Inc., Caruthers, CA
Baldwin-Minkler Farms, Orland, CA
Blue Diamond Growers, Sacramento, CA
Campos Brothers, Caruthers, CA
Chico Nut Company, Chico, CA
Del Rio Nut Company, Livingston, CA
Fair Trade Corner, Inc., Chico, CA
Fisher Nut Company, Modesto, CA
Hilltop Ranch, Inc., Ballico, CA
Hughson Nut, Inc., Hughson, CA
Mariani Nut Company, Winters, CA
Nutco, LLC d.b.a. Spycher Brothers, Turlock, CA
Pearl Crop, Inc., Stockton, CA
P–R Farms, Inc., Clovis, CA
Roche Brothers International Family Nut Co., Escalon, CA
RPAC, LLC, Los Banos, CA
South Valley Almond Company, LLC, Wasco, CA
Stewart & Jasper Marketing, Inc., Newman, CA
SunnyGem, LLC, Wasco, CA
Western Nut Company, Chico, CA
Wonderful Pistachios & Almonds, LLC, Los Angeles, CA

Dated: August 30, 2019.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2019–19174 Filed 9–4–19; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–108]

Ceramic Tile From the People's Republic of China: Postponement of Preliminary Determination in the Less-Than-Fair-Value Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable September 5, 2019.

FOR FURTHER INFORMATION CONTACT: Paul Walker, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0413.

SUPPLEMENTARY INFORMATION:

Background

On April 30, 2019, the Department of Commerce (Commerce) initiated a less-than-fair-value (LTFV) investigation on imports of ceramic tile from the People's Republic of China.[1] Currently, the preliminary determination is due no later than September 17, 2019.

Postponement of Preliminary Determination

Section 733(b)(1)(A) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in an LTFV investigation within 140 days after the date on which Commerce initiated the investigation. However, section 733(c)(1)(A)(b)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 190 days after the date on which Commerce initiated the investigation if: (A) The petitioner makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On August 19, 2019, the petitioner[2] submitted a timely request that Commerce postpone the preliminary determination of the LTFV investigation.[3] The petitioner stated that it requests postponement to allow Commerce time to collect surrogate value data, sufficiently review all questionnaires responses, and request clarification and additional information as necessary.[4]

For the reasons stated above, and because there are no compelling reasons

[1] *See Ceramic Tile from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 84 FR 20093 (May 8, 2019).

[2] The petitioner is The Coalition for Fair Trade in Ceramic Tile.

[3] *See* Petitioner's Letter, ''Antidumping Duty Investigation of Ceramic Tile from the People's Republic of China: Petitioner's Request for Postponement of the Preliminary Determination and Provisional Measures,'' dated August 19, 2019.

[4] *Id.*

to deny the request, Commerce, in accordance with section 733(c)(1)(A) of the Act, is postponing the deadline for the preliminary determination by 50 days (*i.e.,* 190 days after the date on which this investigation was initiated). As a result, Commerce will issue its preliminary determination no later than November 6, 2019. In accordance with section 735(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination of this investigation will continue to be 75 days after the date of the preliminary determination, unless postponed at a later date.

Notification to Interested Parties

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: August 28, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2019–19193 Filed 9–4–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–045]

1-Hydroxyethylidene-1, 1-Diphosphonic Acid From the People's Republic of China: Rescission of Antidumping Duty Administrative Review; 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding its administrative review of the antidumping duty order on 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP) from the People's Republic of China (China) for the period May 1, 2018, through April 30, 2019.

DATES: Applicable September 5, 2019.

FOR FURTHER INFORMATION CONTACT: Genevieve Coen, Enforcement and Compliance, Office V, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3251.

SUPPLEMENTARY INFORMATION:

Background

On May 1, 2019, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty (AD) order on HEDP from China for the period of review (POR) May 1, 2018, through April 30, 2019.[1] On May 31, 2019, Commerce received a timely request to conduct an administrative review of the AD order on HEDP from China from Compass Chemical International LLC (the petitioner) for three companies: Henan Qingshuiyuan Technology Co., Ltd. (Qingshuiyuan); Nantong Uniphos Chemicals Co., Ltd. (Nantong Uniphos); and Nanjing University of Chemical Technology Changzhou Wujin Water Quality Stabilizer Factory (Changzhou Wujin).[2] On July 15, 2019, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.221(c)(1)(i), Commerce initiated an administrative review of the AD order on HEDP from China with respect to Qingshuiyuan, Nantong Uniphos, and Changzhou Wujin.[3]

On July 22, 2019, Commerce placed on the record information from U.S. Customs and Border Protection (CBP) indicating that there were no reviewable entries of subject merchandise exported by the companies subject to this administrative review during the POR.[4] No parties submitted comments on the CBP data.

On August 26, 2019, the petitioner timely withdrew its request for an administrative review of the AD order on HEDP from China.[5]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the publication date of the notice of initiation of the requested review. The petitioner withdrew its request for review within the 90-day deadline. Because Commerce received no other requests for review of Qingshuiyuan, Nantong Uniphos, and Changzhou Wujin, and no other requests were made for a review of the AD order on HEDP from China with respect to other companies, we are rescinding the administrative review covering the period May 1, 2018, through April 30, 2019, in its entirety, in accordance with 19 CFR 351.213(d)(1).

Assessment

Commerce will instruct CBP to assess AD duties on all appropriate entries of HEDP from China during the POR. For the companies for which this review is rescinded, AD duties shall be assessed at rates equal to the cash deposit rate of estimated AD duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as the only reminder to importers whose entries will be liquidated as a result of this rescission notice, of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of AD duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the presumption that reimbursement of the AD duties occurred and the subsequent assessment of double AD duties.

Notification Regarding Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is published in accordance with section 751 and 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: August 29, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–19192 Filed 9–4–19; 8:45 am]

BILLING CODE 3510–DS–P

---

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 84 FR 18479 (May 1, 2019).

[2] *See* the petitioner's letter, ''Request for Administrative Review: 1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China,'' dated May 31, 2019.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 33739 (July 15, 2019).

[4] *See* Memorandum, ''Release of Customs and Border Protection (CBP) Data Query,'' dated July 22, 2019.

[5] *See* the petitioner's letter, ''1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China,'' dated August 26, 2019.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–520–803]

Polyethylene Terephthalate Film, Sheet, and Strip From the United Arab Emirates: Rescission of Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding its administrative review of the antidumping duty (AD) order on polyethylene terephthalate film, sheet, and strip (PET film) from the United Arab Emirates (UAE) for the period of review (POR), November 1, 2017, through October 31, 2018.

DATES: Applicable September 5, 2019.

FOR FURTHER INFORMATION CONTACT: Andrew Huston, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4261.

SUPPLEMENTARY INFORMATION:

Background

On November 1, 2018, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the AD order on PET film from the UAE.[1] Commerce received a timely request from DuPont Teijin Film, Mitsubishi Polyester Film, Inc., and SKC Inc. (collectively, the petitioners), in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b), to conduct an administrative review of this AD order for Flex Middle East FZE (Flex).[2] No other party requested an administrative review of this order. Pursuant to the review request filed by the petitioners, and in accordance with 19 CFR 351.221(c)(1)(i), on February 6, 2019, Commerce published in the **Federal Register** a notice of initiation of an administrative review covering Flex.[3] On May 3, 2019, the petitioners timely withdrew their request for an administrative review of Flex.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party, or parties, that requested a review withdraw the request/s within 90 days of the publication of the notice of initiation of the requested review. As noted above, the petitioners withdrew their request for review by the 90-day deadline, and no other party requested an administrative review of this order. Therefore, in response to the timely withdrawal of the request for review, and, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this administrative review in its entirety.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue assessment instructions to CBP 15 days after the publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of ADs prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of ADs occurred and the subsequent assessment of double ADs.

Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This notice is published in accordance with section 771(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: August 29, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–19194 Filed 9–4–19; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 83 FR 54912 (November 1, 2018); *see also Correction to Notice of Opportunity to Request Administrative Review,* 83 FR 56819 (November 14, 2018).

[2] *See* Petitioners' Letter, ''Polyethylene Terephthalate Film, Sheet and Strip from the United Arab Emirates: Request for Antidumping Duty Administrative Review,'' dated November 30, 2018.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 2159 (February 6, 2019).

[4] *See* Petitioners' Letter, ''Polyethylene Terephthalate Film, Sheet and Strip from the United Arab Emirates: Withdrawal of Request for Antidumping Duty Administrative Review,'' dated May 3, 2019.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–874]

Certain Hot-Rolled Steel Flat Products From Japan: Notice of Final Results of Antidumping Duty Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 19, 2019, the Department of Commerce (Commerce) published its notice of initiation and preliminary results of a changed-circumstances review (CCR) of the antidumping duty (AD) order on certain hot-rolled steel flat products (hot-rolled steel) from Japan. In that notice, Commerce preliminarily determined that (1) Nippon Steel Corporation (NSC) is the successor-in-interest to Nippon Steel & Sumitomo Metal Corporation (NSSMC); (2) Nippon Steel Nisshin Co., Ltd. (Nippon Nisshin) is the successor in interest to Nisshin Steel Co., Ltd. (Nisshin Steel); and (3) Nippon Steel Trading Corporation (NSTC) is the successor in interest to Nippon Steel & Sumikin Bussan Corporation (NSSBC). Additionally, Commerce preliminarily determined that NSC, Nippon Nisshin, and NSTC should be treated as a single entity, and should receive the same AD cash deposit rate with respect to the subject merchandise as NSSMC, the predecessor company. No interested party submitted comments regarding the initiation and preliminary results. For these final results, Commerce continues to find that NSC is the successor-in-interest to NSSMC.

DATES: Applicable September 5, 2019.

FOR FURTHER INFORMATION CONTACT: Leo Ayala or Jun Jack Zhao, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue

NW, Washington, DC 20230; telephone: (202) 482–3945 or (202) 482–1396, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 19, 2019, Commerce published its notice of initiation and preliminary results of this CCR of the AD order on hot-rolled steel from Japan,[1] preliminarily determining that (1) NSC is the successor-in-interest to NSSMC; (2) Nippon Nisshin is the successor in interest to Nisshin Steel; and (3) NSTC is the successor in interest to NSSBC.[2] Additionally, because Commerce had previously determined that NSSMC, Nisshin Steel, and NSSBC are affiliated companies and should be treated as a single entity, Commerce preliminarily determined that NSC, including Nippon Nisshin and NSTC, should receive the same AD cash deposit rate (*i.e.,* 4.99 percent) with respect to the subject merchandise as NSSMC, its predecessor company.[3] In the *Initiation and Preliminary Results,* Commerce provided all interested parties with an opportunity to comment and to request a public hearing regarding the preliminary findings. Commerce received no comments regarding the preliminary findings and no requests for a public hearing from interested parties within the time period set forth in the *Initiation and Preliminary Results.*

Scope of the Order

The products covered by this order are hot-rolled steel flat products from Japan. For a full description of the scope of the order, *see* the ''Scope of the Order'' at the Appendix to this notice.

Final Results of CCR

For the reasons stated in the *Initiation and Preliminary Results,* and because we received no comments from interested parties to the contrary, Commerce continues to find that NSC, Nippon Nisshin, and NSTC are affiliated companies that should be treated as a single entity that is the successor-in-interest to NSSMC. As a result of this determination, we find that NSC, Nippon Nisshin, and NSTC should receive the AD cash deposit rate previously assigned to NSSMC under the *Order.*[4] Consequently, Commerce will instruct U.S. Customs and Border Protection to suspend liquidation of all shipments of subject merchandise produced or exported by NSC, Nippon Nisshin, and NSTC and entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register** at a cash deposit rate of 4.99 percent, which is the current AD cash deposit rate for NSSMC.[5] This cash deposit requirement shall remain in effect until further notice.

Notification to Interested Parties

Commerce is issuing and publishing these final results and notice in accordance with sections 751(b)(1) and (4) and 777(i) of the Tariff Act of 1930, as amended, and sections 19 CFR 351.216 and 351.221(c)(3)(i).

Dated: August 28, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Order

The products covered by the scope are certain hot-rolled, flat-rolled steel products, with or without patterns in relief, and whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement (''width'') of 12.7 mm or greater, regardless of thickness, and regardless of form of coil (*e.g.,* in successively superimposed layers, spirally oscillating, *etc.*). The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process, *i.e.,* products which have been ''worked after rolling'' (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above unless the resulting measurement makes the product covered by the existing antidumping[1] or countervailing duty[2] orders on Certain Cut-To-Length Carbon-Quality Steel Plate Products From the Republic of Korea (A–580–836; C–580–837), and

(2) where the width and thickness vary for a specific product (*e.g.,* the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, *etc.*), the measurement at its greatest width or thickness applies.

Steel products included in the scope are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, the substrate for motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes hot-rolled steel that has been further processed in a third country, including but not limited to pickling, oiling, levelling, annealing, tempering, temper rolling, skin passing, painting, varnishing, trimming, cutting,

[1] *See Certain Hot-Rolled Steel Flat Products from Australia, Brazil, Japan, the Republic of Korea, the Netherlands, the Republic of Turkey, and the United Kingdom: Amended Final Affirmative Antidumping Determinations for Australia, the Republic of Korea, and the Republic of Turkey and Antidumping Duty Orders,* 81 FR 67962 (October 3, 2016) (*Order*).

[2] *See Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Certain Hot-Rolled Steel Flat Products from Japan,* 84 FR 34865 (July 19, 2019) (*Initiation and Preliminary Results*).

[3] *Id.*

[4] *See Order.*

[5] NSSMC received a cash deposit rate of 4.99 percent in the amended final determination of the investigation of hot-rolled steel products from Japan. *See Order,* 81 FR at 67965.

[1] *See Notice of Amendment of Final Determinations of Sales at Less Than Fair Value and Antidumping Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate Products from France, India, Indonesia, Italy, Japan and the Republic of Korea,* 65 FR 6585 (February 10, 2000).

[2] *See Notice of Amended Final Determinations: Certain Cut-to-Length Carbon-Quality Steel Plate from India and the Republic of Korea; and Notice of Countervailing Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate from France, India, Indonesia, Italy, and the Republic of Korea,* 65 FR 6587 (February 10, 2000).

punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope if performed in the country of manufacture of the hot-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope unless specifically excluded. The following products are outside of and/or specifically excluded from the scope:

- Universal mill plates (*i.e.,* hot-rolled, flat-rolled products not in coils that have been rolled on four faces or in a closed box pass, of a width exceeding 150 mm but not exceeding 1250 mm, of a thickness not less than 4.0 mm, and without patterns in relief);
- Products that have been cold-rolled (cold-reduced) after hot-rolling; [3]
- Ball bearing steels; [4]
- Tool steels; [5] and
- Silico-manganese steels; [6]

The products subject to the scope are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.10.1500, 7208.10.3000, 7208.10.6000, 7208.25.3000, 7208.25.6000, 7208.26.0030, 7208.26.0060, 7208.27.0030, 7208.27.0060, 7208.36.0030, 7208.36.0060, 7208.37.0030, 7208.37.0060, 7208.38.0015, 7208.38.0030, 7208.38.0090, 7208.39.0015, 7208.39.0030, 7208.39.0090, 7208.40.6030, 7208.40.6060, 7208.53.0000, 7208.54.0000, 7208.90.0000, 7210.70.3000, 7211.14.0030, 7211.14.0090, 7211.19.1500, 7211.19.2000, 7211.19.3000, 7211.19.4500, 7211.19.6000, 7211.19.7530, 7211.19.7560, 7211.19.7590, 7225.11.0000, 7225.19.0000, 7225.30.3050, 7225.30.7000, 7225.40.7000, 7225.99.0090, 7226.11.1000, 7226.11.9030, 7226.11.9060, 7226.19.1000, 7226.19.9000, 7226.91.5000, 7226.91.7000, and 7226.91.8000. The products subject to the scope may also enter under the following HTSUS numbers: 7210.90.9000, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7214.91.0015, 7214.91.0060, 7214.91.0090, 7214.99.0060, 7214.99.0075, 7214.99.0090, 7215.90.5000, 7226.99.0180, and 7228.60.6000.

The HTSUS subheadings above are provided for convenience and U.S. Customs and Border Protection (CBP) purposes only. The written description of the scope is dispositive.

[FR Doc. 2019–19195 Filed 9–4–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG233

Groundfish Operational Assessment Peer Review Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: NMFS and the Operational Assessment Oversight Panel will convene the Groundfish Operational Assessment Peer Review Meeting for the purpose of reviewing stock assessments of haddock, cod, yellowtail flounder, windowpane flounder, American plaice, pollock, and white hake. The Operational Assessment Peer Review is a formal scientific peer-review process for evaluating and presenting stock assessment results to managers for fish stocks in the offshore U.S. waters of the northwest Atlantic. Assessments are prepared by Stock Assessment Workshop (SAW) working groups and reviewed by an independent panel of stock assessment experts called the Operational Assessment Oversight Panel (AOP). The public is invited to attend the presentations and discussions between the review panel and the scientists who have participated in the stock assessment process.

DATES: The public portion of the Groundfish Operational Assessment Peer Review Meeting will be held from September 9, 2019–September 13, 2019. The meeting will commence on September 13, 2019 at 5:00 p.m. Eastern Standard Time. Please see **SUPPLEMENTARY INFORMATION** for the daily meeting agenda.

ADDRESSES: The meeting will be held in Stephen H. Clark Conference Room in the Aquarium Building of the National Marine Fisheries Service, Northeast Fisheries Science Center (NEFSC), 166 Water Street, Woods Hole, MA 02543.

FOR FURTHER INFORMATION CONTACT: Jim Weinberg, 508–495–2352; email: *james.weinberg@noaa.gov.*

SUPPLEMENTARY INFORMATION: For further information, please visit the NEFSC website at *http://www.nefsc.noaa.gov.* For additional information about the AOP meeting and the stock assessment peer review, please visit the NMFS/NEFSC SAW web page at *https://www.nefsc.noaa.gov/assessments/2019-assessments/.*

Daily Meeting Agenda—Groundfish Operational Assessment Peer Review Meeting

(Subject to Change; All times are approximate and may be changed at the discretion of the Peer Review Chair).

Monday, September 9, 2019

Time	Activity	Lead
1:00 p.m.–1:15 p.m.	Welcome and Introductions	Jim Weinberg/Pat Sullivan, Chair.
1:15 p.m.–1:30 p.m.	Common Topics	Russ Brown.
1:30 p.m.–4:30 p.m.	Georges Bank Haddock	Liz Brooks.
	Gulf of Maine Haddock	Charles Perretti.
4:30 p.m.–5:00 p.m.	Discussion/Review/Summary	Review Panel.
	Public Comment	Public.
5:00 p.m.	Adjourn.	

[3] For purposes of this scope exclusion, rolling operations such as a skin pass, levelling, temper rolling or other minor rolling operations after the hot-rolling process for purposes of surface finish, flatness, shape control, or gauge control do not constitute cold-rolling sufficient to meet this exclusion.

[4] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[5] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[6] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

Tuesday, September 10, 2019

Time	Activity	Lead
8:30 a.m.–8:45 a.m	Brief Overview and logistics	Jim Weinberg/Pat Sullivan, Chair.
8:45 a.m.–10:45 a.m	Gulf of Maine Cod	Charles Perretti.
10:45 a.m.–11:45 a.m	Break.	
	Discussion/Review/Summary	Review Panel.
	Public Comment	Public.
11:45 a.m.–12:45 p.m	Lunch.	
12:45 p.m.–3:30 p.m	Cape Cod/Gulf of Maine Yellowtail Flounder	Larry Alade.
	Southern New England/Mid-Atlantic Yellowtail Flounder	Larry Alade.
3:30 p.m.–4:15 p.m	Break.	
	Discussion/Review/Summary	Review Panel.
	Public Comment	Public.
4:15 p.m	Adjourn.	

Wednesday, September 11, 2019

Time	Activity	Lead
8:30 a.m.–8:45 a.m	Brief Overview and logistics	Jim Weinberg/Pat Sullivan, Chair.
8:45 a.m.–11:30 a.m	Northern Windowpane Flounder	Toni Chute.
	Gulf of Maine Winter Flounder	Lisa Hendrickson.
11:30 a.m.–12:15 p.m	Discussion/Review/Summary	Review Panel.
	Public Comment	Public.
12:15 p.m.–1:15 p.m	Lunch.	
1:15 p.m.–4:00 p.m	American Plaice	Larry Alade.
	Pollock	Brian Linton.
4:00 p.m.–4:30 p.m	Break.	
	Discussion/Review/Summary	Review Panel.
	Public Comment	Public.
4:30 p.m	Adjourn.	

Thursday, September 12, 2019

Time	Activity	Lead
8:30 a.m.–8:45 a.m	Brief Overview and logistics	Jim Weinberg/Pat Sullivan, Chair.
8:45 a.m.–9:45 a.m	White Hake	Kathy Sosebee.
9:45 a.m.–10:45 a.m	Discussion/Review/Summary	Review Panel.
	Public Comment	Public.
	Break.	
10:30 a.m.–12:00 p.m	Meeting Wrap Up and Discussion of Key Topics	Review Panel.
12:00 p.m.–1:00 p.m	Lunch.	
1:00 p.m.–5:00 p.m	Report Writing	Review Panel.
5:00 p.m	Adjourn.	

Friday, September 12, 2019

Time	Activity	Lead
8:30 a.m.–12:00 p.m	Report Writing	Review Panel.
12:00 p.m.–1:00 p.m	Lunch.	
1:00 p.m.–5:00 p.m	Report Writing	Review Panel.
5:00 p.m	Adjourn.	

The meeting is open to the public; however, during the 'Report Writing/Species Summaries' session on Thursday, September 12th, and Friday, September 13th, the public should not engage in discussion with the peer review Panel.

Special Accommodations

This meeting is physically accessible to people with disabilities. Special requests should be directed to James Weinberg at the NEFSC, 508–495–2352, at least 5 days prior to the meeting date.

Dated: August 30, 2019.

Jennifer M. Wallace,

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

[FR Doc. 2019–19166 Filed 8–30–19; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF EDUCATION

Docket No. ED–2019–ICCD–0062]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; FFEL/Direct Loan/Perkins Military Service Deferment/Post-Active Duty Student Deferment Request

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before October 7, 2019.

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–2019–ICCD–0062. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: FFEL/Direct Loan/Perkins Military Service Deferment/Post-Active Duty Student Deferment Request.

OMB Control Number: 1845–0080.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 16,000.

Total Estimated Number of Annual Burden Hours: 8,000.

Abstract: The Military Service/Post-Active Duty Student Deferment request form serves as the means by which a Federal Family Education Loan (FFEL), Perkins, or Direct Loan borrower requests a military service deferment and/or post-active duty student deferment and provides his or her loan holder with the information needed to determine whether the borrower meets the applicable deferment eligibility requirements. The form also serves as the means by which the U.S. Department of Education identifies Direct Loan borrowers who qualify for the Direct Loan Program's no accrual of interest benefit for active duty service members.

Dated: August 30, 2019.

Kate Mullan,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–19124 Filed 9–4–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Meeting of the National Advisory Council on Indian Education

AGENCY: National Advisory Council on Indian Education (NACIE), U.S. Department of Education.

ACTION: Announcement of an open meeting.

SUMMARY: This notice sets forth the agenda for an upcoming public meeting of the National Advisory Council on Indian Education (NACIE). Notice of the meeting is required by section 10(a)(2) of the Federal Advisory Committee Act (FACA) and is intended to notify members of the public who may be interested in attending. This notice is being posted late because of difficulties ensuring the availability of enough members to constitute a quorum.

DATES: The NACIE meetings will be held on September 11–12, 2019 from 9:00 a.m.–5:00 p.m. (EST).

ADDRESSES: The September 11 meeting will be held at the U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202, Room 1W113. The September 12 meeting will also be held at the U.S. Department of Education in Room 1W128.

FOR FURTHER INFORMATION CONTACT: Angeline Boulley, Director of the Office of Indian Education (OIE)/Designated Federal Official, Office of Elementary and Secondary Education (OESE), U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202. Telephone: 202–453–7042, Email: *Angeline.Boulley@ed.gov.*

SUPPLEMENTARY INFORMATION:

Statutory Authority and Function: NACIE is authorized by section 6141 of the Elementary and Secondary Education Act of 1965. NACIE is established within the U.S. Department of Education to advise the Secretary of Education (Secretary) and the Secretary of Interior on the funding and administration (including the development of regulations, and administrative policies and practices) of any program over which the Secretary has jurisdiction and includes Indian children or adults as participants or that

may benefit Indian children or adults, including any program established under Title VI, Part A of the Elementary and Secondary Education Act. In addition, NACIE advises the White House Initiative on American Indian and Alaska Native Education, in accordance with section 5(a) of Executive Order 13592. NACIE submits to the Congress each year a report on the activities of the Council and include recommendations that are considered appropriate for the improvement of Federal education programs that include Indian children or adults as participants or that may benefit Indian children or adults, and recommendations concerning the funding of any such program.

Meeting Agenda: The purpose of the meeting is to convene NACIE to conduct the following business:

September 11

(1) Welcome and Introductions; (2) Presentation—White House Initiative on American Indian and Alaska Native Education (WHIAIANE); (3) Presentation—Office of Special Education Programs; (4) Presentation—Director of the National Indian Education Association (NIEA); (5) Discussion of Data Requests for the NACIE 2020 Annual Report to Congress; (6) Discussion on NACIE Vacancies; and (7) Confirmation of NACIE Calendar for 2019–2010.

September 12

(1) Presentation—Office of Program and Grantee Support Services; (2) Presentation—Native American-Serving Non-Tribal Institutions Program; (3) Presentation—Bureau of Indian Education; (4) Presentation—Office of Indian Education (OIE); and (5) Public Comments.

Access to the Meeting: All attendees must RSVP for the meeting to ensure there is sufficient space to accommodate everyone. Please RSVP via email to *Angeline.Boulley@ed.gov* no later than September 9, 2019. There will be online and teleconference capabilities for individuals who would like to remotely attend the meeting. To pre-register for online or teleconference attendance: *https://tinyurl.com/y4959f5a.*

Virtual hyperlink inserted: NACIE MEETING ROOM LINK.

To copy and paste the hyperlink into browser: https://tribaltech.adobeconnect.com/rlsrws0as4df/.

To join by telephone use call-in toll-free number 1–800–832–0736. Access code: 6241321.

Public Comment: If you would like to provide public comment, please submit your request no later than September 9, 2019 to *Angeline.Boulley@ed.gov.* Speakers will have five (5) minutes to provide a comment, with a limit of one hour available for public comment. Members of the public interested in submitting written comments may do so via email at *Angeline.Boulley@ed.gov.* Comments should pertain to the work of NACIE and/or the Office of Indian Education.

Reasonable Accommodations: The hearing site is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify Brandon Dent on 202–453–6450 or at *brandon.dent@ed.gov* no later than September 3, 2019. Although we will attempt to meet a request received after the request due date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to make arrangements.

Access to Records of the Meeting: The Department will post the official report of the meeting on the OESE website at: *http://www2.ed.gov/about/offices/list/oese/index.html?src=oc* 21 days after the meeting. Pursuant to the FACA, the public may also inspect NACIE records at the Office of Indian Education, United States Department of Education, 400 Maryland Avenue SW, Washington, DC 20202, Monday–Friday, 8:30 a.m. to 5:00 p.m. Eastern Time. Please email to schedule an appointment. *Angeline.Boulley@ed.gov* or by calling Erica Outlaw at (202) 358–3144 to schedule an appointment.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* 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 Adobe 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.

Authority: Sec. 6141 of the Elementary and Secondary Education Act of 1965 (ESEA) as amended by Every Student Succeeds Act (ESSA) (20 U.S.C. 7471).

Frank T. Brogan,

Assistant Secretary Office of Elementary and Secondary Education.

[FR Doc. 2019–19164 Filed 9–4–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–478]

Application To Export Electric Energy; Enel Trading North America, LLC

AGENCY: Office of Electricity, Department of Energy (DOE).

ACTION: Notice of application.

SUMMARY: Enel Trading North America, LLC (Applicant or ETNA) has applied for authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before October 7, 2019.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed to: Office of Electricity, Mail Code: OE–20, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585–0350. Because of delays in handling conventional mail, it is recommended that documents be transmitted by overnight mail, by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to 202–586–8008.

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On July 31, 2019, DOE received an application from ETNA for authorization to transmit electric energy from the United States to Canada as a power marketer for a five-year term using existing international transmission facilities.

In its application, the Applicant states that it ''does not have its own transmission or distribution system on

which its exports of energy could have an impact with respect to electric supply.'' The electric energy that the Applicant proposes to export to Canada ''would be surplus energy purchased in wholesale markets using bilateral, voluntary transactions.'' The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214). Five (5) copies of such comments, protests, or motions to intervene should be sent to the address provided above on or before the date listed above.

Comments and other filings concerning ETNA's application to export electric energy to Canada should be clearly marked with OE Docket No. EA–478. An additional copy is to be provided directly to Nicolette Blades, Esq., Enel Green Power North America, Inc., 100 Brickstone Square, Suite 300, Andover, MA 01810.

A final decision will be made on this application after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE determines that the proposed action will not have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above, by accessing the program website at *http://energy.gov/node/11845,* or by emailing Angela Troy at *Angela.Troy@hq.doe.gov.*

Signed in Washington, DC, on August 30, 2019.

Christopher Lawrence,

Management and Program Analyst, Transmission Permitting and Technical Assistance, Office of Electricity.

[FR Doc. 2019–19156 Filed 9–4–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, September 25, 2019; 1:00 p.m.–5:15 p.m.

ADDRESSES: New Mexico Highlands University, Student Center, 800 National Avenue, Las Vegas, New Mexico 87701.

FOR FURTHER INFORMATION CONTACT: Menice Santistevan, Northern New Mexico Citizens' Advisory Board (NNMCAB), 94 Cities of Gold Road, Santa Fe, NM 87506. Phone (505) 995–0393; Fax (505) 989–1752 or Email: *Menice.Santistevan@em.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

- Call to Order
- Welcome and Introductions
- Approval of Agenda
- Old Business
  - Report from NNMCAB Chair
  - Other Items
- New Business
- Election of Chair and Vice-Chair for Fiscal Year 2020
- Update on Chromium Cleanup Project at the Los Alamos National Laboratory
- Break
- Public Comment Period
- Update from New Mexico Environment Department
- Update from EM-Los Alamos Field Office
- Update from NNMCAB Deputy Designated Federal Officer and Executive Director
- Wrap-Up Comments from NNMCAB Members
- Adjourn

Public Participation: The meeting is open to the public. The EM SSAB, Northern New Mexico, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Menice Santistevan at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Menice Santistevan at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Menice Santistevan at the address or telephone number listed above. Minutes and other Board documents are on the internet at: *https://energy.gov/em/nnmcab/meeting-materials.*

Signed in Washington, DC on August 29, 2019.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2019–19122 Filed 9–4–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Biological and Environmental Research Advisory Committee; Meeting

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Biological and Environmental Research Advisory Committee (BERAC). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, October 24, 2019; 8:30 a.m.–5:30 p.m., Friday, October 25, 2019; 8:30 a.m.–12:30 p.m.

ADDRESSES: Canopy by Hilton Washington DC Bethesda North, 940 Rose Avenue, North Bethesda, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Dr. Tristram West, Designated Federal Officer, BERAC, U.S. Department of Energy, Office of Science, Office of

Biological and Environmental Research, SC–23/Germantown Building, 1000 Independence Avenue SW, Washington, DC 20585–1290. Phone (301) 903–5155; Fax (301) 903–5051 or email: *tristram.west@science.doe.gov.* The most current information concerning this meeting can be found on the website: *https://science.osti.gov/ber/berac/Meetings.*

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: To provide advice on a continuing basis to the Director, Office of Science of the Department of Energy, on the many complex scientific and technical issues that arise in the development and implementation of the Biological and Environmental Research Program.

Tentative Agenda Topics:

- News from the Office of Science
- News from the Office of Biological and Environmental Research (BER)
- News from the Biological Systems Science and Climate and Environmental Sciences Divisions
- Report from the Climate and Environmental Sciences Division Committee of Visitors
- Workshop briefing and research topic discussions
- Science talks
- New business
- Public comment

Public Participation: The day and a half meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Tristram West at *tristram.west@science.doe.gov* (email) or (301) 903–5051 (fax). You must make your request for an oral statement at least five business days before the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will be limited to five minutes each.

Minutes: The minutes of this meeting will be available for public review and copying within 45 days at the BERAC website: *https://science.osti.gov/ber/berac/Meetings/BERAC-Minutes.*

Signed in Washington, DC, on August 30, 2019.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2019–19199 Filed 9–4–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration

Defense Programs Advisory Committee; Meeting

AGENCY: Office of Defense Programs, National Nuclear Security Administration, Department of Energy.

ACTION: Notice of closed meeting.

SUMMARY: This notice announces a closed meeting of the Defense Programs Advisory Committee (DPAC). The Federal Advisory Committee Act requires that public notice of meetings be announced in the **Federal Register**. Due to national security considerations, the meeting will be closed to the public and matters to be discussed are exempt from public disclosure under Executive Order 13526 and the Atomic Energy Act of 1954.

DATES: September 25, 2019, 8:30 a.m. to 5:00 p.m.

ADDRESSES: 950 L'Enfant Plaza SW, Suite 110, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Rachel Barnhill, Office of RDT&E (NA–11), National Nuclear Security Administration, U.S. Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585, (202) 586–7183 or email: *rachel.barnhill@nnsa.doe.gov.*

SUPPLEMENTARY INFORMATION:

Background: The DPAC provides advice and recommendations to the Deputy Administrator for Defense Programs on the stewardship and maintenance of the Nation's nuclear deterrent.

Purpose of the Meeting: The purpose of this meeting of the DPAC is to finalize the report on High Performance Computing and discuss the path ahead on new topics.

Type of Meeting: In the interest of national security, the meeting will be closed to the public. The Federal Advisory Committee Act, 5 U.S.C. App.2, section 10(d), and the Federal Advisory Committee Management Regulation, 41 CFR 102–3.155, incorporate by reference the Government in the Sunshine Act, 5 U.S.C. 552b, which, at 552b(c)(1) and (c)(3) permits closure of meetings where restricted data or other classified matters will be discussed. Such data and matters will be discussed at this meeting.

Tentative Agenda: Welcome; reading of final draft of report; discussion of report, as necessary; (tentative) acceptance of report; discussion of next charges; conclusion.

Public Participation: There will be no public participation in this closed meeting. Those wishing to provide written comments or statements to the Committee are invited to send them to Rachel Barnhill at the address listed above.

Minutes: The minutes of the meeting will not be available.

Signed in Washington, DC, on August 30, 2019.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2019–19202 Filed 9–4–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR19–74–000.
Applicants: DTE Gas Company.
Description: Tariff filing per 284.123(b),(e)/: DTE Gas Company Rate Filing to be effective 9/1/2019.
Filed Date: 8/28/19.
Accession Number: 201908285077.
Comments/Protests Due: 5 p.m. ET 9/18/19.

Docket Number: PR19–75–000.
Applicants: DCP Raptor Pipeline, LLC.
Description: Tariff filing per 284.123(b)(2)+(g): DCP Raptor Pipeline, LLC Rate Case to be effective 9/1/2019.
Filed Date: 8/28/19.
Accession Number: 201908285138.
Comments Due: 5 p.m. ET 9/18/19.
284.123(g) Protests Due: 5 p.m. ET 10/28/19.

Docket Numbers: RP19–1488–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Amendment to a Negotiated Rate Agreement—Macquarie to be effective 8/28/2019.
Filed Date: 8/28/19.
Accession Number: 20190828–5000.
Comments Due: 5 p.m. ET 9/9/19.

Docket Numbers: RP19–1489–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Filing to incorporate approved changes (RP19–1057 into RP19–1387) to be effective 8/28/2019.
Filed Date: 8/28/19.
Accession Number: 20190828–5024.
Comments Due: 5 p.m. ET 9/9/19.

Docket Numbers: RP19–1490–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate—Boston to SFE 799788 eff 9–1–19 to be effective 9/1/2019.
Filed Date: 8/28/19.
Accession Number: 20190828–5028.
Comments Due: 5 p.m. ET 9/9/19.

Docket Numbers: RP19–1491–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate—BUG to Emera 799788 eff 9–1–19 to be effective 9/1/2019.
Filed Date: 8/28/19.
Accession Number: 20190828–5034.
Comments Due: 5 p.m. ET 9/9/19.

Docket Numbers: RP19–1492–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: § 4(d) Rate Filing: Fuel Filing on 8–28–19 to be effective 10/1/2019.
Filed Date: 8/28/19.
Accession Number: 20190828–5097.
Comments Due: 5 p.m. ET 9/9/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or 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 date(s). 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: August 29, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–19132 Filed 9–4–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19–500–000]

Northern Natural Gas Company; Notice of Application

Take notice that on August 15, 2019, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124, filed in Docket No. CP19–479–000 an application pursuant to section 7 of the Natural Gas Act (NGA) and Part 157 of the Commission's Regulations, requesting authorization to (1) abandon in-place Northern's A-line located in Otoe, Lancaster, Saunders, Dodge, Burt, Thurston, and Dakota counties, Nebraska, and (2) construct and operate pipeline loops consisting of approximately 4.2 miles of 24-inch-diameter pipeline and associated appurtenances in Otoe and Dodge counties, Nebraska. On August 28, 2019, Northern submitted supplemental information clarifying the separate utility of this project to other Northern projects filed or to be filed with the Commission. Details of this project are more fully set forth in the application which is on file with the Commission and open to public inspection.

The filings may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the documents. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions concerning this application may be directed to Michael T. Loeffler, Senior Director, Certificates and External Affairs, Northern Natural Gas Company, 1111 South 103rd Street, Omaha, Nebraska 68124, or by calling (402) 398–7103.

Specifically, Northern proposes to

(1) abandon in place a total of approximately 44.2 miles of 20-inch-diameter pipeline and approximately 14.8 miles of 16-inch-diameter pipeline on Northern's M581A pipeline system and 58.7 miles of 16-inch-diameter pipeline on the M570A pipeline system (collectively referred to as the A-line) from Northern's Palmyra compressor station near Palmyra, Nebraska, to Northern's Dakota County launcher site near South Sioux City, Nebraska; and

(2) construct and operate

(a) approximately 1.7 miles of new 24-inch-diameter natural gas pipeline loop, with pig launcher and receiver and valve sites, from Northern's existing Palmyra compressor station to a tie-in with its existing C-line in Otoe County, Nebraska; and

(b) 2.5 miles of a new 24-inch-diameter natural gas pipeline loop, with a pig launcher and valve sites, from Northern's existing Fremont compressor station to a tie-in with its existing C-line in Dodge County, Nebraska.

The cost to construct the proposed Palmyra North D-line and the Fremont North D-line loops is estimated at $19,468,116.

Pursuant to section 157.9 of the Commission's rules (18 CFR 157.9), within 90 days of this Notice, the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit five copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to

the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

As of the February 27, 2018 date of the Commission's order in Docket No. CP16–4–001, the Commission will apply its revised practice concerning out-of-time motions to intervene in any new Natural Gas Act section 3 or section 7 proceeding. Persons desiring to become a party to a certificate proceeding are to intervene in a timely manner. If seeking to intervene out-of-time, the movant is required to ''show good cause why the time limitation should be waived,'' and should provide justification by reference to factors set forth in Rule 214(d)(1) of the Commission's Rules and Regulations.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit original and five copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on September 19, 2019.

Dated: August 29, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–19133 Filed 9–4–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2839–015]

Village of Lyndonville Electric Department; 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 a new license for the Great Falls Hydroelectric Project, located on the Passumpsic River in the Town of Lyndon, Caledonia County, Vermont, and has prepared an Environmental Assessment (EA) for the project.

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.

A copy of the EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *http://www.ferc.gov/* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, 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 *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–2839–015.

For further information, contact Patrick Crile at (202) 502–8042 or by email at *patrick.crile@ferc.gov.*

Dated: August 28, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–19069 Filed 9–4–19; 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: ER19–1575–002; ER10–3251–014; ER14–2382–014.
Applicants: Alta Oak Realty, LLC, Oak Creek Wind Power, LLC, ON Wind Energy LLC.
Description: Notice of Non-Material Change in Status of Alta Oak Realty, LLC, et al.
Filed Date: 8/29/19.
Accession Number: 20190829–5044.
Comments Due: 5 p.m. ET 9/19/19.

Docket Numbers: ER19–2697–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: 1st Amended GIA New-Indy Ontario for New-Indy Ontario Proj to be effective 8/29/2019.
Filed Date: 8/28/19.
Accession Number: 20190828–5159.
Comments Due: 5 p.m. ET 9/18/19.

Docket Numbers: ER19–2698–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 2463R2 KEPCO NITSA NOA to be effective 8/1/2019.
Filed Date: 8/29/19.
Accession Number: 20190829–5020.
Comments Due: 5 p.m. ET 9/19/19.

Docket Numbers: ER19–2699–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 3055R1 Associated Electric Cooperative, Inc. NITSA NOA to be effective 8/1/2019.
Filed Date: 8/29/19.
Accession Number: 20190829–5027.
Comments Due: 5 p.m. ET 9/19/19.

Docket Numbers: ER19–2700–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 1148R26 American Electric Power

NITSA and NOA to be effective 8/1/2019.

Filed Date: 8/29/19.

Accession Number: 20190829–5047.

Comments Due: 5 p.m. ET 9/19/19.

Docket Numbers: ER19–2701–000.

Applicants: Louisville Gas and Electric Company.

Description: § 205(d) Rate Filing: 2019 Amd Attachment Q Amd Rstd RC Agreement to be effective 9/1/2019.

Filed Date: 8/29/19.

Accession Number: 20190829–5055.

Comments Due: 5 p.m. ET 9/19/19.

Docket Numbers: ER19–2702–000.

Applicants: Oceanside Power LLC.

Description: Notice of Cancellation of Market-Based Rate Tariff of Oceanside Power LLC.

Filed Date: 8/27/19.

Accession Number: 20190829–0001.

Comments Due: 5 p.m. ET 9/17/19.

Docket Numbers: ER19–2703–000.

Applicants: PJM Interconnection, L.L.C., North Carolina Electric Membership Corporation.

Description: § 205(d) Rate Filing: PJM and NCEMC Submit Correction to Revised Service Agreement No. 3347 to be effective 7/1/2019.

Filed Date: 8/29/19.

Accession Number: 20190829–5097.

Comments Due: 5 p.m. ET 9/19/19.

Docket Numbers: ER19–2704–000.

Applicants: Idaho Power Company.

Description: § 205(d) Rate Filing: IPC–PAC JOOA Dated August 2019—Changes to Reflect One Mile, etc. to be effective 10/28/2019.

Filed Date: 8/29/19.

Accession Number: 20190829–5116.

Comments Due: 5 p.m. ET 9/19/19.

Docket Numbers: ER19–2705–000.

Applicants: Dominion Energy South Carolina, Inc.

Description: § 205(d) Rate Filing: Rate Schedule No. 228 Migration and OATT Attachment C Corrections to be effective 6/15/2019.

Filed Date: 8/29/19.

Accession Number: 20190829–5121.

Comments Due: 5 p.m. ET 9/19/19.

Docket Numbers: ER19–2706–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: Idaho Power JOOA Concurrence RS 708 to be effective 10/28/2019.

Filed Date: 8/29/19.

Accession Number: 20190829–5134.

Comments Due: 5 p.m. ET 9/19/19.

Docket Numbers: ER19–2707–000.

Applicants: Poseidon Wind, LLC.

Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization, Request for Related Waivers to be effective 10/29/2019.

Filed Date: 8/29/19.

Accession Number: 20190829–5140.

Comments Due: 5 p.m. ET 9/19/19.

Docket Numbers: ER19–2708–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Revisions to Sch. 12–Appx A: July 2019 RTEP, 30-day Comments due to be effective 11/27/2019.

Filed Date: 8/29/19.

Accession Number: 20190829–5156.

Comments Due: 5 p.m. ET 9/19/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or 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: August 29, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–19131 Filed 9–4–19; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2019–0075; FRL–9992–81]

Certain New Chemicals; Receipt and Status Information for July 2019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to make information publicly available and to publish information in the **Federal Register** pertaining to submissions under TSCA Section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 07/01/2019 to 07/31/2019.

DATES: Comments identified by the specific case number provided in this document must be received on or before October 7, 2019.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2019–0075, and the specific case number for the chemical substance related to your comment, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jim Rahai, Information Management Division (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8593; email address: *rahai.jim@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 07/01/2019 to 07/31/2019. The Agency

is providing notice of receipt of PMNs, SNUNs and MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its website about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its website at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

B. What is the Agency's authority for taking this action?

Under the TSCA, 15 U.S.C. 2601 *et seq.,* a chemical substance may be either an ''existing'' chemical substance or a ''new'' chemical substance. Any chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a ''new chemical substance,'' while a chemical substance that is listed on the TSCA Inventory is classified as an ''existing chemical substance.'' (See TSCA section 3(11).) For more information about the TSCA Inventory go to: *https://www.epa.gov/tsca-inventory.*

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for ''test marketing'' purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to: *http://www.epa.gov/oppt/newchems.*

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the **Federal Register** certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting confidential business information (CBI).* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending or concluded. In 1995, the Agency modified its approach and streamlined the information published in the **Federal Register** after providing notice of such changes to the public and an opportunity to comment (See the **Federal Register** of May 12, 1995, (60 FR 25798) (FRL–4942–7). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of TSCA section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its website about cases reviewed under the amended TSCA, including the TSCA section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its website at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs that have passed an initial screening by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the notices screened by EPA during this period: The EPA case number assigned to the notice that indicates whether the submission is an initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (*i.e.,* domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter ''A'' (*e.g.,* P–18–1234A). The version column designates submissions in sequence as ''1'', ''2'', ''3'', etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier version(s) were rejected as incomplete or invalid submissions. Note also that

future versions of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

TABLE I—PMN/SNUN/MCANS APPROVED* FROM 07/01/2019 TO 07/31/2019

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
J–19–0024	1	6/28/2019	CBI	(G) Ethanol production	(G) Biofuel producing Saccharomyces cerevisiae modified, genetically stable.
J–19–0025	1	6/28/2019	CBI	(G) Ethanol production	(G) Biofuel producing Saccharomyces cerevisiae modified, genetically stable.
P–16–0354A	4	7/8/2019	CBI	(G) Intermediate	(G) Esteramine.
P–16–0354A	5	7/9/2019	CBI	(G) Intermediate	(G) Esteramine.
P–16–0355A	4	7/8/2019	CBI	(G) Intermediate	(G) Esteramine.
P–16–0355A	5	7/9/2019	CBI	(G) Intermediate	(G) Esteramine.
P–17–0003A	9	6/25/2019	CBI	(G) Printing ink applications	(G) Styrene(ated) copolymer with alkyl(meth)acrylate, and (meth)acrylic acid.
P–17–0346A	6	7/2/2019	CBI	(G) Destructive use	(G) triarylalkyl phosphonium halide salt.
P–17–0346A	7	7/8/2019	CBI	(G) Destructive use	(G) triarylalkyl phosphonium halide salt.
P–17–0375A	5	6/30/2019	CBI	(G) Paint additive	(G) 2-Oxepanone, polymer with diisocyanatohexane, alkyl-((hydroxyalkyl)-alkanediol and isocyanato-(isocyanatoalkyl)-trialkylcyclohexane, di-alkyl malonate- and polyalkylene glycol mono-Me ether-blocked, reaction products with (methylalkyl)-propanamine.
P–17–0383A	2	7/17/2019	Toagosei America, Inc.	(G) Binder	(G) Alkenoic acid, polymer will ammonium alkenoate (1:1) and polyalkylenediol diacrylate.
P–17–0387A	5	7/8/2019	CBI	(G) Paint	(G) Dicarboxylic acids, polymers with alkanoic acid, alkanediol, susbtituted-alkylalkanoic acid, substituted alkyl carbomonocyle, alkanedioic acid and alkanediol, alkanolamine blocked, compds with alkanolamine.
P–17–0388A	5	7/8/2019	CBI	(G) Paint	(G) Dicarboxylic acids, polymers with alkanoic acid, alkanediol, susbtituted-alkylalkanoic acid, substituted alkyl carbomonocyle, alkanedioic acid and alkanediol, alkanolamine blocked, compds with alkanolamine.
P–17–0398A	12	6/28/2019	Nexus Fuels	(G) Component of complex formulations for blending.	(G) Branched Cyclic and Linear Hydrocarbons from Plastic Depolymerization.
P–17–0399A	12	6/28/2019	Nexus Fuels	(G) Stock use	(G) Alkane, Alkene, Styrenic Compounds Derived from Plastic Depolymerization.
P–17–0400A	6	7/8/2019	CBI	(G) Rubber products	(G) Terpolymer of Vinylidene fluoride, Tetrafluoroehylene and 2,3,3,3-Tetrafluoropropene.
P–17–0404A	2	7/17/2019	Arlanxeo	(G) Intermediate completely used on site	(G) Nitrile-butadiene-acrylate-terpolymers.
P–17–0405A	4	7/3/2019	CBI	(G) Oil and gas well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0406A	4	7/3/2019	CBI	(G) Oil and gas well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0407A	3	7/3/2019	CBI	(G) Well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0408A	2	7/3/2019	CBI	(G) Well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0409A	3	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0409A	2	6/27/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0410A	2	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0411A	2	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0412A	2	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0414A	3	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0415A	3	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0416A	3	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0417A	3	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0418A	3	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0420A	4	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0421A	3	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0422A	3	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid.
P–17–0423A	2	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated benzoic acid ethyl ester.
P–17–0441A	2	6/28/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0442A	2	7/2/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0443A	3	7/2/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0444A	2	7/2/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0445A	3	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0446A	2	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0447A	2	6/27/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0447A	3	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0448A	2	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0449A	2	7/3/2019	CBI	(G) Monitor well performance	(G) halogenated sodium benzoate.
P–17–0450A	2	7/3/2019	CBI	(G) Monitor well performance	(G) Halogenated benzoic acid.
P–18–0001A	11	6/27/2019	Nexus Fuels	(G) Additive	(G) Carbon compound derived from plastic depolymerization.
P–18–0003A	5	6/27/2019	ETNA Products, Inc	(S) Lubricant for metal working applications	(G) fatty acids, diesters with dihydroxyalkane, Fatty acids, esters with dihydroxyalkane.
P–18–0009A	6	7/22/2019	CBI	(G) Lubricant additive	(G) Phosphonic acid, dimethyl ester, polymer with alkyl diols.

TABLE I—PMN/SNUN/MCANs APPROVED* FROM 07/01/2019 TO 07/31/2019—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–18–0012A	4	7/12/2019	CBI	(G) Adhesives	(G) Polyester polyol.
P–18–0028A	6	6/28/2019	Nexus Fuels	(G) Feedstock, blending	(G) Branched cyclic and linear hydrocarbons from plastic depolymerization.
P–18–0028A	7	7/2/2019	Nexus Fuels	(G) Feedstock, blending	(G) Branched cyclic and linear hydrocarbons from plastic depolymerization.
P–18–0121A	2	7/29/2019	Kyodo Yushi USA, Inc.	(G) Additive for Lubricating Grease	(S) Benzene, 1,1'-oxybis-, branched eicosyl derivs.
P–18–0150A	4	7/18/2019	CBI	(G) Component of an industrial coating	(G) Tertiary amine, compounds with amino sulfonic acid blocked aliphatic isocyanate homopolymer.
P–18–0165	5	7/17/2019	Cabot Corporation	(S) Chemical intermediate	(G) 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy-substituted butyl amide, sodium salts.
P–18–0166	5	7/17/2019	Cabot Corporation	(S) Chemical Intermediate	(G) 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy- substituted butyl [3-[2-[1-[[(2-methoxyphenyl)amino]carbonyl]-2-oxopropyl]diazenyl]phenyl]substituted, sodium salts.
P–18–0167A	3	7/17/2019	Cabot Corporation	(S) Chemical intermediate	(G) Butanamide, 2-[2-[(substitutued phenyl)diazenyl]-N-(2-methoxyphenyl)-3-oxo-.
P–18–0175A	7	7/29/2019	Hexion, Inc	(S) Food can coating and Non-food contact can coating.	(S) Formaldehyde, polymer with 4-(1,1-dimethylethyl)phenol and phenol, Bu ether.
P–18–0190	2	7/17/2019	Cabot Corporation	(S) Pigment Dispersing Aid	(G) 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy-substituted butyl amide, polymers with epichlorohydrin and trimethylolpropane, sodium salts.
P–18–0191	2	7/17/2019	Cabot Corporation	(S) Pigment Dispersing Aid	(G) 2,5-Furandione, polymer with ethenylbenzene, 4-hydroxy-substitutedbutyl [3-[2-[1-[[(substitutedphenyl)amino]carbonyl]-2-oxopropyl]diazenyl]phenyl]methyl amide, polymers with epichlorohydrin and trimthylolpropane, sodium salts.
P–18–0214A	3	7/22/2019	CBI	(G) Curing agent	(G) Polycyclic substituted alkane, polymer with cyclicalkylamine, epoxide, and polycyclic epoxide ether, reaction products with dialkylamine substituted alkyl amine.
P–18–0215A	3	7/22/2019	CBI	(G) Curing agent	(G) Polycyclic alkane, polymer with monocyclic amine, polycyclic epoxide ether, reaction products with dialkylamine alkyl amine.
P–18–0216A	3	7/22/2019	CBI	(G) Curing agent	(G) Polycyclic substituted alkane, polymer with epoxide, reaction products with cyclicalkylamine and dialkylamine substituted alkyl amine.
P–18–0223A	2	7/12/2019	Clariant Corporation	(S) Selectivity improver for catalysts used in the production of polyolefins.	(G) Alkane, bis(alkoxymethyl)-dimethyl-.
P–18–0241A	4	6/27/2019	CBI	(G) Additive for automotive coating	(G) 2-Propenoic acid, 2-methyl-, methyl ester, polymer with ethenylbenzene, ethyl 2-propenoate, 2-oxiranylmethyl 2-methyl-2-propenoate and 1,2-propanediol mono(2-methyl-2-propenoate), reaction products with diethanolamine, polymers with substituted-alkyl acrylate, formates (salts).
P–18–0242A	4	6/27/2019	CBI	(S) Withdrawn	(S) Substance withdrawn.
P–18–0243A	4	6/27/2019	CBI	(S) Withdrawn	(S) Substance withdrawn.
P–18–0244A	4	6/27/2019	CBI	(G) Additive for automotive coating	(G) 2-Propenoic acid, 2-methyl, methyl ester, polymer with ethenylbenzene, ethyl 2-propenoate, 2-oxiranylmethyl 2-methyl-2-propenoate and 1,2-propanediol mono(2-methyl-2-propenoate), reaction products with diethanolamine, polymers with substituted-alkyl methacrylate, formates (salts).
P–18–0245A	4	6/27/2019	CBI	(G) Additive for automotive coating	(G) 2-Propenoic acid, 2-methyl-, methyl ester, polymer with ethenylbenzene, ethyl 2-propenoate, 2-oxiranylmethyl 2-methyl-2-propenoate, and 1,2-propanediol mono(2-methyl-2-propenoate), reaction products with diethanolamine, polymers with alkylene glycol monoacrylate, formates (salts).
P–18–0246A	4	6/27/2019	CBI	(S) Withdrawn	(S) Substance withdrawn.
P–18–0257A	3	7/1/2019	Everris NA, Inc	(S) Inorganic fertilizer	(S) Phosphoric acid, potassium salt (2:3).
P–18–0267A	3	7/22/2019	CBI	(G) Curing agent	(G) Branched alkanoic acid, epoxy ester, reaction products with monocyclic dialkylamine and polycyclic alcohol epoxy polymer.
P–18–0268A	3	7/22/2019	CBI	(G) Curing agent	(G) Branched alkanoic acid, epoxy ester, reaction products with monocyclicdialkanamine and polycyclic dialkanol ether polymer.

TABLE I—PMN/SNUN/MCANs APPROVED* FROM 07/01/2019 TO 07/31/2019—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–18–0269A	3	7/22/2019	CBI	(G) Curing agent	(G) Branched alkanoic acid, epoxy ester, reaction products with monocyclicalkanamine, polycyclic alcohol ether homopolymer, and polycyclic alcohol epoxy polymer.
P–18–0292A	4	7/21/2019	CBI	(G) Use in print resins	(G) alkanediol, polymer with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, alkylaminoalkyl methacrylate-blocked.
P–18–0300A	2	2/8/2019	CBI	(S) Additive for automatic dishwashing detergent.	(G) Heteromonocycle, alkenoic 1:1 salt, polymer with alpha-(2-methyl-1-oxo-2-propen-1-y)l-omegamethoxypoly(oxy-1,2-ethanediyl) and methyl-alkenoic acid.
P–18–0334A	2	7/12/2019	Sirrus, Inc	(S) Intermediate use	(S) Propanedioic acid, 1,3-dihexyl ester.
P–18–0335A	2	7/12/2019	Sirrus, Inc	(S) Intermediate use	(S) Propanedioic acid, 1,3-dicyclohexyl ester.
P–18–0336A	2	6/26/2019	Sirrus, Inc	(S) Intermediate use	(S) Propanedioic acid, 2,2-bis(hydroxymethyl)-, 1,3-dihexyl ester.
P–18–0336A	3	7/1/2019	Sirrus, Inc	(S) Intermediate use	(S) Propanedioic acid, 2,2-bis(hydroxymethyl)-, 1,3-dihexyl ester.
P–18–0337A	2	6/26/2019	Sirrus, Inc	(S) Intermediate use	(S) Propanedioic acid, 2,2-bis(hydroxymethyl)-, 1,3-dicyclohexyl ester.
P–18–0337A	3	7/1/2019	Sirrus, Inc	(S) Intermediate use	(S) Propanedioic acid, 2,2-bis(hydroxymethyl)-, 1,3-dicyclohexyl ester.
P–18–0341A	4	7/2/2019	CBI	(G) Component in coatings	(G) Alkane dicarboxylic acid, polymer with alkoxylated polyalcohol, alkyl polyglycol, alkyl dialcohol, and functionalized carboxylic acid.
P–18–0341A	5	7/2/2019	CBI	(G) Component in coatings	(G) Alkane dicarboxylic acid, polymer with alkoxylated polyalcohol, alkyl polyglycol, alkyl dialcohol, and functionalized carboxylic acid.
P–18–0341A	6	7/30/2019	CBI	(G) Component in coatings	(G) Alkane dicarboxylic acid, polymer with alkoxylated polyalcohol, alkyl polyglycol, alkyl dialcohol, and functionalized carboxylic acid.
P–18–0342A	4	7/2/2019	CBI	(G) Component in coatings	(G) Alkane dicarboxylic acid, polymer with alkyl polyglycol, alkyl dialcohol, and functionalized carboxylic acid.
P–18–0342A	5	7/2/2019	CBI	(G) Component in coatings	(G) Alkane dicarboxylic acid, polymer with alkyl polyglycol, alkyl dialcohol, and functionalized carboxylic acid.
P–18–0342A	6	7/30/2019	CBI	(G) Component in coatings	(G) Alkane dicarboxylic acid, polymer with alkyl polyglycol, alkyl dialcohol, and functionalized carboxylic acid.
P–18–0343A	4	7/2/2019	CBI	(G) Component in coatings	(G) Alkane dicarboxylic acid, polymer with alkoxylated polyalcohol, and alkyl dialcohol, (hydroxy alkyl) ester.
P–18–0343A	5	7/2/2019	CBI	(G) Component in coatings	(G) Alkane dicarboxylic acid, polymer with alkoxylated polyalcohol, and alkyl dialcohol, (hydroxy alkyl) ester.
P–18–0343A	6	7/30/2019	CBI	(G) Component in coatings	(G) Alkane dicarboxylic acid, polymer with alkoxylated polyalcohol, and alkyl dialcohol, (hydroxy alkyl) ester.
P–18–0344A	4	7/2/2019	CBI	(G) Component in coatings	(G) Aromatic dicarboxylic acid, polymer with alkane dicarboxylic acid, alkoxylated polyalcohol, and alkyl dialcohol.
P–18–0344A	5	7/2/2019	CBI	(G) Component in coatings	(G) Aromatic dicarboxylic acid, polymer with alkane dicarboxylic acid, alkoxylated polyalcohol, and alkyl dialcohol.
P–18–0344A	6	7/30/2019	CBI	(G) Component in coatings	(G) Aromatic dicarboxylic acid, polymer with alkane dicarboxylic acid, alkoxylated polyalcohol, and alkyl dialcohol.
P–18–0394A	3	7/30/2019	CBI	(G) Chemical intermediate	(G) substituted benzylic ether polyethylene glycol alkyl ether derivative.
P–18–0403A	2	7/15/2019	Clariant Plastics & Coatings USA, Inc.	(S) Dispersing agent for pigments, paints, and coatings.	(S) 2-Propenoic acid, 2-methyl-, butyl ester, polymer with 2-(dimethylamino)ethyl 2-methyl-2-propenoate and 2-ethylhexyl 2-methyl-2-propenoate.
P–19–0009A	5	7/8/2019	Allnex USA, Inc	(S) The PMN substance is used as a coating resin additive for corrosion protection.	(G) Carbonmonocycles, polymer with haloalkyl substituted heteromonocycle and hydrohydroxypoly[oxy(alkyl-alkanediyl)], dialkylalkanediamine-terminated, hydroxyalkylated, acetates (salts).
P–19–0011	2	7/17/2019	Shin Etsu Silicones of America.	(G) Additive to the EPDM rubber compounds	(G) Polysulfides, bis[3-(trialkoxysilyl)propyl].
P–19–0012A	11	6/13/2019	CBI	(S) Resin component for the polyisocyanurate, and resin component in specialty polyurethane kits and systems for aerospace and military applications.	(G) Benzenedicarboxylic acid, rection products with isobenzofurandione and diethylene glycol.

TABLE I—PMN/SNUN/MCANs APPROVED* FROM 07/01/2019 TO 07/31/2019—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–19–0024A ...	5	7/2/2019	Sales and Distribution Services, Inc.	(S) Hot Mix Asphalt Application: The PMN compound will be used as asphalt additive for hot mix (HMA) as well as cold mix (CMA) asphalt applications. The PMN substance chemically reacts with the surface of the aggregate and changes surface characteristics of aggregate from hydrophilic to hydrophobic. This change provides stronger bonding between asphalt and aggregates and reduces the potential for stripping away asphalt binder from an aggregate due to water. Asphalt Emulsion Application: The PMN substance is water soluble and can be used as an asphalt emulsion in road construction. This additive provides better bonding with ground surface, quick drying and reduced tire pickup of the asphalt emulsion by application equipment.	(S) 1-Octadecanaminium, N,N-dimethyl-N-[3-(trimethoxysilyl)propyl]-, chloride (1:1) , reaction products with water, Trimethoxy(propyl) silane, Trimethoxy(methyl)silane, Tetraethyl orthosilicate and ethane-1,2-diol.
P–19–0024A ...	6	7/3/2019	Sales and Distribution Services.	(S) Hot Mix Asphalt Application: The PMN compound will be used as asphalt additive for hot mix (HMA) as well as cold mix (CMA) asphalt applications. The PMN substance chemically reacts with the surface of the aggregate and changes surface characteristics of aggregate from hydrophilic to hydrophobic. This change provides stronger bonding between asphalt and aggregates and reduces the potential for stripping away asphalt binder from an aggregate due to water; Waterproofing Application: The PMN substance is expected to be used in waterproofing of building materials, including cementitious material, masonry, concrete, plaster, bricks, etc. It is initially intended to be used at a maximum of 5 sites by trained commercial applicators. The PMN substance is modification of a quaternary silane compound by a hydrolysis reaction with other silanes to make it an oligomeric compound. These quaternary silane products have been manufactured and marketed for waterproofing uses for over 35 years. The solution of PMN substance in water is applied as a waterproofing sealer for building materials by spray application; Asphalt Emulsion Application: The PMN substance is water soluble and can be used as an asphalt emulsion in road construction. This additive provides better bonding with ground surface, quick drying and reduced tire pickup of the asphalt emulsion by application equipment.	(S) 1-Octadecanaminium, N,N-dimethyl-N-[3-(trimethoxysilyl)propyl]-, chloride (1:1) , reaction products with water, Trimethoxy(propyl) silane, Trimethoxy(methyl)silane, Tetraethyl orthosilicate and ethane-1,2-diol.
P–19–0034A ...	5	7/26/2019	CBI	(G) Contained use as a component of tires	(G) Metal, bis(2,4-pentanedionato-kO2,kO4)-, (T–4)-.
P–19–0037A ...	2	7/11/2019	CBI	(G) Chemical intermediate	(G) D-Glucaric acid, mixed alkali metal salt.
P–19–0051A ...	6	7/29/2019	CBI	(G) UV curable inks	(G) 1,3-Propanediamine, N1,N1-dimethyl-, polymers with alkylene glycol ether with alkyltriol (3:1) mixed acrylates and adipates, and alkylene glycol monoacrylate ether with alkyltriol (3:1).
P–19–0058	2	7/8/2019	Essential Industries, Inc.	(S) Wood Coating	(S) Butanoic acid, 3-oxo-, 2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl ester, polymer with butyl 2-propenoate, ethenylbenzene, methyl 2-methyl-2-propenoate and 2-methyl-2-popenoic acid, ammonium salt.
P–19–0059	3	7/30/2019	Essential Industries, Inc.	(S) Wood Coating	(S) Butanoic acid, 3-oxo-, 2-[(2-methyl-1-oxo-1-propen-1-yl)oxy]ethyl ester, polymer with butyl 2-propenoate, ethenylbenzene, 1,1'-[(1-methyl-1,2-ethanediyl)bis[oxy(methyl-2,1-ethanediyl)]] di-2-propenoate, methyl 2-methyl-2-propenoate and 2-methyl-2-propenoic acid, ammonium salt.
P–19–0064A ...	3	7/11/2019	The Sherwin Williams Company.	(G) Polymeric film former for coatings	(G) 4,4'-methylenebis[2,6-dimethyl phenol] polymer with 2-(chloromethyl)oxirane, 1,4-benzyl diol, 2-methyl-2-propenoic acid, butyl 2-methyl 2-propenoate, ethyl 2-methyl 2-propenoate, and ethyl 2-propenoate, reaction products with 2-(dimethylamino) ethanol.
P–19–0077A ...	3	7/10/2019	CBI	(G) Agricultural	(G) alkenylamide.
P–19–0077A ...	4	7/11/2019	CBI	(G) Agricultural	(G) alkenylamide.

TABLE I—PMN/SNUN/MCANs APPROVED* FROM 07/01/2019 TO 07/31/2019—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–19–0088A	2	7/17/2019	CBI	(G) Feedstock for amine recovery	(S) Ethanamine, N-ethyl-, 2-hydroxy-1,2,3-propanetricarboxylate (1:?).
P–19–0095A	4	6/28/2019	CBI	(G) Consumer Disposables, Polymer Sheet, and Durable Goods.	(G) Poly hydroxy alkanoate.
P–19–0099A	3	7/10/2019	Essential Industries, Inc.	(S) Clear coat for wood	(S) Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with dimethyl carbonate, 1,2-ethanediamine, 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 1,6-hexanediol and 1,1'-methylenebis[4-isocyanatocyclohexane], compd. with N,N-diethylethanamine.
P–19–0101A	5	7/16/2019	CBI	(G) Monitor well performance	(G) Halogenated alkylbenzoic acid, ethyl ester.
P–19–0111	2	7/1/2019	SHIN–ETSU MICROSI	(G) Contained use for microlithography for electronic device manufacturing.	(G) Dibenzotheiophenium, aryl substituted trifluoro-hydroxy-(triheterosubstitutedalkyl)alkaoate (1:1).
P–19–0117A	4	7/18/2019	CBI	(G) Additive	(G) Polycyclic amine, reaction products with polyalkylalkene, polymers.
P–19–0118A	2	7/2/2019	CBI	(G) Component of lubricant	(G) Substituted polyalkylenepoly, reaction products with alkene polymer.
P–19–0121	2	7/11/2019	H.B. Fuller Company	(S) Industrial adhesives	(G) Plant based oils, polymer with 1,1'-methylenebis[4-isocyanatobenzene], pentaerythritol, phthalic esters, polypropylene glycol and polypropylene glycol ether with glycerol (3:1).
P–19–0122	1	6/28/2019	CBI	(G) Reactant monomer in a polymer for industrial use.	(G) Alkylamidoethyl acrylate.
P–19–0123	1	6/28/2019	CBI	(G) Reactant monomer in a polymer for industrial use.	(G) Alkylamidoethyl acrylate.
P–19–0124	1	6/28/2019	SEFA Group, Inc	(S) Additive for polymers: *e.g.,* rubber, plastics, adhesives, coatings and sealants.	(G) Ashes (residues), reaction products with alkenetrialkoxysilane and silicic acid (H4SiO4) tetra-Et ester.
P–19–0124A	2	7/11/2019	SEFA Group, Inc	(S) Additive for polymers: *e.g.,* rubber, plastics, adhesives, coatings and sealants.	(G) Ashes (residues), reaction products with alkenetrialkoxysilane and silicic acid (H4SiO4) tetra-Et ester.
P–19–0125	1	6/28/2019	SEFA Group, Inc	(S) Additive for polymers: *e.g.,* rubber, plastics, adhesives, coatings and sealants.	(G) Ashes (residues), reactions products with alkenyltrialkoxysilane, silicic acid (H4SiO4) tetra-Et ester and trialkoxyalkylsilane.
P–19–0125A	2	7/11/2019	SEFA Group, Inc	(S) Additive for polymers: *e.g.,* rubber, plastics, adhesives, coatings and sealants.	(G) Ashes (residues), reactions products with alkenyltrialkoxysilane, silicic acid (H4SiO4) tetra-Et ester and trialkoxyalkylsilane.
P–19–0126	1	6/28/2019	SEFA Group, Inc	(S) Additive for polymers: *e.g.,* rubber, plastics, adhesives, coatings and sealants.	(G) Ashes (residues), reaction products with 1-alkenyl-N-(alkenyldialkylsilyl)-1,1-dialkylsilanamine.
P–19–0126A	2	7/11/2019	SEFA Group, Inc	(S) Additive for polymers: *e.g.,* rubber, plastics, adhesives, coatings and sealants.	(G) Ashes (residues), reaction products with 1-alkenyl-N-(alkenyldialkylsilyl)-1,1-dialkylsilanamine.
P–19–0127	1	6/28/2019	SEFA Group, Inc	(S) Additive for polymers: *e.g.,* rubber, plastics, adhesives, coatings and sealants.	(G) Ashes (residues), reaction products with alkenyltrialkoxysilane, silicic acid (H4SiO4) tetra-Et ester and (trialkoxysilyl)carbomonocycle.
P–19–0127A	2	7/11/2019	SEFA Group, Inc	(S) Additive for polymers: *e.g.,* rubber, plastics, adhesives, coatings and sealants.	(G) Ashes (residues), reaction products with alkenyltrialkoxysilane, silicic acid (H4SiO4) tetra-Et ester and (trialkoxysilyl)carbomonocycle.
P–19–0128	1	6/28/2019	SEFA Group, Inc	(S) Additive for polymers: *e.g.,* rubber, plastics, adhesives, coatings and sealants.	(G) Ashes (residues), reaction products with alkenyltrialkoxysilane, silicic acid (H4SiO4) tetra-Et ester and 1,1,1-trialkyll-N-(trialkylsilyl)silanamine.
P–19–0128A	2	7/11/2019	SEFA Group, Inc	(S) Additive for polymers: *e.g.,* rubber, plastics, adhesives, coatings and sealants.	(G) Ashes (residues), reaction products with alkenyltrialkoxysilane, silicic acid (H4SiO4) tetra-Et ester and 1,1,1-trialkyll-N-(trialkylsilyl)silanamine.
P–19–0129	1	6/28/2019	SEFA Group, Inc	(S) Additive for polymers: *e.g.,* rubber, plastics, adhesives, coatings and sealants.	(G) Ashes (residues), reactions products with alkenyltrialkoxysilane, silicic acid (H4SiO4) tetra-Et ester and trialkoxyalkylsilane.
P–19–0129A	2	7/11/2019	SEFA Group, Inc	(S) Additive for polymers: *e.g.,* rubber, plastics, adhesives, coatings and sealants.	(G) Ashes (residues), reactions products with alkenyltrialkoxysilane, silicic acid (H4SiO4) tetra-Et ester and trialkoxyalkylsilane.
P–19–0130	2	7/8/2019	CBI	(G) Dye	(G) Aminohydroxy naphthalenesulfonic acid, coupled with diazotized[(aminophenyl)sulfonyl]ethyl hydrogen sulfate and diazotized amino[[(sulfooxy)ethyl]sulfonyl]benzenesulfonic acid, salts.
P–19–0130A	3	7/11/2019	CBI	(G) Dye	(G) Aminohydroxy naphthalenesulfonic acid, coupled with diazotized[(aminophenyl)sulfonyl]ethyl hydrogen sulfate and diazotized amino[[(sulfooxy)ethyl]sulfonyl]benzenesulfonic acid, salts.
P–19–0131	2	7/17/2019	CBI	(G) Additive for horizontal oil drilling	(G) Isoalkylaminium, N-isoalkyl,-N, N-dimethyl chloride.

TABLE I—PMN/SNUN/MCANS APPROVED* FROM 07/01/2019 TO 07/31/2019—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–19–0132	1	7/15/2019	Allnex USA, Inc.	(S) Adhesion-enhancing resin for wood applications.	(G) Fatty acid, polymer with alkanedioic acid dialkyl ester, alkanoic acid, oxo alkyl ester, substituted carbomonocycle, alkyl substituted alkanediol, and alkylol substituted alkane.
P–19–0133	1	7/18/2019	SHIN–ETSU MICROSI	(G) Contained use for microlithography for electronic device manufacturing.	(G) Heterotrisubstituted-bile acid, 1-(difluorosulfomethyl)-2,2,2-trifluoroethyl ester, ion(1-), (5)-, triphenylsulfonium (1:1).
P–19–0136	1	7/23/2019	CBI	(S) Intermediate	(G) iso-alkylamine, N-isoalkyl-N-methyl.
P–19–0138	2	7/25/2019	CBI	(G) Intermediate	(G) Perfluorodioxaalkanoyl fluoride.
P–19–0139	1	7/26/2019	CBI	(G) Intermediate	(G) Perfluoro-2-methyl-trioxaalkanoyl fluoride.
P–19–0140	1	7/29/2019	CBI	(G) Intermediate	(G) Perfluorodioxaalkyl vinyl ether.
SN–19–0004A	5	6/7/2019	CBI	(S) A lubricating agent used in the production of automotive disc brakes.	(G) Pitch coke.

* The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission prior to the start of the 90-day review period, and in no way reflects the final status of a complete submission review.

In Table II of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs that have passed an initial screening by EPA during this period: The EPA case number assigned to the NOC including whether the submission was an initial or amended submission, the date the NOC was received by EPA, the date of commencement provided by the submitter in the NOC, a notation of the type of amendment (*e.g.,* amendment to generic name, specific name, technical contact information, etc.) and chemical substance identity.

TABLE II—NOCS APPROVED * FROM 07/01/2019 TO 07/31/2019

Case No.	Received date	Commencement date	If amendment, type of amendment	Chemical substance
J–18–0002A	7/16/2019	6/19/2018	Provided CBI substantiation	(G) Biofuel producing Saccharomyces cerevisiae modified, genetically stable.
J–18–0028	7/19/2019	6/24/2019	N	(S) Genetically engineered yeast FS0205.
J–18–0028A	7/24/2019	6/24/2019	Removed CAS#	(S) Genetically modified yeast.
J–18–0028A	7/26/2019	6/24/2019	Revised generic name	(S) Genetically modified yeast FS0205.
J–18–0028A	7/30/2019	6/24/2019	Revised generic name	(S) Saccharomyces cerevisiae FS0205.
P–02–0796A	7/29/2019	2/13/2018	Provided CBI substantiation	(G) Polyglycerin alkyl ether.
P–16–0420	7/17/2019	7/6/2019	N	(G) Dimethylcyclohexene propanol.
P–16–0420A	7/19/2019	7/6/2019	Provided CBI substantiation	(G) Dimethylcyclohexene propanol.
P–17–0382	7/9/2019	6/20/2019	N	(S) Amides, tallow, N,N-bis(2-hydroxypropyl).
P–18–0048	7/3/2019	6/25/2019	N	(S) (2-Butoxyethoxy)acetic acid.
P–18–0048A	7/9/2019	6/25/2019	Revised chemical name	(S) Acetic acid, 2-(2-butoxyethoxy)-.
P–18–0120	7/2/2019	7/2/2019	N	(S) 1H-Pyrrole-2,5-dione, 1,1′-C36-alkylenebis-.
P–18–0129A	7/2/2019	5/28/2019	Provided CBI substantiation	(S) Benzenepropanal, .alpha.,.alpha.,3-trimethyl-.
P–18–0168A	7/2/2019	4/2/2019	Revised generic name	(G) Alkoxylated amine substituted triaryl methane.
P–18–0266	7/19/2019	6/26/2019	N	(S) Alkanes, C20–45-branched and linear.
P–18–0322	7/22/2019	7/6/2019	N	(G) Heteromonocycle, 4,6-dimethyl-2-(1-phenylethyl)-,.
P–18–0404	7/5/2019	7/5/2019	N	(G) Alkylmultiheteroatom,2-functionalisedalkyl-2-hydroxyalkyl-, polymer with alkylheteroatom-multialkylfunctionalised carbomonocyleheteroatom and multiglycidylether difunctionalised polyalkylene glycol.
P–19–0056	7/3/2019	7/1/2019	N	(S) Alkanes, C8–20-branched and linear.
P–19–0060	7/29/2019	7/24/2019	N	(S) Alkanes, C8–18-branched and linear.
P–19–0071	7/17/2019	7/9/2019	N	(S) 2,4-Hexadienoic acid, 1,1′-[2-ethyl-2-[[(1-oxo-2,4-hexadien-1-yl)oxy]methyl]-1,3-propanediyl] ester.

* The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission.

In Table III of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information that has been received during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

TABLE III—TEST INFORMATION RECEIVED FROM 07/01/2019 TO 07/31/2019

Case No.	Approved date	Type of test information	Chemical substance
P–00–0281	7/16/2019	Surface Tension of Aqueous Solutions (OECD Test Guideline 115), Water Solubility (OECD Test Guideline 105).	(G) Alkylaryl sulfonic acid, sodium salts.
P–05–0075	7/30/2019	Anaerobic Transformation in Aquatic Sediment Systems (OECD Test Guideline 308), Test Substance Characterization.	(G) Polymer of perfluoroalkylethylmethacryalte, alkylacrylate, chloroethene, and urethane methacrylate.
P–05–0107	7/30/2019	Anaerobic Transformation in Aquatic Sediment Systems (OECD Test Guideline 308), Test Substance Characterization.	(G) Polymer of perfluoroalkylethylacrylate, alkylaminomethacrylate, hydroxyalkylmethacrylate, organic acid salt.
P–06–0388	7/30/2019	Anaerobic Transformation in Aquatic Sediment Systems (OECD Test Guideline 308), Test Substance Characterization.	(G) Perfluoroalkylethylmethacrylate copolymer.
P–10–0470	7/1/2019	Impurity Analytical Results	(G) Fluoro modified, polyether modified, and alkyl modified polymethylsiloxane.
P–10–0471	7/1/2019	Impurity Analytical Results	(G) Fluoro modified, polyether modified polyacrylate.
P–15–0054	7/16/2019	Fish Acute Toxicity Test (OECD Test Guideline 203), Fish, Prolonged Toxicity Test: 14-day Study (OECD Test Guideline 204), *Daphnia* sp. Acute Immobilization Test (OECD Test Guideline 202), *Daphnia magna* Reproduction Test (OECD Test Guideline 211), Alga, Growth Inhibition Test (OECD Test Guideline 201), Soil Microorganisms: Nitrogen Transformation Test (OECD Test Guideline 216), Activated Sludge, Respiration Inhibition Test (OECD Test Guideline 209).	(G) Carbon nanotubes powder.
P–15–0443	7/17/2019	90-Day Inhalation Toxicity (OECD Test Guideline 413).	(G) Rare earth doped zirconium oxide.
P–15–0445	7/17/2019	90-Day Inhalation Toxicity (OECD Test Guideline 413).	(G) Rare earth doped zirconium oxide.
P–16–0462	7/5/2019	Metals Analysis Report	(G) Ash (residues), reaction products with tetraethoxydioxa-polyheteroatom-disilaalkane.
P–16–0543	7/16/2019	Exposure Monitoring Report	(G) Halogenophosphoric acid metal salt.
P–18–0035	7/16/2019	Fish Acute Toxicity Test, Freshwater and Marine (OECD Test Guideline 203).	(G) Methacrylic acid heterocyclic alkyl ester, methacrylic acid heterocyclic alkyl ester.
P–19–0073	7/16/2019	Acute Oral Toxicity (OECD Test Guideline 423, 425), Acute Dermal Toxicity (OECD Test Guideline 402), Acute Dermal Irritation (OECD Test Guideline 404), In Vitro Skin Corrosion (OECD Test Guideline 431).	(G) Propoxylated, ethoxylated alkoxyalkyl ether.

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: August 29, 2019.

Pamela Myrick,

Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2019–19123 Filed 9–4–19; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT ADMINISTRATION

Sunshine Act Meeting; Farm Credit Administration Board

AGENCY: Farm Credit Administration.

ACTION: Notice, regular meeting.

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act, of the regular meeting of the Farm Credit Administration Board (Board).

DATES: The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on September 12, 2019, from 9:00 a.m. until such time as the Board concludes its business.

ADDRESSES: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090. Submit attendance requests via email to *VisitorRequest@FCA.gov.* 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 (703) 883–4056.

SUPPLEMENTARY INFORMATION: This meeting of the Board will be open to the public (limited space available), and parts will be closed to the public. Please send an email to *VisitorRequest@FCA.gov* at least 24 hours before the meeting. In your email include: Name, postal address, entity you are representing (if applicable), and telephone number. You will receive an email confirmation from us. Please be prepared to show a photo identification when you arrive. 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:

Open Session

A. *Approval of Minutes*

- August 8, 2019

B. *Reports*

- Quarterly Report on Economic Conditions and FCS Conditions

C. *Closed Session*

- Office of Examination Quarterly Report [1]

[1] Session Closed-Exempt pursuant to 5 U.S.C. Section 552b(c)(8) and (9).

Dated: September 3, 2019.

Dale Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2019–19234 Filed 9–3–19; 11:15 am]

BILLING CODE 6705–01–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Request for Comment on the Exposure Draft of a Proposed Technical Bulletin, Loss Allowance for Intragovernmental Receivables

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act (Pub. L. 92–463), as amended, and the FASAB Rules Of Procedure, as amended in October 2010, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) staff has issued an exposure draft of a proposed Technical Bulletin titled *Loss Allowance for Intragovernmental Receivables.*

The exposure draft is available on the FASAB website at *https://www.fasab.gov/documents-for-comment/.* Copies can be obtained by contacting FASAB at (202) 512–7350.

Respondents are encouraged to comment on any part of the exposure draft. Written comments are requested by October 1, 2019, and should be sent to *fasab@fasab.gov* or Monica R. Valentine, Executive Director, Federal Accounting Standards Advisory Board, 441 G Street NW, Suite 1155, Washington, DC 20548.

FOR FURTHER INFORMATION CONTACT: Ms. Monica R. Valentine, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act, Pub. L. 92–463.

Dated: August 30, 2019.

Monica R. Valentine,

Executive Director.

[FR Doc. 2019–19191 Filed 9–4–19; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0360]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before November 4, 2019. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0360.

Title: Section 80.409, Station Logs (Maritime Services).

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, and state, local and tribal government.

Number of Respondents: 19,214 respondents; 19,214 responses.

Estimated Time per Response: 27.3–95 hours.

Frequency of Response: Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in 47 U.S.C. 151–155, 301–609.

Total Annual Burden: 538,082 hours.

Annual Cost Burden: None.

Privacy Act 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 Commission will submit this extension (no change in the recordkeeping requirement) to the OMB after this 60 day comment period to obtain the full three-year clearance from them. The information collection requirements are as follows:

Section 80.409(c), Public Coast Station Logs: This requirement is necessary to document the operation and public correspondence of public coast radio telegraph, public coast radiotelephone stations, and Alaska public-fixed stations, including the logging of distress and safety calls where applicable. Entries must be made giving details of all work performed which may affect the proper operation of the station. Logs must be retained by the licensee for a period of two years from the date of entry, and, where applicable, for such additional periods such as logs relating to a distress situation or disaster must be retained for three years from the date of entry in the log. If the Commission has notified the licensee of an investigation, the related logs must be retained until the licensee is specifically authorized in writing to destroy them. Logs relating to any claim or complaint of which the station licensee has notice must be retained until the claim or complaint has been satisfied or barred by statute limiting the time for filing suits upon such claims.

Section 80.409(d), Ship Radiotelegraph Logs: Logs of ship stations which are compulsorily equipped for radiotelegraphy and operating in the band 90 to 535 kHz must contain specific information in log entries according to this subsection.

Section 80.409(e), Ship Radiotelephone Logs: Logs of ship stations which are compulsorily equipped for radiotelephony must contain specific information in applicable log entries and the time of their occurrence.

The recordkeeping requirements contained in section 80.409 is necessary to document the operation and public correspondence service of public coast radiotelegraph, public coast radiotelephone stations and Alaska-public fixed stations, ship

radiotelegraph, ship radiotelephone and applicable radiotelephone including the logging of distress and safety calls where applicable.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–19134 Filed 9–4–19; 8:45 am]

BILLING CODE 6712–01–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 on the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573, within twelve 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.: 201319.

Agreement Name: ''K'' Line/Kyowa Shipping—Japan/Guam/Saipan Car Carrier Space Charter Agreement.

Parties: Kawasaki Kisen Kaisha, Ltd. and Kyowa Shipping Co., Ltd.

Filing Party: John Meade; ''K'' Line America, Inc.

Synopsis: The Agreement authorizes the parties to charter space on each other's Ro/Ro vessels and to agree on cooperative working arrangements in the trade between ports in Japan, Guam, and Saipan.

Proposed Effective Date: 8/23/2019.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/22434.

Agreement No.: 012440–001.

Agreement Name: WW Ocean and NYK Space Charter Agreement.

Parties: Wallenius Wilhelmsen Ocean AS and Nippon Yusen Kaisha.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The amendment changes the name of the Wallenius Wilhelmsen entity that is a party to the Agreement, corrects its address, and restates the Agreement.

Proposed Effective Date: 8/26/2019.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/1914.

Agreement No.: 011836–002.

Agreement Name: WW Ocean/K-Line Space Charter Agreement.

Parties: Wallenius Wilhelmsen Ocean AS and Kawasaki Kisen Kaisha, Ltd.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The amendment changes the name of the Wallenius Wilhelmsen entity that is party to the Agreement, corrects its address, deletes obsolete language, and restates the Agreement. The amendment also expands the geographic scope of the agreement to cover all U.S. trades.

Proposed Effective Date: 10/12/2019.

Location: *https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/564.*

Dated: August 30, 2019.

Rachel E. Dickon,

Secretary.

[FR Doc. 2019–19196 Filed 9–4–19; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than September 19, 2019.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *The Wade Family Partnership, Ltd. (''Partnership''), Carrollton, Alabama; William Oliver Kirk, Jr., individually and as general partner of the Partnership, Carrollton, Alabama; Geraldon Campbell Wade, Tuscaloosa, Alabama; the Andrew C. Wade Non-GST Exempt Marital Trust, Andrew C. Wade GST Exempt Marital Trust, and Andrew C. Wade GST Exempt Family Trust (collectively, the ''Trusts''), each of Birmingham, Alabama; Argent Trust Company, as trustee of the Trusts; Carol Wade McKinzey, individually and as trustee of the Trusts, Aliceville, Alabama; Andrew Cox Wade Jr., individually and as trustee of the Trusts, Tuscaloosa, Alabama; Donna Wade Cornelius, individually and as trustee of the Trusts, Tuscaloosa, Alabama; Mary Wade Price, Wiggins, Mississippi; John Jeffery Campbell, Gordo, Alabama; Carole Lamb Campbell, Gordo, Alabama; William Pate Wade, Tuscaloosa, Alabama; Andrew Cox Wade, III, Tuscaloosa, Alabama; Mary Ashley Wade, Tuscaloosa, Alabama; Caroline McKinzey Wright, Tuscaloosa, Alabama; and Jeffrey Kirk Cornelius, Jr., Tuscaloosa, Alabama;* to retain voting shares of West Alabama Capital Corp. and thereby indirectly retain shares of West Alabama Bank & Trust, both of Reform, Alabama.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Ryan G. Tessendorf, Columbus, Nebraska; and Wendy K. Matthews, Bemidji, Minnesota;* as a group acting in concert, to acquire voting shares of Bellwood Community Holding Company and thereby indirectly acquire shares of Bank of the Valley, both of Bellwood, Nebraska.

Board of Governors of the Federal Reserve System, August 30, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–19160 Filed 9–4–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–19–1156; Docket No. CDC–2019–0078]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Performance Monitoring of Working

with Publicly Funded Health Centers to Reduce Teen Pregnancy among Youth from Vulnerable Populations (OMB Control No. 0920–1156, Exp. 01/30/2020). A Revision is requested to continue collecting data through the end of the funding period and to develop systematic approaches to referring youth at risk for a teen pregnancy to reproductive health care.

DATES: CDC must receive written comments on or before November 4, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0078 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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.
5. Assess information collection costs.

Proposed Project

Performance Monitoring of Working with Publicly Funded Health Centers to Reduce Teen Pregnancy among Youth from Vulnerable Populations—Revision—Division of Reproductive Health (DRH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Although the 2017 US rate of 18.8 births per 1,000 female teens aged 15–19 years represents a continued decline, the United States has one of the highest teen birth rates of all Western industrialized countries. Access to reproductive health services and the most effective types of contraception has been shown to reduce the likelihood that teens become pregnant. Nevertheless, recent research and lessons learned through a previous teen pregnancy prevention project implemented through CDC in partnership with the Office of Adolescent Health (2010–2015; OMB No. 0920–0952, Exp. 12/31/2015), demonstrate that many health centers serving teens do not engage in youth-friendly best practices that may enhance access to care and to the most effective types of contraception. Furthermore, youth at highest risk of experiencing a teen pregnancy are often not connected to the reproductive health care that they need, even when they are part of a population that is known to be at high risk for a teen pregnancy. Significant racial, ethnic and geographic disparities in teen birth rates persist and continue to be a focus of public health efforts.

To address these challenges, CDC has provided funding to three organizations to strengthen partnerships and processes that improve reproductive health services for teens. These awardees are working with 25 publicly funded health centers to support implementation of evidence-based recommendations for health centers and providers to improve adolescent access to reproductive health services. In addition, awardees have worked with approximately 30 youth-serving organizations (YSO) to provide staff training and develop systematic approaches to identifying youth who are at risk for a teen pregnancy and referring those youth to reproductive health care services. Finally, awardees have developed communication campaigns that increase awareness of the partner health centers' services for teens. Activities are expected to result in changes to health center and YSO partners' policies, to staff practices, and to youth health care seeking and teen pregnancy prevention behaviors.

The best practices to improve adolescent access to reproductive health services included in this program are supported by evidence in the literature and recommended by major medical associations. Each of the components of the current project has been implemented as part of past teen pregnancy prevention efforts. Consistent with CDC's mission of using evidence to improve public health programs, conducting an evaluation of combined best practices, in concert with community-clinical linkage of youth to services to increase their access to reproductive health care, can provide further information to inform future teen pregnancy prevention efforts.

CDC has been collecting the information needed to assess these efforts under Performance Monitoring of Working with Publicly Funded Health Centers to Reduce Teen Pregnancy among Youth from Vulnerable Populations (OMB Control No. 0920–1156, Exp. 1/31/2020). CDC is using the information to determine the types of training and technical assistance that may be needed to monitor whether awardees meet objectives related to health center and YSO partners' policies and staff practices, to support a data-driven quality improvement process for adolescent sexual and reproductive health care services and referrals, and to assess whether the project model was effective in increasing the utilization of services by youth.

A Revision of the currently approved information collection is being requested through 9/30/2020 in order to continue data collection until the end of the project. Remaining information collection activities will include awardees, health center partner organizations, and providers at the health center partners; information collection during the extension period

will not include YSOs or youths being served by health centers, as significant changes are not expected to be found for YSOs in the final year and that the youth survey will not need to be conducted beyond late 2019. Participation in the organizational assessment activities is required for awardees and partner organizations. Participation in a survey of health center providers is voluntary. The total estimated burden hours for the extension period are 485 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Private Sector	Health Center Organizational Assessment	21	1	2	42
	Quarterly Health Center Performance Reporting Tool.	21	2	4	168
	Annual Health Center Performance Measure Reporting Tool.	21	1	6	126
	Health Center Provider Survey	84	1	20/60	28
	Awardee Training and Technical Assistance Tool.	3	8	2	48
	Awardee Performance Measure Reporting Tool	3	1	1	3
State and Local Government.	Health Center Organizational Assessment	4	1	2	8
	Quarterly Health Center Performance Measure Reporting Tool.	4	2	4	32
	Annual Health Center Performance Measure Reporting Tool.	4	1	6	24
	Health Center Provider Survey	16	1	20/60	6
Total					485

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–19083 Filed 9–4–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0662]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug—Patent Submission and Listing Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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.

DATES: Fax written comments on the collection of information by October 7, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0513. Also include the FDA docket number found in brackets in the heading of this document.

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, *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.

Applications for Food and Drug Administration Approval To Market a New Drug: Patent Submission and Listing Requirements

OMB Control Number 0910–0513—Extension

Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(c)(1)) requires all NDA applicants to file, as part of the NDA, the patent number and the expiration date of any patent that claims the drug for which the applicant submitted the application or that claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. Section 505(c)(2) of the FD&C Act imposes a similar patent submission obligation on holders of approved NDAs when the NDA holder could not have submitted the patent information with its application. After approval of an NDA, under section 505(b)(1) of the FD&C Act, FDA publishes the patent information in the list entitled ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (the Orange Book). When the patent information is submitted after NDA approval, section 505(c)(2) of the FD&C Act directs FDA to publish the patent information upon its submission.

FDA regulations in §§ 314.50(h) (21 CFR 314.50(h)) and 314.53 (21 CFR 314.53) clarify the types of patent information that must and must not be submitted to FDA as part of an NDA, an amendment, or a supplement to an NDA, and also require persons submitting an NDA, an amendment, or a supplement to make a detailed patent declaration on Form FDA 3542a, or when submitting information on a patent after approval of the NDA or supplement, to make a detailed patent declaration using Form FDA 3542.

The reporting burden for submitting an NDA, an amendment, or a supplement to an NDA, in accordance with § 314.50(a) through (f), (i), (h), and (k) has been estimated by FDA and the collection of information has been approved by OMB under control number 0910–0001. In addition, the reporting burden for submitting an appropriate patent certification or statement for each patent listed in the Orange Book for one drug product approved in an NDA that is pharmaceutically equivalent to the proposed drug product for which the original 505(b)(2) application was submitted (if certain criteria are met) in accordance with § 314.50(i)(1)(i)(C) and the reporting burden for submitting an amended patent certification in certain circumstances in accordance with § 314.50(i)(6) are approved by OMB under OMB control number 0910–0786. In addition, the reporting burden for responding to a patent listing dispute in accordance with § 314.53(f)(1) and the reporting burden for submitting corrections, changes, or withdrawal of patent information in accordance with § 314.53(f)(2) also are approved by OMB under OMB control number 0910–0786. We are not re-estimating these approved burdens in this document. Only the reporting burdens associated with patent submission and listing, as described below, are estimated in this document.

The information collection reporting requirements are as follows:

Section 314.50(h) requires that an NDA, or an amendment or a supplement to an NDA, contain patent information described under § 314.53. Section 314.53 requires that an applicant submitting an NDA, or an amendment or a supplement to an NDA, except as provided in § 314.53(d)(2), submit on Forms FDA 3542 and 3542a the required patent information described in this section. Section 314.53(d)(2) requires submission of patent information only for a supplement that seeks approval to add or change the dosage form or route of administration, to add or change the strength, to change the drug product from prescription to over-the-counter use, or to revise previously submitted patent information that differently or no longer claims the product as changed by the supplement.

Compliance with the information collection burdens under §§ 314.50(h) and 314.53 consists of submitting with an NDA, or an amendment or a supplement to an NDA (collectively referred to as an ''application'') the required patent declaration(s) on Form FDA 3542a for each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product (§ 314.53(b)). Such patents claim the drug substance (active ingredient), drug product (formulation and composition), or method(s) of use. If a patent is issued after the application is filed with FDA, but before the application is approved, the applicant must submit the required patent information on Form FDA 3542a as an amendment to the application, within 30 days of the date of issuance of the patent.

Within 30 days after the date of approval of an application, the applicant must submit Form FDA 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method(s) of use of the product for listing in the Orange Book. For patents issued after the date of approval of an application, Form FDA 3542 must be submitted within 30 days of the date of issuance of the patent. In addition, an NDA applicant's amendment to the description of the approved method(s) of use claimed by the patent must be submitted within the timeframes described in §§ 314.50(i)(4) and 314.94(a)(12)(vi) (21 CFR 314.94(a)(12)(vi)) to be considered timely filed.

Description of Respondents: The respondents to this collection of information are NDA applicants for original applications, amendments, or supplements to an NDA or NDA applicants submitting information on a patent after approval of the NDA or supplement.

The final rule ''Abbreviated New Drug Applications and 505(b)(2) Applications,'' implemented portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and also amended certain regulations regarding 505(b)(2) applications and abbreviated new drug applications (ANDAs) to facilitate compliance with and efficient enforcement of the FD&C Act (81 FR 69580; October 6, 2016) (MMA Final Rule). In the MMA Final Rule, we estimated that the burden for Form FDA 3542a would be reduced by 5 hours from 20 hours to 15 hours per response; we further estimated that the burden for Form FDA 3542 would increase by 5 hours from 5 to 10 hours per response. The burden hours were adjusted to shift a portion of the time spent preparing Form FDA 3542a to the estimated time spent preparing Form FDA 3542 to reflect the additional time spent by the NDA holder to develop the use code in accordance with FDA's revised regulations and identify the specific section(s) and subsection(s) of labeling that describe the specific approved method of use claimed by the patent. The burden hours of Forms FDA 3542 and 3542a in this notice reflect the reporting burden approved by OMB under OMB control number 0910–0786 in connection with the MMA Final Rule. The effective date of the MMA Final Rule was December 5, 2016. Consequently, the annual reporting burden estimated below is based on calendar year 2017 data only to reflect the post-MMA Final Rule regulatory requirements and reporting burden estimate.

In the **Federal Register** of May 20, 2019 (84 FR 22858), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR 314.50 (citing § 314.53)	Number of respondents	Number of responses per respondent	Total annual responses CY 2017	Hours per response	Total hours
Form FDA 3542	281	2.875	808	10	8,080
Form FDA 3542a	310	2.084	646	15	9,690
Total					17,770

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

For purposes of this analysis, we consider the number of respondents to correspond to the number of NDAs and efficacy supplements submitted or approved, respectively, in calendar year (CY) 2017, even though one company may submit or hold multiple NDAs or may submit multiple efficacy supplements to one or more NDAs. FDA approved 127 NDAs and 154 efficacy supplements to NDAs during CY 2017, which corresponds to 281 respondents. Based on information provided by the Orange Book staff, approximately 623 patent records were created in CY 2017, which corresponds to an estimated 513 Forms FDA 3542 submitted to FDA for listing of patent information in the Orange Book for NDAs approved in CY 2017 and an estimated 110 Forms FDA 3542 submitted to FDA for listing of patent information in the Orange Book for efficacy supplements approved in CY 2017. In addition, based on information provided by the Orange Book staff and FDA's experience, we estimate that approximately 185 Forms FDA 3542 were submitted in CY 2017 to modify patent information, which results in an estimated total of 808 Forms FDA 3542 submitted in CY 2017.

During calendar year 2017, FDA received 141 original NDAs and 169 efficacy supplements to NDAs for FDA review and approval. We estimate that applicants submitted approximately 405 Forms FDA 3542a for the original NDAs submitted during CY 2017. In addition, based on a review of the submitted efficacy supplements, FDA received 241 Forms FDA 3542a with the efficacy supplements received during CY 2017, resulting in a total of 646 Forms FDA 3542a submitted in CY 2017.

Our estimated burden for the information collection reflects an overall decrease. We attribute this adjustment to a decrease in the number of duplicative submissions of Forms FDA 3542a and 3542 in connection with supplements submitted or approved after the effective date of the MMA final rule, and improved data collection from upgraded data software tools.

Dated: August 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19130 Filed 9–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3657]

Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation Scheme for Conformity Assessment Pilot Program

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 information collection associated with the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.

DATES: Submit either electronic or written comments on the collection of information by November 4, 2019.

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 November 4, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 4, 2019. 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–2019–N–3657 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.'' 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.

- 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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.

Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

OMB Control Number 0910–NEW

The FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d(d)) by adding a new subsection (d) entitled ''Pilot Accreditation Scheme for Conformity Assessment.'' [1] Section 514(d) of the FD&C Act requires FDA to establish a pilot program under which testing laboratories may be accredited by accreditation bodies meeting criteria specified by FDA to assess the conformance of a device within certain FDA-recognized standards. Determinations by testing laboratories so accredited that a device conforms with an eligible standard included as part of the ASCA Pilot Program shall be accepted by FDA for the purposes of demonstrating such conformity unless FDA finds that a particular such determination shall not be so accepted.[2]

The statute provides that FDA may review determinations by accredited testing laboratories, including by conducting periodic audits of such determinations or processes of accreditation bodies or testing laboratories.[3] Following such a review, or if FDA becomes aware of information materially bearing on safety or effectiveness of a device assessed by an accredited testing laboratory, FDA may take additional measures as determined appropriate, including suspension or withdrawal of accreditation of a testing laboratory or a request for additional information regarding a specific device.[4]

FDA intends to issue guidance regarding the goals and implementation of the voluntary Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program (hereafter referred to as the ASCA Pilot) in accordance with amendments made to section 514 of the FD&C Act [5] by FDARA, and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV).[6]

The establishment of the goals, scope, procedures, and a suitable framework for the voluntary ASCA Pilot supports the Agency's continued efforts to use its scientific resources effectively and efficiently to protect and promote public health. FDA believes the voluntary ASCA Pilot may further encourage international harmonization of medical device regulation because it incorporates elements, where appropriate, from a well-established set of international conformity assessment practices and standards (*e.g.,* ISO/IEC 17000 series). The voluntary ASCA Pilot does not supplant or alter any other existing statutory or regulatory requirements governing the decision making process for premarket submissions.

Under the ASCA Pilot's conformity assessment scheme, recognized accreditation bodies accredit testing laboratories using ASCA program specifications associated with each eligible standard and ISO/IEC 17025:2017: *General requirements for the competence of testing and calibration laboratories.* ASCA-accredited testing laboratories may conduct testing to determine conformance of a device with at least one of the standards eligible for inclusion in the ASCA Pilot. When an ASCA-accredited testing laboratory conducts such testing, it may provide a complete test report to the device manufacturer. A device manufacturer who utilizes an ASCA-accredited testing laboratory to perform testing in accordance with the provisions of the ASCA Pilot can then include a declaration of conformity with supplemental documentation (including a summary test report) as part of a premarket submission to FDA. Testing performed by an ASCA-accredited testing laboratory can be used to support a premarket submission for any device if the testing was conducted using a standard eligible for inclusion in the ASCA Pilot and in accordance with the ASCA Pilot program specifications for that standard.

The ASCA Pilot includes participation from accreditation bodies, testing laboratories, device manufacturers, and FDA staff. Each of these entities plays a critical role in the ASCA Pilot to ensure that patients and health care providers have timely and continued access to safe, effective, and high-quality medical devices.

To participate in the ASCA Pilot, accreditation bodies and testing laboratories apply to FDA to demonstrate that they have the qualifications for their respective roles within the pilot. An application includes agreement to terms of participation. For example, a participating accreditation body or

[1] *See* Public Law 115–52, section 205.

[2] *See* section 514(d)(1)(B) of the FD&C Act.

[3] *See* section 514(d)(2)(A) of the FD&C Act.

[4] *See* section 514(d)(2)(A)–(B) of the FD&C Act.

[5] *See* section 514(d)(3)(B) of the FD&C Act.

[6] *See also* MDUFA IV Commitment Letter: *https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf.*

testing laboratory agrees to attend training, regularly communicate with FDA, and support periodic FDA audits. FDA recognizes qualified applicants as participants. In its recognition, FDA will identify the scope of recognition of specific standards and test methods to which each participant may accredit or test as part of the ASCA Pilot.

After recognizing a testing laboratory as a participant in the ASCA Pilot, FDA will generally grant the testing laboratory ASCA Accreditation. During the ASCA Pilot, FDA generally will accept determinations from ASCA-accredited testing laboratories that a medical device is in conformity with the specified testing to a particular standard, and does not intend to review complete test reports from ASCA-accredited testing laboratories in support of a declaration of conformity submitted with a premarket submission except in certain circumstances.

Note that ASCA Accreditation is separate from any accreditation that an accreditation body may provide to a testing laboratory for purposes other than the ASCA Pilot. FDA's decision to recognize the accreditation for purposes of the ASCA Pilot is separate and distinct from any independent decision by the accreditation body with respect to a testing laboratory for purposes outside of the ASCA Pilot.

The ASCA Pilot does not address specific content for a particular premarket submission. Information collections associated with premarket submissions have been previously approved.

This collection also refers to previously approved collections of information found in FDA regulations and guidance. The collections of information in 21 CFR part 807, subpart E (premarket notification) have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814, subparts A through E (premarket approval) have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H (humanitarian device exemption) have been approved under OMB control number 0910–0332; the collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 312 (investigational new drug application) have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR part 601 (biologics license application) have been approved under OMB control number 0910–0338.

Respondents are accreditation bodies (ABs) and testing laboratories (TLs). In tables 1 through 3, these abbreviations are used.

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 (hours)	Total hours [2]
Application by AB for ASCA recognition	8	1	8	6	48
Request by AB to continue participation in ASCA	1	1	1	6	6
Request by AB to participate (subsequent to withdrawal).	1	1	1	6	6
Request by AB to expand scope of participation	1	1	1	6	6
AB annual status report	8	1	8	3	24
AB notification of change	8	1	8	1	8
Application by TL for ASCA recognition	150	1	150	4	600
Request by TL to continue participation in ASCA	15	1	15	4	60
Request by TL to participate (subsequent to withdrawal or suspension).	5	1	5	4	20
Request by TL to expand scope of participation	75	1	75	4	300
TL annual status report	150	1	150	1.5	225
TL notification of change	5	1	5	1	5
Request for withdrawal (ABs or TLs) or suspension (TLs) from ASCA program.	6	1	6	0.08 (5 minutes)	1
Pilot feedback questionnaire (ABs and TLs)	158	1	158	0.5 (30 minutes)	79
Total					1,388

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded to the nearest hour.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of respondents	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)
AB setup documentation standard operating procedures (SOPs) and training (one-time burden)	8	1	8	25	200
TL setup documentation (SOPs) and training (one-time burden)	150	1	150	25	3,750
AB record maintenance	8	1	8	1	8
TL record maintenance	150	1	150	1	150

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity	Number of respondents	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)
Total					4,108

[1] There are no capital costs or operating and maintenance costs associated with the collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (hours)	Total hours
Request for Accreditation (TLs requesting accreditation from ABs).	150	1	150	0.5 (30 minutes)	75
Review/Acknowledgement of accreditation request (ABs).	8	22	176	40	7,040
Test Report (TLs)	880	1	880	1	880
Total					7,995

[1] There are no capital costs or operating and maintenance costs associated with the collection of information.

Our estimate of eight ABs is based on the number of International Laboratory Accreditation Cooperation (ILAC) signatories in the United States economy. We estimate that approximately 150 testing laboratories will seek accreditation. Our estimate of Test Reports is based on the number of premarket submissions we expect per year with testing from an ASCA-accredited testing laboratory as part of the ASCA Pilot Program.

Our estimates for the average burden per response, recordkeeping, and disclosure are based on the burden for similar programs.

Dated: August 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19102 Filed 9–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–E–2597]

Determination of Regulatory Review Period for Purposes of Patent Extension; GIAPREZA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for GIAPREZA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by November 4, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 3, 2020. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 November 4, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 4, 2019. 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–

2018–E–2597 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; GIAPREZA.'' 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.

• 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 § 10.20 (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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, GIAPREZA (angiotensin II). GIAPREZA is a vasoconstrictor to increase blood pressure in adults with septic or other distributive shock. Subsequent to this approval, the USPTO received a patent term restoration application for GIAPREZA (U.S. Patent No. 9,572,856) from George Washington University and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated September 18, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of GIAPREZA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for GIAPREZA is 1,639 days. Of this time, 1,463 days occurred during the testing phase of the regulatory review period, while 176 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* June 28, 2013. The applicant claims November 16, 2014, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 28, 2013, which was 30 days after FDA receipt of the first IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* June 29, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for GIAPREZA (NDA 209360) was initially submitted on June 29, 2017.

3. *The date the application was approved:* December 21, 2017. FDA has verified the applicant's claim that NDA 209360 was approved on December 21, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 241 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the

Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19110 Filed 9–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3327]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on E6(R2) Good Clinical Practice; International Council for Harmonisation; Integrated Addendum to International Council for Harmonisation E6(R1)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection recommendations found in Agency guidance pertaining to the development of a system to manage quality as well as information to include in a clinical study report about the quality management approach.

DATES: Submit either electronic or written comments on the collection of information by November 4, 2019.

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 November 4, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 4, 2019. 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–2015–D–3327 for ''Guidance for Industry on E6(R2) Good Clinical Practice; International Council for Harmonisation; Integrated Addendum to ICH E6(R1).'' 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.

• 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.gpo.gov/fdsys/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.

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, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''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.

Guidance for Industry on E6(R2) Good Clinical Practice; International Council for Harmonisation; Integrated Addendum to ICH E6(R1)

OMB Control Number 0910–0843—Extension

This information collection request supports recommendations found in the Agency guidance entitled ''E6(R2) Good Clinical Practice; Integrated Addendum to ICH E6(R1)'' (ICH E6(R2). The guidance was originally prepared under the auspices of the International Council for Harmonisation (ICH) (formerly the International Conference on Harmonisation); it amends the ICH guidance for industry entitled ''E6 Good Clinical Practice: Consolidated Guidance'' (issued in April 1996). The guidance is intended to facilitate implementation of improved and more efficient approaches to clinical trial design, including conduct, oversight, recording, and reporting. This is intended to increase clinical trial quality and efficiency while continuing to ensure human subject protection and reliability of trial results. Included in the guidance are additions identified as ''ADDENDUM'' and marked with vertical lines on both sides of the text.

Standards regarding electronic records and essential documents intended to increase clinical trial quality and efficiency have also been updated. The guidance is available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r2-good-clinical-practice-integrated-addendum-ich-e6r1.*

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS [1]

Guidance for industry on E6(R2) good clinical practice; International Council for Harmonisation; integrated addendum to ICH E6(R1)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Section 5. Quality Management (including sections 5.0.1 to 5.0.7)—Developing a Quality Management System	1,457	1	1,457	60	87,420

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

Guidance for industry on E6(R2) good clinical practice; International Council for Harmonisation; integrated addendum to ICH E6(R1)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section 5.0.7. Risk Reporting—Describing the Quality Management Approach Implemented in a Clinical Trial and Summarizing Important Deviations From the Predefined Quality Tolerance Limits and Remedial Actions Taken in the Clinical Study Report	1,457	4.6	6,702	3	20,106

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS [1]

Guidance for industry on E6(R2) good clinical practice; International Council for Harmonisation; integrated addendum to ICH E6(R1)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Section 5. Quality Management (including sections 5.0.1 to 5.0.7)—Developing a Quality Management System	423	1	423	60	25,380

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]

Guidance for industry on E6(R2) good clinical practice; International Council for Harmonisation; integrated addendum to ICH E6(R1)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section 5.0.7. Risk Reporting—Describing the Quality Management Approach Implemented in a Clinical Trial and Summarizing Important Deviations From the Predefined Quality Tolerance Limits and Remedial Actions Taken in the Clinical Study Report	423	1.56	660	3	1,980

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In table 1, we estimate 1,457 sponsors of clinical trials of human drugs will develop approximately 1,457 quality management systems per year (as described in ICH E6(R2) in section 5.0, including sections 5.0.1 to 5.0.7). We assume it will take respondents 60 hours to develop and implement each quality management system, totaling 87,420 hours annually. The estimated number of sponsors who will develop a quality management system as described in ICH E6(R2) is based on the number of annual investigational new drug applications (INDs) and new drug applications (NDAs) submitted to FDA's Center for Drug Evaluation and Research. The estimated number of hours we assume it takes to develop a quality management system is based on informal interactions with industry about activities that support drug development plans.

In table 2, we estimate 1,457 sponsors of clinical trials of human drugs will describe the quality management approach implemented in a clinical trial and summarize important deviations from the predefined quality tolerance limits and remedial actions taken in the clinical study report (as described in section 5.0.7 of ICH E6(R2)). We further estimate that sponsors will submit approximately 4.6 responses per respondent and that it will take sponsors 3 hours to complete this reporting task, totaling 20,106 reporting hours annually. These estimates are based on our past experiences with INDs and NDAs.

In table 3, we estimate 423 sponsors of clinical trials of biological products will develop 423 quality management systems per year (as described in ICH E6(R2) in section 5.0, including sections 5.0.1 to 5.0.7). We assume it will take respondents 60 hours to develop and implement each quality management system, totaling 25,380 hours annually. The estimated number of sponsors who will develop a quality management system as described in ICH E6(R2) is based on the number of annual INDs and biologics license applications (BLAs) submitted to FDA's Center for Biologics Evaluation and Research. The estimated number of hours we assume it takes to develop a quality management system is based on informal interactions with industry about activities that support drug development plans.

In table 4, we estimate 423 sponsors of clinical trials of biological products will describe the quality management approach implemented in a clinical trial and summarize important deviations from the predefined quality tolerance limits and remedial actions taken in a clinical study report (as described in section 5.0.7 of ICH E6(R2)). We further estimate that sponsors will submit approximately 660 responses per respondent and that it will take sponsors 3 hours to complete this reporting task, totaling 1,980 reporting hours annually. As described previously, these estimates are based on past experiences with INDs and BLAs submitted to FDA.

Although our estimated burden for the information collection reflects an overall decrease of 433 hours, we have increased the estimate by 861 records. We are making this adjustment based on an increase in the number of submissions we received over the last few years.

Dated: August 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19113 Filed 9–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

The National Institutes of Health (NIH) Sexual & Gender Minority Research Listening Session

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) Sexual & Gender Minority Research Office (SGMRO) will be holding a listening session with the Sexual & Gender Minority (SGM) community. The primary objectives of the NIH's listening session are: (1) To hear from community stakeholders about what issues are on their minds with regard to SGM-related research and related activities at the NIH, and (2) to use these individual viewpoints to help inform the development of the NIH SGM Research FY 2021–2025 strategic plan. The goal is to hold a listening session every year, to provide different SGM focused organizations an opportunity to join a session in person.

DATES: The listening session with the SGM community will be held on October 22, 2019 at 11:00 a.m. ET.

ADDRESSES: The meeting will be held at the National Institutes of Health, Building 1, Wilson Hall, Bethesda, MD 20892 for invited participants; the meeting will be open to the public remotely at 1–877–951–0634, Passcode: 6617257#.

FOR FURTHER INFORMATION CONTACT: Karen Parker, Ph.D., MSW, Director, Sexual & Gender Minority Research Office (SGMRO), 6555 Rock Spring Drive, Rm 2SE31K, Bethesda, MD 20817, *klparker@mail.nih.gov,* 301–451–2055.

SUPPLEMENTARY INFORMATION: ''Sexual and gender minority'' is an umbrella term that includes, but is not limited to, individuals who identify as lesbian, gay, bisexual, asexual, transgender, two-spirit, queer, and/or intersex. Individuals with same-sex or -gender attractions or behaviors and those with a difference in sex development are also included. These populations also encompass those who do not self-identify with one of these terms but whose sexual orientation, gender identity or expression, or reproductive development is characterized by non-binary constructs of sexual orientation, gender, and/or sex.

The Sexual and Gender Minority Research Office (SGMRO) coordinates sexual and gender minority (SGM)–related research and activities by working directly with the NIH Institutes, Centers, and Offices. The Office was officially established in September 2015 within the NIH Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) in the Office of the Director.

The SGMRO has the following research-related goals: (1) Expand the knowledge base of SGM health and well-being through NIH-supported research; (2) Remove barriers to planning, conducting, and reporting NIH-supported research about SGM health and well-being; (3) Strengthen the community of researchers and scholars who conduct research relevant to SGM health and well-being; and (4) Evaluate progress on advancing SGM research.

Listening Session Details

The listening session event will be a trans-NIH effort, with representation from several NIH Institutes, Centers, and Offices. The listening session will be open to the public to listen in; comments submitted via email will be accepted post-listening session. Comments, questions, or feedback can be shared with *SGMRO@nih.gov.* SGMRO will invite approximately 20 SGM focused organizations to attend the listening session in-person. Selection of the organizations will be based on the diversity of their missions and efforts.

Dated: August 27, 2019.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2019–19085 Filed 9–4–19; 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 Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel: R13 Conference Grant Applications.

Date: September 26, 2019.

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, (Telephone Conference Call).

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–7799, *yangj@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel: Fellowships in Digestive Diseases and Nutrition.

Date: October 17–18, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–7799, *yangj@extra.niddk.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: August 29, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–19121 Filed 9–4–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Shared and High-End Instruments: Mass Spectrometers.

Date: October 7, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Royal Sonesta Harbor Court, 550 Light Street, Baltimore, MD 21202.

Contact Person: Nuria E. Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Language and Communication Study Section.

Date: October 7–8, 2019.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7770, Bethesda, MD 20892, (301) 455–1761, *kellya2@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Surgery, Anesthesiology and Trauma Study Section.

Date: October 8–9, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Weihua Luo, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435–1170, *luow@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Understanding Alzheimer's Disease.

Date: October 9–10, 2019.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Boris P. Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301–408–9115, *bsokolov@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer; Biology AREA/REAP Review.

Date: October 9, 2019.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, *sarita.sastry@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–19116 Filed 9–4–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group Psychosocial Development, Risk and Prevention Study Section.
Date: October 3–4, 2019.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.
Contact Person: Anna L. Riley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7759, Bethesda, MD 20892, 301–435–2889, *rileyann@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel Bioengineering Sciences and Technologies: AREA Review.
Date: October 3, 2019.
Time: 9:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).
Contact Person: David Filpula, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6181, MSC 7892, Bethesda, MD 20892, 301–435–2902 *filpuladr@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR Panel: Development of Appropriate Pediatric Formulations and Pediatric Drug Delivery Systems.
Date: October 4, 2019.
Time: 2:00 p.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Paek-Gyu Lee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4201, MSC 7812, Bethesda, MD 20892, 301–613–2064, *leepg@csr.nih.gov*.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group Skeletal Biology Structure and Regeneration Study Section.
Date: October 7–8, 2019.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Baltimore Marriott Waterfront, 700 Aliceanna Street, Baltimore, MD 21202.
Contact Person: Yanming Bi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–451–0996, *ybi@csr.nih.gov*.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group Bioengineering, Technology and Surgical Sciences Study Section.
Date: October 7–8, 2019.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.
Contact Person: Khalid Masood, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, 301–435–2392, *masoodk@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel Shared and High-End Instruments: Mass Spectrometers.
Date: October 7, 2019.
Time: 8:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Royal Sonesta Harbor Court, 550 Light Street, Baltimore, MD 21202.
Contact Person: Sudha Veeraraghavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–1504, *sudha.veeraraghavan@nih.gov*.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group Skeletal Muscle and Exercise Physiology Study Section.
Date: October 7–8, 2019.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Virginian Suites, 1500 Arlington Boulevard, Arlington, VA 22209.
Contact Person: Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301–496–8551, *ingrahamrh@mail.nih.gov*.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group Motor Function, Speech and Rehabilitation Study Section.
Date: October 7–8, 2019.
Time: 8:00 a.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.
Contact Person: Biao Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7848, Bethesda, MD 20892, 301–402–4411, *tianbi@csr.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group Auditory System Study Section.
Date: October 7–8, 2019.
Time: 8:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Washington Marriott Georgetown, 1221 22nd Street NW, Washington, DC 20037.
Contact Person: Janita N. Turchi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, *turchij@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 29, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–19117 Filed 9–4–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Immunology Integrated Review Group; Innate Immunity and Inflammation Study Section.
Date: October 10–11, 2019.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Embassy Suites by Hilton Denver Int'l Airport, 7001 Yampa Street, Denver, CO 80249.
Contact Person: Tina McIntyre, Ph.D., Scientific Review Officer Center for Scientific Review National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892 301–594–6375, *mcintyrt@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Neural Basis of Psychopathology, Addictions and Sleep Disorders Study Section.
Date: October 10–11, 2019.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: New Orleans Marriott, 555 Canal Street, New Orleans, LA 70130.
Contact Person: Brian H. Scott, Ph.D., Scientific Review Officer, National Institutes

of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–7490, *brianscott@mail.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroimmunology and Brain Tumors Study Section.

Date: October 10–11, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Wei-Qin Zhao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181, MSC 7846, Bethesda, MD 20892–7846, 301–435–1236, *zhaow@csr.nih.gov*.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group Host Interactions with Bacterial Pathogens Study Section.

Date: October 10–11, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street NW, Washington, DC 20037.

Contact Person: Fouad A El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7808, Bethesda, MD 20892, (301) 435–1149, *elzaataf@csr.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review; Group Neuroendocrinology, Neuroimmunology, Rhythms and Sleep Study Section.

Date: October 10–11, 2019.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Baltimore Marriott Waterfront, 700 Aliceanna Street, Baltimore, MD 21202.

Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119, *mselmanoff@csr.nih.gov*.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Synthetic and Biological Chemistry B Study Section.

Date: October 10–11, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael Eissenstat, Ph.D., Scientific Review Officer, BCMB IRG, Center for Scientific Review; National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806, Bethesda, MD 20892, 301–435–1722, *eissenstatma@csr.nih.gov*.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function B Study Section.

Date: October 10, 2019.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: C–L Albert Wang, Ph.D., Scientific Review Officer, Center for Scientific Review; National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7806, Bethesda, MD 20892, 301–435–1016, *wangca@csr.nih.gov*.

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Enabling Bioanalytical and Imaging Technologies Study Section.

Date: October 10–11, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Kimpton Hotel Palomar Washington, 2121 P Street NW, Washington, DC, MD 20037.

Contact Person: Kenneth Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7717, Bethesda, MD 20892, 301–435–0229, *kenneth.ryan@nih.hhs.gov*.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Pathogenic Eukaryotes Study Section.

Date: October 10–11, 2019.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Tera Bounds, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, 301 435–2306, *boundst@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–19118 Filed 9–4–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–1085]

RIN 1625–AA09

Notice of Availability of Final Environmental Assessment and Finding of No Significant Impact for the Proposed Construction of Railroad Bridges Across Sand Creek and Lake Pend Oreille at Sandpoint, Bonner County, Idaho

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The United States Coast Guard (USCG) announces the availability of a Final Environmental Assessment (FEA) and Finding of No Significant Impact (FONSI) in accordance with National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*) and the National Historic Preservation Act (NHPA), as amended (16 U.S.C. 470 *et seq.*) for the proposed construction of railroad bridges across Lake Pend Oreille and Sand Creek at Sandpoint, Bonner County, Idaho. The proposed bridges will be built parallel to existing railroad bridges crossing the same waterbodies. As structures over navigable waters of the United States, the proposed bridges require a Coast Guard Bridge Permit. This notice provides information on where to view the FEA and FONSI. There is no comment period associated with this notice.

ADDRESSES: We have uploaded the FEA and FONSI to our online docket at *http://www.regulations.gov*. Additionally, the East Bonner County Library at 1407 Cedar Street, Sandpoint, Idaho, 83864 will maintain printed copies of the FEA and FONSI for public review. The documents will be available for inspection at this location between 9 a.m. and 7 p.m. Monday through Thursday and 10 a.m. and 5 p.m. Friday and Saturday, except Sundays and Federal holidays. The Thirteenth Coast Guard District Bridge Office at 915 2nd Avenue, Seattle, WA 98174–1067 will also maintain printed copies of the FEA and FONSI for public review. The documents will be available for inspection at this location between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice please contact Mr. Steven Fischer, District Bridge Manager, Thirteenth

Coast Guard District, U.S. Coast Guard; telephone 206–220–7282.

SUPPLEMENTARY INFORMATION:

I. Authority

The FEA and FONSI have been prepared in accordance with the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*); Council on Environmental Quality (CEQ) Regulations for Implementing NEPA (40 CFR 1500–1508) and associated CEQ guidelines: Department of Homeland Security Directive 5100.1, National Environmental Policy Act Implementing Procedures and Policy for Considering Environmental Impacts.

II. Viewing the FEA and FONSI

To view the FEA and FONSI, please visit *http://www.regulations.gov,* enter ''USCG–2018–1085'' in the search field, press ''Enter,'' and then select the ''Open Docket Folder'' option. The FEA and FONSI are also available for public review at the East Bonner County Library at 1407 Cedar Street, Sandpoint, Idaho, 83864, between 9 a.m. and 7 p.m. Monday through Thursday and 10 a.m. and 5 p.m. Friday and Saturday, except Sundays and Federal holidays. The Thirteenth Coast Guard District Bridge Office at 915 2nd Avenue, Seattle, WA 98174–1067 will also maintain printed copies of the FEA and FONSI for public review. The documents will be available for inspection at this location between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

III. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act system of records notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

IV. Background and Purpose

The BNSF Railway Company (BNSF) has proposed to construct a second mainline track and associated bridges across Lake Pend Oreille and Sand Creek parallel to existing BNSF railroad track and bridges in and around Sandpoint, Bonner County, Idaho (Project). The present single-track configuration has become a constraint to efficient rail movement, resulting in congestion on the BNSF main line, rail yards and sidings as trains await clearance to cross the existing single-track bridges. Moreover, trains awaiting an opportunity to cross the bridges often block vehicular traffic at both public and private at-grade rail crossings. The delays attributable to this congestion hinder the timely transport and delivery of people, goods and services to local and regional destinations. This Project is intended to relieve this congestion and enable more efficient movement of trains through the Lake Pend Oreille region. The capacity of the rail line through Sandpoint and across Lake Pend Oreille is approximately 79 trains per day while the current average rail traffic volume on that line segment is approximately 60 trains per day. Adding a second main line track along this segment would not increase capacity of the rail line because there are other constraints outside of the Lake Pend Oreille area.

Alternatives considered for the Project include a ''No Action Alternative'' that simply preserves the status quo and a Proposed Action Alternative that satisfies the purpose and need of the Project. Several additional alternatives including (a) a second main line track placed east of the existing main track line, (b) alternate routes and (c) shifting rail traffic to other railroads were considered and dismissed based on infeasibility or impracticability.

The federal bridge statutes, including the River and Harbors Act of 1899, as amended, the Act of March 23, 1906, as amended, and the General Bridge Act of 1946 (33 U.S.C. 525 *et seq.*), require that the location and plans for bridges in or over navigable waters of the United States be approved by the Secretary of Homeland Security, who has delegated that responsibility to the Coast Guard. Lake Pend Oreille and Sand Creek are navigable waters of the U.S. as defined in 33 CFR 2.36(a). In exercising these bridge authorities, the Coast Guard considers navigational and environmental impacts, which include historic and tribal effects. The Coast Guard's primary responsibility regarding BNSF's proposed railroad bridges is to ensure these structures do not unreasonably obstruct navigation.

Because the intent of the bridge statutes is to preserve navigation, the Coast Guard's permit authority is limited to the bridge and its essential components including approaches and abutments. Consequently, the Coast Guard does not have the authority to approve or disapprove broader aspects of a project beyond the bridges themselves. For example, if a project sponsor proposes to build a new highway or rail line and the project includes a bridge, the Coast Guard's permit authority is limited to the bridge and its effect upon navigation, but does not extend to the connecting highway or rail line.

As lead federal agency for this Project, the Coast Guard is responsible for the review of its potential effects on the human environment, including historic properties and tribal impacts, pursuant to NEPA and the NHPA. The Coast Guard is therefore required by law to ensure potential environmental effects are carefully evaluated in each bridge permitting decision.

- On July 13, 2018, as part of this evaluation process, the Coast Guard solicited comments from State and Federal agencies with expertise in, and authority over, particular resources that may be impacted by the project. Additionally, the Coast Guard sought input from all tribes that may be affected or otherwise have expertise or equities in the Project. Following tribal and expert agency outreach, the Coast Guard revised its evaluation, and then sought comments from the general public. Agencies that have participated in the environmental review of this Project include the U.S. Army Corps of Engineers (USACE), the U.S. Fish and Wildlife Service (USFWS), the U.S. Environmental Protection Agency (EPA), Idaho Department of Lands (IDL) and the Idaho Department of Environmental Quality (IDEQ).

On February 6, 2019, the USCG issued a notice in the **Federal Register** announcing the availability of a Draft Environmental Assessment for public review and comment (FR USCG–2018–1085). The Coast Guard then held Public Meetings in Ponderay, Idaho on March 13, 2019. During the comment period, the USCG received comments in favor of and opposed to the Project. The comments in favor of the Project generally spoke to economic benefits and requests to expedite the environmental review and issue required permits. The comments in opposition to the Project identified a variety of concerns including, but not limited to, (a) requests to elevate the level of federal environmental review to an Environmental Impact Statement (EIS); (b) concern regarding derailments within the Lake Pend Oreille region and preparedness for response to a derailment causing a spill of coal or petroleum products; (c) fugitive coal dust emissions and the effects upon air and water quality; and (d) the potential for increased rail traffic through the Lake Pend Oreille rail corridor.

With regard to derailments, the Federal Railroad Administration accident statistics and additional detail regarding BNSF's plan to prevent derailments has been added to Section 3.14 (Hazardous Materials and Wastes)

to better characterize derailment risk. Additional details regarding spill response planning for different types of spills under various weather conditions have been added to Section 3.14. In addition, the Lake Pend Oreille Geographic Response Plan, which is to be implemented in the event of a rail accident, is included in Appendix N of the Final EA.

With regard to fugitive coal dust emissions and the effects upon air and water quality, Section 3.1 of the Final EA explains that the current use of load profiling and dust suppressants has been shown to achieve at least an 85 percent reduction in fugitive coal dust and allow only trace amounts to be lost during transit, which are well below levels that could be harmful to human or ecological health. Section 3.1 also references several NEPA documents from the U.S. Army Corps of Engineers and the Surface Transportation Board supporting this determination.

With regard to concern for increased rail traffic through the Lake Pend Oreille rail corridor, the maximum capacity of the rail line through Sandpoint and across Lake Pend Oreille is approximately 79 trains per day while the current average rail traffic volume on that line segment is approximately 60 trains per day. This Project does not add any origin or destination facilities; therefore, it would not induce increases or decreases in rail traffic, but rather is designed to increase efficiency of rail current rail transportation. The market conditions influencing rail train traffic growth in the study area exist with or without construction of a second main line track and associated bridges. Adding a second main line track along this segment would not increase overall capacity of the rail line because there are other constraints on the main lines leading into the Sandpoint and Lake Pend Oreille area.

Based on the information examined through the study of this Project, the USCG has determined that an Environmental Assessment is the appropriate level of environmental documentation. The USCG has determined that there are no significant impacts associated with the Project and has issued a Finding of No Significant Impact.

This notice is being provided for information purposes only, and as such, there is no public comment period associated with this notice.

This notice is issued under the authority of 5 U.S.C. 552(a).

Dated: August 29, 2019.

Brian L. Dunn,

Chief, Office of Bridge Programs, U.S. Coast Guard.

[FR Doc. 2019–19120 Filed 9–4–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2019–0604]

Cook Inlet Regional Citizens' Advisory Council (CIRCAC) Recertification

AGENCY: Coast Guard, DHS.

ACTION: Notice of recertification.

SUMMARY: This notice informs the public that the Coast Guard has recertified the Cook Inlet Regional Citizens' Advisory Council (CIRCAC) as an alternative voluntary advisory group for Cook Inlet, Alaska. This certification allows the CIRCAC to monitor the activities of terminal facilities and crude oil tankers under an alternative composition, other than prescribed, Cook Inlet Program established by statue.

DATES: This recertification is effective for the period from September 1, 2019 through August 31, 2020.

FOR FURTHER INFORMATION CONTACT: LCDR Jonathan Dale, Seventeenth Coast Guard District (dpi), by phone at (907) 463–2812, email at *jonathan.dale@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

As part of the Oil Pollution Act of 1990, Congress passed the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (the Act), 33 U.S.C. 2732, to foster a long-term partnership among industry, government, and local communities in overseeing compliance with environmental concerns in the operation of crude oil terminals and oil tankers.

The President has delegated his authority under 33 U.S.C 2732(o) respecting certification of advisory councils, or groups, subject to the Act to the Secretary of the Department of Homeland Security. Section 8(g) of Executive Order 12777, (56 FR 54757, October 22, 1991), as amended by section 34 of Executive Order 13286 (68 FR 10619, March 5, 2003). The Secretary redelegated that authority to the Commandant of the USCG. Department of Homeland Security Delegation No. 0170.1, paragraph 80 of section II. The Commandant redelegated that authority to the Chief, Office of Marine Safety, Security and Environmental Protection (G–M) on March 19, 1992 (letter #5402).

The Assistant Commandant for Marine Safety and Environmental Protection (G–M), redelegated recertification authority for advisory councils, or groups, to the Commander, Seventeenth Coast Guard District on February 26, 1999 (letter #16450).

On July 7, 1993, the USCG published a policy statement, ''Alternative Voluntary Advisory Groups, Prince William Sound and Cook Inlet'' (58 FR 36504), to clarify the factors considered in making the determination as to whether advisory councils, or groups, should be certified in accordance with the Act.

On September 16, 2002, the USCG published a policy statement, 67 FR 58440, which changed the recertification procedures such that applicants are required to provide the USCG with comprehensive information every three years (triennially). For each of the two years between the triennial application procedures, applicants submit a letter requesting recertification that includes a description of any substantive changes to the information provided at the previous triennial recertification. Further, public comment is only solicited during the triennial comprehensive review.

Recertification

By letter dated Jul 31 2019, the Commander, Seventeenth Coast Guard District, certified that the CIRCAC qualifies as an alternative voluntary advisory group under 33 U.S.C. 2732(o). This recertification terminates on August 31, 2020.

Dated: July 31, 2019.

Matthew T. Bell Jr.,

Rear Admiral, U.S. Coast Guard, Commander, Seventeenth Coast Guard District.

[FR Doc. 2019–19151 Filed 9–4–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Modification and Clarification of the National Customs Automation Program Test Regarding Periodic Monthly Statements

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

ACTION: General notice.

SUMMARY: This document announces changes to the U.S. Customs and Border

Protection's (CBP) National Customs Automation Program (NCAP) test concerning periodic monthly statements (PMS) to reflect that CBP will identify PMS as paid upon the completion of the funds transfer when payment is made via Automated Clearinghouse (ACH). The trade community will experience no delays, interruptions, or process changes associated with the modifications. Except to the extent expressly announced or modified by this document, all aspects, rules, terms and conditions announced in previous notices regarding the test remain in effect. For ease of reference, CBP is reproducing the entire test, with the changes, in this document.

DATES: The changes made by this notice are effective September 7, 2019.

ADDRESSES: Comments concerning this test program may be submitted via email to Kara Welty at *collectionscapabilityowners@cbp.dhs.gov* with a subject line identifier reading, ''Periodic Monthly Statements.''

FOR FURTHER INFORMATION CONTACT: For policy-related questions, contact Kara Welty, Debt Management Branch, Revenue Division, Office of Finance, *collectionscapabilityowners@cbp.dhs.gov,* or (866) 530–4172. For technical questions related to transmissions using the Automated Broker Interface (ABI), contact your assigned client representative. Interested parties without an assigned client representative should direct their questions via email to the Client Representative Branch at *gmb.clientrepoutreach@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on National Customs Automation Program (NCAP) Test Concerning PMS

The National Customs Automation Program (NCAP) was established by Subtitle B of Title VI—Customs Modernization in the North American Free Trade Agreement (NAFTA) Implementation Act (Customs Modernization Act) (Pub. L. 103–182, 107 Stat. 2057, 2170, December 8, 1993) (19 U.S.C. 1411). Through NCAP, the thrust of customs modernization was on trade compliance and the development of the Automated Commercial Environment (ACE) as the CBP-authorized electronic data interchange (EDI) system. ACE is an automated and electronic system for commercial trade processing which is intended to streamline business processes, facilitate growth in trade, ensure cargo security, and foster participation in global commerce, while ensuring compliance with U.S. laws and regulations and reducing costs for CBP and all of its communities of interest. The ability to meet these objectives depends on successfully modernizing CBP's business functions and the information technology that supports those functions. CBP's modernization efforts are accomplished through phased releases of ACE component functionality. Section 101.9(b) of title 19 of the Code of Federal Regulations (19 CFR 101.9(b)) provides for the testing of NCAP components.

On February 4, 2004, CBP published a notice in the **Federal Register** that announced a plan to conduct an NCAP test concerning PMS (hereinafter, referred to as the ''PMS test''), which allows an importer or an importer's designated broker to deposit estimated duties, taxes, and fees on a monthly basis. *See* 69 FR 5362 (February 4, 2004). CBP modified and clarified the PMS test in thirteen (13) subsequent **Federal Register** notices published on: September 8, 2004 (69 FR 54302); February 1, 2005 (70 FR 5199); August 8, 2005 (70 FR 45736); September 22, 2005 (70 FR 55623); January 20, 2006 (71 FR 3315); June 2, 2006 (71 FR 32114); October 17, 2008 (73 FR 61891); December 12, 2016 (81 FR 89482); January 9, 2017 (82 FR 2385); January 17, 2017 (82 FR 4900); June 8, 2017 (82 FR 26699); June 30, 2017 (82 FR 29910); and November 1, 2017 (82 FR 50656).

As part of the PMS test, CBP issues a Preliminary PMS for entries to NCAP test participants on a monthly basis. NCAP test participants must then deposit payment for the estimated duties, taxes, and fees attributable to the entries, with CBP, via Automated Clearinghouse (ACH). There are two (2) ACH payment processes—the ACH debit process and the ACH credit process. In the sections below, this document contains a description of the current state of the PMS test as it relates to the ACH debit and the ACH credit payment processes, as well as the modifications and clarifications to the PMS test made by this document. For ease of reference, this document also republishes the PMS test in its entirety, with updates to reflect the modifications and clarifications made in the past, as well as by this document.

II. ACH Debit Process

A. Background on Payment of PMS via ACH Debit Process

An ACH debit participant initiates the payment process by transmitting one ACH debit authorization per Periodic Daily Statement to CBP through ABI. If the ACH debit authorization is error-free, CBP accepts the ACH debit authorization and provides the ACH debit participant with a message confirming CBP's acceptance of the ACH debit authorization. The ACH debit participant is required to ensure that the money amount, which will be identified on the Preliminary PMS, is—in fact—available in the ACH debit participant's bank account on the 15th day of the month following the month in which the merchandise scheduled for monthly processing is either entered or released, whichever comes first, unless the importer or the importer's designated broker elects an earlier date. On that day, CBP transmits the debit authorizations compiled in the Preliminary PMS from the Periodic Daily Statements to the designated financial institution, and CBP then identifies the Preliminary PMS as paid.

CBP subsequently generates the Final PMS on the night that CBP transmits the debit authorizations to the designated financial institution, and then transmits the Final PMS to the importer or the importer's designated broker. The Final PMS serves as evidence of the payment of the Preliminary PMS through an ACH transaction; but, the funds transfer is usually not completed until two (2) business days after the transmission of the debit authorizations to the designated financial institution.

B. PMS Test Modification and Clarification Related to ACH Debit Process

This document announces that, in order to more accurately reflect the status of the funds transfer, CBP will no longer identify an ACH debit participant's Preliminary PMS as paid immediately upon the transmission of the ACH debit authorizations to the designated financial institution by CBP (which occurs on the 15th day of the month following the month in which the merchandise scheduled for monthly processing is either entered or released, whichever comes first, unless the importer or the importer's designated broker selects an earlier date). The Preliminary PMS will still be issued; but, instead, CBP will issue the Final PMS and identify it as paid upon receiving confirmation from the Department of the Treasury (Treasury) that the funds are available and transferred to CBP (which marks the completion of the funds transfer).

The modifications announced in this document do not affect the timeliness of the payment, which remains based upon the date of CBP's acceptance of the ACH debit authorizations for the entries. Once CBP receives confirmation from Treasury that the funds are available

and transferred to CBP, then CBP will treat the date of CBP's acceptance of the ACH debit authorizations as the effective payment date for purposes of determining the timeliness of the payments for the entries. The date of CBP's acceptance of the ACH debit authorizations also remains the date for the calculation of interest and/or liquidated damages, if applicable; the calculation is unaffected by the modifications announced in this document. It is important to note that this modification only applies to importers who participate in the test program. For all other importers participating in statement processing via ABI, the current regulation, 19 CFR 24.25(c)(4), continues to govern when CBP identifies a statement as paid.

III. ACH Credit Process

A. Background on Payment of PMS via ACH Credit Process

The ACH credit process permits participants to electronically transmit payment for PMS, through the ACH credit participant's financial institution, directly to the CBP account maintained by Treasury. The ACH credit participant is required to ensure that CBP receives the ACH credit payment no later than the 15th day of the month following the month in which the merchandise scheduled for monthly processing is either entered or released, whichever comes first, unless the importer or the importer's designated broker elects an earlier date. If the 15th day of that month falls on a weekend or holiday, the ACH credit participant is required to ensure that CBP receives the ACH credit payment by the business day directly preceding such weekend or holiday. Currently, CBP identifies a Preliminary PMS as paid upon the acceptance of the ACH credit payment by CBP, which equates to the collection and settlement date. CBP generates the Final PMS on the night that CBP accepts the ACH credit payment, and then transmits the Final PMS to the importer or the importer's designated broker. The Final PMS serves as evidence of the payment of the Preliminary PMS through an ACH transaction.

B. Test Modification and Clarification Related to ACH Credit Process

In order to promote consistency with the modifications of the PMS test in relation to ACH debit payments, this document also modifies the PMS test to reflect that CBP will identify the Final PMS, as opposed to Preliminary PMS, as paid for the ACH credit process. As explained above for the ACH debit process, these changes do not affect either the timeliness of the payment or the date for the calculation of interest and/or liquidated damages, if applicable, for the ACH credit process. It is important to note that this modification only applies to importers who participate in the test program. For all other importers participating in statement processing via ABI, the current regulation, 19 CFR 24.25(c)(4), continues to govern when CBP identifies a statement as paid.

IV. Republication of Periodic Monthly Statement (PMS) Test

A. Overview of Modifications and Clarifications of the Test

This section provides a description of the process for entries scheduled for monthly payment, as of this date, including the modifications and clarifications made by this notice. Several modifications and clarifications of the PMS test have been announced after the PMS test's most recent republication in a **Federal Register** notice on January 20, 2006. *See* 71 FR 3315 (January 20, 2006). Accordingly, this republication of the PMS test reflects several substantive modifications and clarifications of the PMS test that were not reflected in the PMS test's previous republication in the January 20, 2006 **Federal Register** notice.

First, in order to reflect the modifications and clarifications made by this notice, this document addresses the ACH payment processes in three (3) separate paragraphs—paragraph f pertains exclusively to the ACH debit process, paragraph g pertains exclusively to the ACH credit process, and new paragraph h pertains to both ACH payment processes.

- Paragraph f establishes when ACH debit participants are required to submit the ACH debit authorizations, when CBP will transmit the ACH debit authorizations to the financial institution, and when the money amount identified on the Preliminary Periodic Monthly Statement should, in fact, be available in an ACH debit participant's bank account.
- Paragraph g provides when, for ACH credit participants, CBP must receive the ACH credit payment.
- New Paragraph h provides that, upon the completion of the funds transfer, CBP will issue the Final Periodic Monthly Statement and identify it as paid, transmit the Final Periodic Monthly Statement to the importer or the importer's designated broker, and treat the date of CBP's acceptance as the effective payment date of the PMS for purposes of calculation of interest and/or liquidated damages, if applicable. Any references to the marking of a PMS as paid and the generation of the Final Periodic Monthly Statement (previously contained in paragraphs f and g of the republication of the PMS test that was published in the January 20, 2006 **Federal Register** notice) have been moved to paragraph h to reflect that, for both ACH debit and ACH credit participants, CBP will no longer identify a PMS as paid or issue a Final Periodic Monthly Statement prior to the completion of the funds transfer.

Second, new paragraphs i and j contain modifications of the PMS test that were announced in a **Federal Register** notice published on June 2, 2006. *See* 71 FR 32114 (June 2, 2006). Paragraph i pertains to the payment of estimated duties, taxes, and fees for single entries or incremental entries involving split shipments. Paragraph j pertains to the payment of estimated duties, taxes, and fees for single entries or incremental entries involving unassembled or disassembled entities.

B. Periodic Monthly Statement (PMS) Test

Entries scheduled for monthly payment will be processed as follows:

a. As entries are filed with CBP, the importer or the importer's designated broker schedules them for monthly payment.

b. CBP posts all entries that are scheduled for monthly payment on the Preliminary Periodic Daily Statement.

c. The importer or the importer's designated broker processes entry summary presentation transactions for each Preliminary Periodic Daily Statement within 10 working days of the date of entry.

d. After summary information has been filed, CBP posts the scheduled entries on the Final Periodic Daily Statement.

e. Entries appearing on the Final Periodic Daily Statements and scheduled for monthly payment appear on the Preliminary Periodic Monthly Statement. CBP will generate the Preliminary Periodic Monthly Statement by the 11th calendar day of the month following the month in which the merchandise is either entered or released, whichever comes first, unless the importer or the importer's designated broker selects an earlier date.

f. Automated Clearinghouse (ACH) debit participants are required to submit one debit authorization for each Preliminary Periodic Daily Statement at any time from the creation of the Preliminary Periodic Daily Statement until the creation of the related

Preliminary Periodic Monthly Statement. If an ACH debit participant fails to submit an ACH debit authorization for a Preliminary Periodic Daily Statement within 10 working days of the date of entry, payment for the Preliminary Periodic Daily Statement is considered late; however, the ACH debit participant will still be permitted to submit the ACH debit authorization. CBP will transmit the debit authorizations compiled in the Preliminary Periodic Monthly Statement to the financial institution on the 15th working day of the month following the month in which the merchandise is either entered or released, whichever comes first, unless the importer or the importer's designated broker selects an earlier date. ACH debit participants must ensure that the money amount identified on the Preliminary Periodic Monthly Statement is, in fact, available in their bank account by the 15th working day of that month.

g. For ACH credit participants, CBP must receive the ACH credit payment no later than the 15th day of the month following the month in which the merchandise scheduled for monthly processing is either entered or released, whichever comes first, or if that day falls on a weekend or holiday, the business day directly preceding such weekend or holiday, unless the importer or the importer's designated broker selects an earlier date.

h. For both ACH credit and ACH debit participants, once CBP receives confirmation from Treasury that the funds are available and transferred to CBP (which marks the completion of the funds transfer), then CBP will: (1) Issue the Final Periodic Monthly Statement and identify it as paid; (2) transmit the Final Periodic Monthly Statement to the importer or the importer's designated broker; and (3) treat the date of CBP's acceptance of the ACH credit or debit payment as the effective payment date of the PMS for purposes of the calculation of interest and/or liquidated damages, if applicable. CBP will generate the Final Periodic Monthly Statement on the night that payment is processed.

i. Importers choosing to file a single entry involving split shipments consistent with the provisions of 19 CFR 141.57(d)(1) or unassembled or disassembled entities consistent with the provisions of 19 CFR 141.58(d)(1) may pay estimated duties, taxes, and fees attributable to those entries through the method set forth in the PMS test. The date of filing of that entry identifies the month in which entry is filed and establishes the obligation to pay estimated duties, taxes, and fees by the 15th working day of the month following the month in which entry is filed.

j. Importers choosing to file incremental entries involving split shipments consistent with the provisions of 19 CFR 141.57(d)(2) or unassembled or disassembled entities consistent with the provisions 19 CFR 141.58(d)(2) as a special permit for immediate delivery after the arrival of the first portion (Incremental Release) also may pay estimated duties, taxes, and fees attributable to that entry through the method set forth in the PMS test. The date that the importer obtains release of the first portion of the entity (as provided in 19 CFR 141.57(e) or 19 CFR 141.58(e)) will identify the month that the entry is filed and establishes the obligation to pay estimated duties, taxes, and fees by the 15th working day of the month following the month in which entry is filed.

Participants should note that if they voluntarily remove an entry from a Periodic Daily Statement before expiration of the 10-working-day period after release, that entry may be placed on another Periodic Daily Statement falling within the same 10-working-day period. If, however, participants remove an entry from a Periodic Daily Statement after expiration of the 10-working-day period after release, the entry may be the subject of a claim for liquidated damages for late payment.

V. Previous Notices and Suspension of Regulations

For purposes of this test, any provision in title 19 of the Code of Federal Regulations including, but not limited to, the provisions found in parts 24, 141, 142, and 143 thereof relating to entry summary filing and processing that are inconsistent with the requirements set forth in this notice are waived for the duration of the test. *See* 19 CFR 101.9(b). This document does not waive any recordkeeping requirements found in part 163 of title 19 of the Code of Federal Regulations (19 CFR part 163) and the Appendix to part 163 (commonly known as the ''(a)(1)(A) list'').

Dated: August 29, 2019.

Brenda B. Smith,

Executive Assistant Commissioner, Office of Trade.

[FR Doc. 2019–19147 Filed 9–4–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–LE–2019–N091; FF09L00200–FX–LE18110900000; OMB Control Number 1018–0129]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Captive Wildlife Safety Act

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before October 7, 2019.

ADDRESSES: Send written comments on this information collection request (ICR) to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at *OIRA_Submission@omb.eop.gov;* or via facsimile to (202) 395–5806. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: JAO/1N PRB/PERMA, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov.* Please reference OMB Control Number 1018–0129 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

On December 27, 2018, we published a **Federal Register** notice soliciting

comments on this collection of information for 60 days, ending on February 25, 2019 (83 FR 66740). We received one comment in response to the **Federal Register** notice:

Comment: On February 11, 2019, we received a comment from the Executive Director of the Zoological Association of America (ZAA). The ZAA strongly opposes the elimination of recordkeeping requirements or any further preference proposed by the Service for wildlife sanctuaries under the Captive Wildlife Safety Act. The ZAA specifically cited their objection to the ''accredited wildlife sanctuary'' exemption that they feel largely hinges on IRS 501(c)(3) status and not wildlife expertise. ZAA stated that any reputable wildlife holding facility should have extensive records, including acquisition and disposition records, as well as husbandry and medical records. These records establish the basis of knowledge and care of every animal in the care of a facility, and no facility, accredited or not, should be exempt from having such records.

Agency Response: No action required. The Service is not seeking to eliminate the records keeping requirement. The **Federal Register** notice announced our intention to renew the information collection requirements established under the CWSA for accredited wildlife sanctuaries. Additionally, changes to, or removal of, the eligibility requirements by accredited wildlife sanctuaries under the CWSA would require a substantive change to the Act by Congress. Such changes would not be part of this information collection.

We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the Service; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Service enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Service minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Captive Wildlife Safety Act (CWSA; Pub. L. 108–191; 16 U.S.C. 3371 note and 16 U.S.C. 3372 note) amends the Lacey Act (16 U.S.C. 3371 *et seq.;* 18 U.S.C. 42–43) by making it illegal to import, export, buy, sell, transport, receive, or acquire, in interstate or foreign commerce, live lions, tigers, leopards, snow leopards, clouded leopards, cheetahs, jaguars, or cougars, or any hybrid combination of any of these species, unless certain exceptions are met. The CWSA was signed into law in 2003 and enforcement began on September 17, 2007. There are several exemptions to the prohibitions of the CWSA, including accredited wildlife sanctuaries. There is no requirement for wildlife sanctuaries to submit applications to qualify for the accredited wildlife sanctuary exemption. Wildlife sanctuaries themselves will determine if they qualify. As a matter of routine, we do not inspect or follow-up on wildlife sanctuaries unless we have cause for concern. To qualify, they must meet all of the following criteria:

- Obtain approval by the U.S. Internal Revenue Service (IRS) as a corporation that is exempt from taxation under section 501(a) of the IRS Code of 1986 (Pub. L. 99–514), which is described in sections 501(c)(3) and 170(b)(1)(A)(vi) of that code.
- Do not engage in commercial trade in the prohibited wildlife species, including offspring, parts, and products.
- Do not propagate the prohibited wildlife species.
- Have no direct contact between the public and the prohibited wildlife species.

The basis for this information collection is the recordkeeping requirement that we place on accredited wildlife sanctuaries. We require accredited wildlife sanctuaries to maintain complete and accurate records of any possession, transportation, acquisition, disposition, importation, or exportation of the prohibited wildlife species as defined in the CWSA (see title 50 of the Code of Federal Regulations (CFR) at part 14, subpart K). Records must be up to date and include: (1) Names and addresses of persons to or from whom any prohibited wildlife species has been acquired, imported, exported, purchased, sold, or otherwise transferred; and (2) dates of these transactions. Accredited wildlife sanctuaries must:

- Maintain these records for 5 years.
- Make these records accessible to Service officials for inspection at reasonable hours.
- Copy these records for Service officials, if requested.

Title of Collection: Captive Wildlife Safety Act, 50 CFR 14.250–14.255.

OMB Control Number: 1018–0129.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Accredited wildlife sanctuaries.

Total Estimated Number of Annual Respondents: 750.

Total Estimated Number of Annual Responses: 750.

Estimated Completion Time per Response: 1 hour.

Total Estimated Number of Annual Burden Hours: 750.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Ongoing.

Total Estimated Annual Nonhour Burden Cost: $300.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: August 30, 2019.

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2019–19173 Filed 9–4–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/ A0A501010.999900 253G; OMB Control Number 1076–NEW]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Native Language Immersion Grant

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, Bureau of Indian Education (BIE) are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before October 7, 2019.

ADDRESSES: Send written comments on this information collection request (ICR)

to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at *OIRA_Submission@omb.eop.gov;* or via facsimile to (202) 395–5806. Please provide a copy of your comments to Ms. Maureen Lesky, Ph.D., Bureau of Indian Education, 1011 Indian School Road, Albuquerque, NM 87104; or by email to *Maureen.lesky@bie.edu.* Please reference OMB Control Number 1076–NEW in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Ms. Maureen Lesky, Ph.D. by email at *Maureen.lesky@bie.edu,* or by telephone at (505) 563–5397. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on April 16, 2018 (83 FR 16380). No comments were received.

We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the BIE; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the BIE enhance the quality, utility, and clarity of the information to be collected; and (5) how might the BIE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Native Language Immersion Grant instructional funding document will be made available on the *www.bie.edu* website and by email, as requested. The funding document will include instructions on how to complete the document and identify required information applicants need to provide. The Native Language Immersion Grant requires the following be submitted for consideration:

- A project summary including program title, school name, Tribal language(s), geographic location with a brief overview of the need for the program including goals, objectives, specific program activities, and anticipated outputs and outcomes;
- Indication of receipt of funding previously from Department of Education or Administration for Native Americans for this specific program work and confirmation of no duplication;
- Data collection and stakeholder collaboration activities, and timetable;
- Detailed monitoring and evaluation plan including measure indicators and methods, timetable and budget references, products/services to be delivered and how/to whom they will be delivered, if applicable;
- Expected direct effect(s) of the program on beneficiaries;
- Complete budget information, requested budget items/costs for non-construction programs;
- And a completed SF–424A.

Each proposal is rated individually based on the quality of the items above and not against other applications. A summary of the review panel comments may be provided to the applicant if requested.

Title of Collection: Native Language Immersion Grant.

OMB Control Number: 1076–NEW.

Form Number: SF–424A.

Type of Review: New.

Respondents/Affected Public: Bureau of Indian Education funded schools.

Total Estimated Number of Annual Respondents: 60.

Total Estimated Number of Annual Responses: 270.

Estimated Completion Time per Response: 2 to 67 hours.

Total Estimated Number of Annual Burden Hours: 1,335.

Respondent's Obligation: Required to Obtain or Retain a Benefit.

Frequency of Collection: One time for the proposal and annual report, 12 times for the monthly meetings, and quarterly for the budget reports.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2019–19111 Filed 9–4–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCA942000 L57000000.BX0000 17XL5017AR; MO#4500135998]

Filing of Plats of Survey: California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of lands described in this notice are scheduled to be officially filed in the Bureau of Land Management (BLM), California State Office, Sacramento, California, 30 calendar days from the date of this publication. The surveys, which were executed at the request of the U.S. Fish and Wildlife Service, U.S. Forest Service and the Bureau of Land Management, are necessary for the management of these lands.

DATES: Unless there are protests to this action, the plats described in this notice will be filed on October 7, 2019.

ADDRESSES: You may submit written protests to the BLM California State Office, Cadastral Survey, 2800 Cottage Way, W–1623, Sacramento, CA 95825. A copy of the plats may be obtained from the BLM California State Office, Public Room, 2800 Cottage Way, W–1623, Sacramento, California 95825, upon required payment.

FOR FURTHER INFORMATION CONTACT: Jon Kehler, Chief, Branch of Cadastral Survey, Bureau of Land Management, California State Office, 2800 Cottage Way, W–1623, Sacramento, California 95825; 1–916–978–4323; *jkehler@blm.gov.*

Persons who use a telecommunications device for the deaf may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The Service is available 24 hours a day, 7 days a week, to leave a message or question with the above individual.

You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The lands surveyed are:

Mount Diablo Meridian, California

T. 4 S, R. 7 E, meander survey and metes-and-bounds survey, for Group No. 1743, accepted April 25, 2019.
T. 6 N, R. 5 E, dependent resurvey and metes-and-bounds survey, for Group No. 1705, accepted May 23, 2019.
T. 47 N, R. 2 E, dependent resurvey, for Group No. 1756, accepted July 18, 2019.
T. 2 N, R. 17 E, dependent resurvey, subdivision and metes-and-bounds survey, for Group No. 1749, accepted July 23, 2019.
T. 2 N, R. 18 E, dependent resurvey and subdivision of sections, for Group No. 1677, accepted July 23, 2019.

San Bernardino Meridian, California

T. 10 N, R. 1 E, dependent resurvey, for Group No. 1764, accepted May 23, 2019.
T. 14 N, R. 12 E, dependent resurvey and subdivision of section 20, for Group No. 1750, accepted June 27, 2019.

A person or party who wishes to protest one or more plats of survey must file a written notice of protest within 30 calendar days from the date of this publication at the address listed in the **ADDRESSES** section of this notice. Any notice of protest received after the due date will be untimely and will not be considered. A written statement of reasons in support of a protest, if not filed with the notice of protest, must be filed at the same address within 30 calendar days after the notice of protest is filed. If a protest against the survey is received prior to the date of official filing, the filing will be stayed pending consideration of the protest. A plat will not be officially filed until the day after all protests have been dismissed or otherwise resolved.

Before including your address, phone number, email address, or other personal identifying information in your notice of protest or statement of reasons, you should be aware that the documents you submit—including your personal identifying information—may be made publicly available at any time. While you can ask the BLM to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C., Chapter 3.

Jon L. Kehler,

Chief Cadastral Surveyor.

[FR Doc. 2019–18995 Filed 9–4–19; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORB00000.L10200000.BS0000. LXSSH1060000.19X.HAG 19–0110]

Notice of Public Meeting for the Southeast Oregon Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior Bureau of Land Management (BLM) Southeast Oregon Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Southeast Oregon RAC will meet Thursday, October 10, 2019, from 8:00 a.m. to 4:15 p.m. Pacific Daylight Time. There will be a 30-minute public comment period beginning at 3:15 p.m.

ADDRESSES: The meeting will be held at the Harney County Community Center, 478 N Broadway, Burns, Oregon.

FOR FURTHER INFORMATION CONTACT: Larisa Bogardus, Public Affairs Officer, 1301 S G Street, Lakeview, Oregon 97630; 541–947–6811; *lbogardus@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member Southeast Oregon RAC provides advice and recommendations to the Secretary of the Interior on a variety of planning and management issues associated with public land management within the BLM's Burns, Vale, and Lakeview Districts, and the U.S. Forest Service's Fremont-Winema and Malheur National Forests. Their diverse perspectives are represented in commodity, noncommodity, and local interests. All meetings are open to the public in their entirety. Information to be distributed to the RAC is requested prior to the start of each meeting.

Agenda item topics include management of energy and minerals, timber, rangeland and livestock grazing, commercial and dispersed recreation, wildland fire and fuels, and wild horses and burros relating to proposed actions by the Burns, Vale, or Lakeview Districts; and any other business that may reasonably come before the RAC. A final agenda will be posted online at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/oregon-washington/southeast-oregon-rac* at least one week prior to the meeting.

Before including your address, phone number, email address, or other personal identifying information in your comments, please be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 CFR 1784.4–2.

Jeffrey Rose,

Burns District Manager.

[FR Doc. 2019–19157 Filed 9–4–19; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM954000.L14400000.BJ0000. BX0000.19XL1109AF]

Notice of Filing of Plats of Survey; New Mexico; Oklahoma; and Texas

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plat of survey of the following described land is scheduled to be officially filed 30 days after the date of this publication in the Bureau of Land Management (BLM), New Mexico Office, Santa Fe, New Mexico. The survey announced in this notice is necessary for the management of lands administered by the agency indicated.

ADDRESSES: This plat will be available for inspection in the New Mexico Office, Bureau of Land Management, 301 Dinosaur Trail, Santa Fe, New Mexico 85004–4427. Protests of the survey should be sent to the New Mexico Director at the above address.

FOR FURTHER INFORMATION CONTACT: Christopher P. McDonald, Cadastral Surveyor; (505) 954–2042; *cpmcdona@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

New Mexico Principal Meridian, New Mexico

The plat, representing the metes-and-bounds survey of a tract of land within Township 22 North, Range 11 East, accepted June 24, 2019, for Group 1195, New Mexico.

This plat was prepared at the request of the U.S. Forest Service.

The Indian Meridian, Oklahoma

The supplemental plat, in three (3) sheets, within Township 10 North, Ranges 22 and 23 East, accepted July 30, 2019.

The supplemental plat, within Township 11 North, Range 23 East, of the Indian Meridian, accepted July 30, 2019.

These plats were prepared at the request of the Arkansas Riverbed Authority.

Cameron County, Texas

The plat representing the survey Palo Alto Battlefield National Historic Site in Cameron County, TX, accepted July 29, 2019, Group 13, TX.

This plat was prepared at the request of the National Parks Service.

A person or party who wishes to protest against any of these surveys must file a written notice of protest within 30 calendar days from the date of this publication with the New Mexico Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within 30 days after the protest is filed. Before including your address, or other personal information in your protest, please be aware that your entire protest, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C. Chap 3.

Jacob Barowsky,

Acting Chief Cadastral Surveyor of New Mexico, Oklahoma, Texas and Kansas.

[FR Doc. 2019–19165 Filed 9–4–19; 8:45 am]

BILLING CODE 4310–FB–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–19–033]

Sunshine Act Meetings

Agency Holding the Meeting: United States International Trade Commission.

TIME AND DATE: September 10, 2019 at 9:30 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. *Agendas for future meetings:* None.
2. Minutes.
3. Ratification List.
4. Vote on Inv. Nos. 731–TA–1455–1457 (Preliminary) (Polyethylene Terephthalate (''PET'') Sheet from Korea, Mexico, and Oman). The Commission is currently scheduled to complete and file its determinations on September 13, 2019; views of the Commission are currently scheduled to be completed and filed on September 20, 2019.
5. Vote on Inv. No. 731–TA–1206 (Review) (Diffusion-Annealed, Nickel-Plated Flat-Rolled Steel Products from Japan). The Commission is currently scheduled to complete and file its determination and views of the Commission by September 24, 2019.
6. *Outstanding action jackets:* None.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: August 29, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019–19235 Filed 9–3–19; 11:15 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–19–033]

Sunshine Act Meetings

Agency Holding the Meeting: United States International Trade Commission.

TIME AND DATE: September 16, 2019 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. *Agendas for future meetings:* None.
2. Minutes.
3. Ratification List.
4. Vote on Inv. No. 731–TA–1427 (Final) (Refillable Stainless Steel Kegs from Mexico). The Commission is currently scheduled to complete and file its determination and views of the Commission by October 2, 2019.
5. *Outstanding action jackets:* None.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: September 3, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019–19279 Filed 9–3–19; 4:15 pm]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–747 (Final)]

Fresh Tomatoes From Mexico; Revised Schedule for the Subject Investigation

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: August 30, 2019.

FOR FURTHER INFORMATION CONTACT: Christopher W. Robinson ((202) 205–2542), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: On August 7, 2019, the Commission published a schedule for the conduct of the final phase of the subject investigation (84 FR 38643). Subsequently, on August 21, 2019, the Department of Commerce (''Commerce'') notified the Commission that Commerce and certain Mexican

tomato producers/exporters initialed a draft agreement to suspend Commerce's antidumping duty investigation on Fresh Tomatoes from Mexico. The Commission, therefore, is revising its schedule.

The Commission's revised dates in the schedule are as follows: Requests to appear at the hearing must be filed with the Secretary to the Commission not later than September 17, 2019; the prehearing conference will be held at the U.S. International Trade Commission Building on September 19, 2019, if deemed necessary; the prehearing staff report will be placed in the nonpublic record on September 3, 2019; the deadline for filing prehearing briefs is September 10, 2019; the hearing will be held at the U.S. International Trade Commission Building at 9:30 a.m. on September 24, 2019; the deadline for filing posthearing briefs is September 30, 2019; the Commission will make its final release of information on October 17, 2019; and final party comments are due on October 21, 2019.

For further information concerning this proceeding, see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: This investigation is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: August 30, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–19154 Filed 9–4–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1424 (Final)]

Mattresses From China; Revised Schedule for the Subject Investigation

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: July 8, 2019.

FOR FURTHER INFORMATION CONTACT: Calvin Chang (202–205–3062), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: On May 28, 2019, the Commission established a schedule for the conduct of the final phase of the subject investigation (84 FR 27657, June 13, 2019). On July 8, 2019, the Commission revised its schedule of the final phase of the subject investigation (84 FR 34408, July 18, 2019). The Commission is revising its schedule by changing the hearing date.

The Commission's revised schedule is as follows: Requests to appear at the hearing must be filed with the Secretary to the Commission not later than October 8, 2019; the prehearing conference will be held at the U.S. International Trade Commission Building on October 10, 2019, if deemed necessary; the prehearing staff report will be placed in the nonpublic record on September 19, 2019; the deadline for filing prehearing briefs is September 26, 2019; the hearing will be held at the U.S. International Trade Commission Building at 9:30 a.m. on October 11, 2019; the deadline for filing posthearing briefs is October 18, 2019; the Commission will make its final release of information on November 12, 2019; and final party comments are due on November 14, 2019.

For further information concerning this proceeding, see the Commission's May 28, 2019 notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: This investigation is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: August 30, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–19152 Filed 9–4–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–19–034]

Sunshine Act Meetings

Agency Holding the Meeting: United States International Trade Commission.

TIME AND DATE: September 13, 2019 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. *Agendas for future meetings:* None.
2. Minutes.
3. Ratification List.
4. Vote on Inv. No. 731–TA–919 (Third Review) (Welded Large Diameter Line Pipe from Japan). The Commission is currently scheduled to complete and file its determination and views of the Commission by September 30, 2019.
5. Vote on Inv. Nos. 731–TA–1140–1142 (Second Review) (Uncovered Innerspring Units from China, South Africa, and Vietnam). The Commission is currently scheduled to complete and file its determinations and views of the Commission by September 27, 2019.
6. *Outstanding action jackets:* None.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: September 3, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019–19277 Filed 9–3–19; 4:15 pm]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Balanced Armature Devices, Products Containing the Same, and Components Thereof, DN 3409*; the Commission is soliciting comments on any public interest issues raised by the

complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Knowles Corporation; Knowles Electronics, LLC; and Knowles Electronics (Suzhou) Co., Ltd. on August 29, 2019. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain balanced armature devices, products containing the same, and components thereof. The complaint names as respondents: Liang Li (a/k/a Ryan Li) of China; Shenzhen Bellsing Acoustic Technology Co., Ltd. of China; Suzhou Bellsing Acoustic Technology Co. Ltd. of China; Bellsing Corporation of Lisle, IL; Dongguan Bellsing Precision Device Co., Ltd. of China; Suzhou Mingshi Intelligent Manufacturing Technology Co., Ltd. a/k/a Suzhou MS Intelligent Manufacturing Technology Co., Ltd. a/k/a Suzhou MS Automation Technology Co., Ltd. of China; Shanghai Mingshi Automation Technology Co., Ltd. a/k/a Shanghai MS Automation Technology of China; Dongguan Xinyao Electronics Industrial Co., Ltd. d/b/a Fidue Acoustics of China; Guangzhou FiiO Electronics Technology Co., Ltd. of China; Hearing Direct Ltd. of the United Kingdom; Soundlink Co. Ltd. of China; GN Hearing A/S of Denmark; GN Hearing Care Corp. of Bloomington, MN; Advanced Affordable Hearing, LLC of Anchorage, AK; Magnatone Hearing Aid Corporation d/b/a Persona Medical and InEarz Audio of Casselberry, FL; Jerry Harvey Audio LLC of Orlando, FL; Magic Dynamics, LLC d/b/a MagicEar of Clearwater, FL; Campfire Audio, LLC of Portland, OR; and Clear Tune Monitors, Inc. of Orlando, FL. The complainant requests that the Commission issue a general exclusion order, or in the alternative a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) Identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) Indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) Explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3409'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: August 29, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–19108 Filed 9–4–19; 8:45 am]

BILLING CODE 7020–02–P

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

[OMB Number 1125–0012]

Agency Information Collection Activities; Proposed Collection; Comments Requested; Request for New Recognition, Renewal of Recognition, Extension of Recognition of a Non-Profit Religious, Charitable, Social Service, or Similar Organization (Form EOIR–31)

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Executive Office for Immigration Review, 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 November 4, 2019.

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 Executive Office for Immigration Review, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension with changes of a currently approved collection.

2. *The Title of the Form/Collection:* Request for New Recognition, Renewal of Recognition, Extension of Recognition of a Non-profit Religious, Charitable, Social Service, or Similar Organization.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form EOIR–31. The applicable component within the Department of Justice is the Office of Legal Access Programs, Executive Office for Immigration Review.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Non-profit organizations seeking new recognition, renewal of recognition, or extension of recognition to be recognized as legal service providers by the Office of Legal Access Programs of the Executive Office for Immigration Review (EOIR). Abstract: This information collection will allow an organization to new recognition, renewal of recognition, or extension of recognition to appear before EOIR and/or the Department of Homeland Security. This information collection is necessary to determine whether a organization meets the eligibility requirements for recognition.

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 129 respondents will complete the form for new recognition annually with an average of 2 hours per response. It is estimated that 131 respondents will complete the form for renewal of recognition annually with an average of 7 hours per response.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1,175 (258 for new + 917 for renewals) total annual burden hours associated with this 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.405B, Washington, DC 20530.

Dated: August 30, 2019.

Melody D. Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–19146 Filed 9–4–19; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF JUSTICE

[OMB Number 1125–0007]

Agency Information Collection Activities; Proposed Collection; Comments Requested; Immigration Practitioner Complaint Form

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Executive Office for Immigration Review, 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 November 4, 2019.

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, 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 Executive Office for Immigration Review, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension without changes of a currently approved collection.

2. *The Title of the Form/Collection:* Immigration Practitioner Complaint Form.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form EOIR–44. The applicable component within the Department of Justice is the Office of General Counsel, Executive Office for Immigration Review.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals who wish to file a complaint against an immigration practitioner authorized to appear before the Board of Immigration Appeals and the immigration courts. Abstract: The information on this form will be used to determine whether the Office of the General Counsel of the Executive Office for Immigration Review should conduct a preliminary disciplinary inquiry, request additional information from the complainant, refer the matter to a state bar disciplinary authority or other law enforcement agency, or take no further action.

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 200 respondents will complete the form annually, with an average of 2 hours per response.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden associated with this collection is 400 hours. It is estimated that respondents will take 2 hours to complete the form. The burden hours for collecting respondent data sum to 400 hours (200 respondents × 2 hours = 400 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: August 30, 2019.

Melody D. Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–19144 Filed 9–4–19; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF JUSTICE

[OMB Number 1125–0013]

Agency Information Collection Activities; Proposed Collection; Comments Requested; Request by Organization for Accreditation or Renewal of Accreditation of Non-Attorney Representative (Form EOIR–31A)

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Executive Office for Immigration Review, 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 November 4, 2019.

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 Executive Office for Immigration Review, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension with changes of a currently approved collection.

2. *The Title of the Form/Collection:* Request by Organization for Accreditation or Renewal Accreditation of Non-Attorney Representative.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form EOIR–31A. The applicable component within the Department of Justice is the Office of Legal Access Programs, Executive Office for Immigration Review.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Non-profit organizations seeking accreditation or renewal of accreditation of its representatives by the Office of Legal Access Programs of the Executive Office for Immigration Review (EOIR). Abstract: This information collection will allow an organization to seek accreditation or renewal of accreditation of a non-attorney representatives to appear before EOIR and/or the Department of Homeland Security. This information collection is necessary to determine whether a representatives meet the eligibility requirements for accreditation.

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 818

respondents will complete the form annually with an average of 2 hours per response.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1,636 total annual burden hours associated with this 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.405B, Washington, DC 20530.

Dated: August 30, 2019.

Melody D. Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–19143 Filed 9–4–19; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Youthful Offender Grants Management Information System

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL's) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Youthful Offender Grants Management Information System.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by November 4, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free by contacting Alex Green by telephone at 202–693–2759 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at *green.alexander.m@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Reentry Employment Opportunities, Alex Green, Room N–4508, 200 Constitution Avenue NW, Washington, DC 20210; by email: *green.alexander.m@dol.gov;* or by Fax 202–693–3313.

FOR FURTHER INFORMATION CONTACT: Alex Green by telephone at 202–693–2759 (this is not a toll-free number) or by email at *green.alexander.m@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

ETA is currently implementing a multi-program web-based performance reporting system for some of its grant programs. However, the seven Reentry Demonstration Project (RDP) grants awarded in June 2016 and the thirteen Pathways to Justice Careers (PJC) grants awarded in June 2016 and January 2017 are still using the legacy youth offender Management Information System (MIS) under OMB Control Number 1205–0513. Based on current funding levels of these grants, one RDP grant and four PJC grants may still be active after the current ICR for this MIS expires on January 31, 2020.

This request is to extend the approval of this MIS for one year so that it may continue to operate until the remaining RDP and PJC grants end. This request includes the collection of data by grantees on participant characteristics, services provided, and participant outcomes; the quarterly performance report submitted by grantees; the quarterly narrative report; and the annual recidivism report. This request continues a reporting and recordkeeping system for a minimum level of information collection that is necessary to comply with Equal Opportunity requirements, to hold Youthful Offender grantees appropriately accountable for the Federal funds they receive, and to allow the Department to fulfill its oversight and management responsibilities. Section 185 of the Workforce Innovation and Opportunity Act authorizes the collection of data from grantees on the demographic characteristics of participants, activities provided, and program outcomes.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0513.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- 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;
- Enhance the quality, utility, and clarity of the information to be collected; 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.

Agency: DOL–ETA.

Type of Review: Extension without changes.

Title of Collection: Youthful Offender Grants Management Information System.

Forms: Quarterly Performance Report, Quarterly Narrative Report, Recidivism Report.

OMB Control Number: 1205–0513.

Affected Public: Private Sector: Not-for-Profit Institutions; State and Local Juvenile and Adult Justice Agencies; Program Participants.

Estimated Number of Respondents: 1,020 (Unduplicated Count).

Frequency: Quarterly for the performance and narrative reports, annually for the recidivism report.

Total Estimated Annual Responses: 3,040.

Estimated Average Time per Response: Varies.

Estimated Total Annual Burden Hours: 3,970.

Total Estimated Annual Other Cost Burden: $0.

John Pallasch,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 2019–19140 Filed 9–4–19; 8:45 am]

BILLING CODE 4510–FT–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; Fidelity Bonding Demonstration

ACTION: Notice.

SUMMARY: The Department of Labor (DOL), Employment and Training Administration (ETA), is soliciting comments on the Fidelity Bonding Demonstration information collection request (ICR). This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: All written comments must be received by November 4, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained for free by contacting Mallery Johnson by telephone at 202–693–3497 (this is not a toll-free number), TTY/TDD by calling the toll-free Federal Information Relay Service at 1–877–889–5627, or by email at *Johnson.Mallery@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Reentry Employment Opportunities, Room N–4508, 200 Constitution Avenue NW, Washington, DC 20210; by email: *Johnson.Mallery@dol.gov;* or by Fax: 202–693–3981.

FOR FURTHER INFORMATION CONTACT: Mallery Johnson by telephone at 202–693–3497 (this is not a toll-free number) or by email at *Johnson.Mallery@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. The program helps ensure that requested data is provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The Federal Bonding Program provides fidelity bonds protecting employers who hire offenders and other at-risk job applicants from theft, forgery, or embezzlement by the employee. Although the bonds have mainly served offenders, any at-risk job applicant is eligible for bonding services, including: Recovering substance abusers (alcohol or drugs), public benefit recipients and other persons having poor financial credit, economically disadvantaged youth and adults who lack a work history, individuals dishonorably discharged from the military, and others. Over the years, the Federal Bonding Program has remained a relatively small program, currently serving about 900 individuals each year. DOL is expanding the use of fidelity bonds to place offenders in jobs by providing grant funds to states to purchase such bonds. In order to account for the accurate use and tracking of the expansion of fidelity bonding, the Department is now seeking approval under the PRA for a Fidelity Bond Issuance Form. This form lists the contact information of the job placement agency and the employer; identifies the person being insured; and provides the amount and the effective date of the bond issued. The form also identifies the occupation, hourly wage, and hours per week of the job placement; the employer type, industry, and size of the firm; and the gender, race, and ethnicity of the person insured. This information collection is conducted under the authority of Section 185(a)(2) of the Workforce Innovation and Opportunity Act (WIOA), which requires recipients of funds under Title I to maintain such records and submit such reports as the Secretary requires regarding the performance of Title I programs and activities (including Federal Bonding, a WIOA Section 169 demonstration). The fidelity bonding demonstration grantees will report a recidivism rate for participants enrolled in Wagner-Peyser Employment Service. The proposed reporting and record-keeping system provides a minimum level of information collection that is necessary to comply with Equal Opportunity requirements, to hold grantees appropriately accountable for the Federal funds they receive to purchase bonds, and to allow the Department to fulfill its oversight and management responsibilities.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid control number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Only written comments will receive consideration. DOL will summarize and include these comments in the request for OMB approval of the final ICR.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- 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;
- Enhance the quality, utility, and clarity of the information to be collected; 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.

Agency: DOL–ETA.

Type of Review: New information collection request.

Title of Collection: Fidelity Bonding Demonstration.

Forms: Fidelity Bonding Issuance Form.

OMB Control Number: 1205–0NEW.

Affected Public: State Workforce Agencies, local American Job Center staff, private employers.

Estimated Number of Respondents: 12,024.

Frequency: Once per Bond.

Total Estimated Annual Responses: 6,000.

Estimated Average Time per Response: 12 minutes.

Estimated Total Annual Burden Hours: 1,200.

Total Estimated Annual Other Cost Burden: $0.

Authority: 44 U.S.C. 3506(c)(2)(A).

John Pallasch,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 2019–19142 Filed 9–4–19; 8:45 am]

BILLING CODE 4510–FT–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meeting of National Council on the Humanities

AGENCY: National Endowment for the Humanities, National Foundation on the Arts and the Humanities.

ACTION: Notice of Meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the National Council on the Humanities will meet to review applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965 and make recommendations thereon to the Chairman.

DATES: The meeting will be held on Thursday, September 19, 2019, from 1 p.m. until 3 p.m.

ADDRESSES: The meeting will be held via teleconference originating from the National Endowment for the Humanities, 400 7th Street SW, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW, 4th Floor, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: The National Council on the Humanities is meeting pursuant to the National Foundation on the Arts and Humanities Act of 1965 (20 U.S.C. 951–960, as amended). The meeting will begin with remarks from the Chairman, after which the National Council on the Humanities will hear reports on and consider applications for NEH funding related to civics education, archaeology, and other humanities topics. The meeting will be closed to the public pursuant to sections 552b(c)(4), 552b(c)(6), and 552b(c)(9)(B) of Title 5 U.S.C., as amended, because it will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, and discussion of certain information, the premature disclosure of which could significantly frustrate implementation of proposed agency action. I have made this determination pursuant to the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: August 28, 2019.

Elizabeth Voyatzis,

Committee Management Officer, National Endowment for the Humanities.

[FR Doc. 2019–19096 Filed 9–4–19; 8:45 am]

BILLING CODE 7536–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0095]

Information Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.''

DATES: Submit comments by October 7, 2019. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit comments directly to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150–0217), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0095 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0095.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The supporting statement is available in ADAMS under Accession ML19231A267.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@NRC.GOV.*

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov* and entered into ADAMS. Comment submissions are not

routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on May 15, 2019 (84 FR 21839).

1. *The title of the information collection:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.
2. *OMB approval number:* 3150–0217.
3. *Type of submission:* Extension.
4. *The form number if applicable:* Not applicable.
5. *How often the collection is required or requested:* On occasion and annually.
6. *Who will be required or asked to respond:* Individuals and households; businesses and organizations; State, Local, or Tribal governments.
7. *The estimated number of annual responses:* 4,200.
8. *The estimated number of annual respondents:* 4,200.
9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 1,087.5.
10. *Abstract:* The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, for the purpose of improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are 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. Feedback collected under this generic clearance will provide useful information, but it will 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.

Dated at Rockville, Maryland, this 29th day of August, 2019.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2019–19088 Filed 9–4–19; 8:45 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

[DFC–013]

Submission for OMB Review; Comments Request

AGENCY: U.S. International Development Finance Corporation (DFC), Overseas Private Investment Corporation (OPIC).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the provisions of the Paperwork Reduction Act, agencies are required to publish a notice in the **Federal Register** notifying the public that the agency is creating a new information collection for OMB review and approval and requests public review and comment on the submission. The agencies received no comments in response to the sixty (60) day notice. The purpose of this notice is to allow an additional thirty (30) days for public comments to be submitted. Comments are being solicited on the need for the information; the accuracy of the burden estimate; the quality, practical utility, and clarity of the information to be collected; and ways to minimize reporting the burden, including automated collected techniques and uses of other forms of technology.

DATES: DFC intends to begin use of this collection upon OMB approval. Comments must be received by October 7, 2019.

ADDRESSES: Comments and requests for copies of the subject information collection may be sent by any of the following methods:

- *Mail:* Catherine F.I. Andrade, Agency Submitting Officer, Overseas Private Investment Corporation, 1100 New York Avenue NW, Washington, DC 20527.
- *Email: fedreg@opic.gov.*

Instructions: All submissions received must include the agency name and agency form number or OMB form number for this information collection. Electronic submissions must include the agency form number in the subject line to ensure proper routing. Please note that all written comments received in response to this notice will be considered public records.

FOR FURTHER INFORMATION CONTACT: Agency Submitting Officer: Catherine F.I. Andrade, (202) 336–8768.

SUPPLEMENTARY INFORMATION: The Better Utilization of Investments Leading to Development (BUILD) Act of 2018, 22 U.S.C. 9601–9689, creates the U.S. International Development Finance Corporation (DFC) by bringing together the Overseas Private Investment Corporation (OPIC) and the Development Credit Authority (DCA) office of the U.S. Agency for International Development (USAID). Section 9685(a) of the Act tasks OPIC staff with assisting DFC in the transition. Section 9686(a)–(b) provides that all completed administrative actions and all pending proceedings shall continue through the transition to the DFC. Accordingly, OPIC is issuing this Paperwork Reduction Act notice

and request for comments on behalf of the DFC.

The agencies received no comments in response to the sixty (60) day notice published in **Federal Register** volume 84 page 30782 on June 27, 2019.

Summary Form Under Review

Title of Collection: Loan Transaction and Qualifying Loan Schedule Reports.

Type of Review: New information collection.

Agency Form Number: DFC–013.

OMB Form Number: Not assigned, new information collection.

Frequency: Semi-annual.

Affected Public: Financial Institutions.

Total Estimated Number of Annual Number of Respondents: 300.

Estimated Time per Respondent: 4 hours.

Total Estimated Number of Annual Burden Hours: 2,400 hours.

Abstract: Semi-annual reporting by partner financial institutions via the Loan Transaction and Qualifying Loan Schedule Reports will be required to monitor financial compliance with the business terms in loan and bond guarantees administered by the DFC's Office of Development Credit and to analyze the guarantee portfolio and loans placed under guarantee coverage. The information collected in the reports may also play a role, when coupled with other methods and tools, in evaluating program effectiveness.

Dated August 30, 2019.

Nichole Skoyles,

Administrative Counsel, Department of Legal Affairs.

[FR Doc. 2019–19172 Filed 9–4–19; 8:45 am]

BILLING CODE 3210–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Reemployment of Annuitants, 3206–0211

AGENCY: U.S. Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on an existing information collection request, Reemployment of Annuitants.

DATES: Comments are encouraged and will be accepted until October 7, 2019.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to: *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this information collection, with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995, OPM is soliciting comments for this collection. The information collection (OMB No. 3206–0211) was previously published in the **Federal Register** on March 12, 2019, at 84 FR 8916, allowing for a 60-day public comment period. No comments were received for this information collection. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of 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.

5 CFR 837.103, Reemployment of Annuitants, requires agencies to collect information from retirees who become employed in Government positions. Agencies need to collect timely information regarding the type and amount of annuity being received so the correct rate of pay can be determined. Agencies provide this information to OPM so a determination can be made whether the reemployed retiree's annuity must be terminated.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: 5 CFR 837.103, Reemployment of Annuitants.

OMB Number: 3206–0211.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 3,000.

Estimated Time per Respondent: 5 minutes.

Total Burden Hours: 250.

U.S. Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2019–19094 Filed 9–4–19; 8:45 am]

BILLING CODE 6325–38–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86811; File No. SR–CboeBZX–2019–079]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Introduce a New Data Product on Its Equity Options Platform ("BZX Options") To Be Known As Open-Close Data

August 29, 2019.

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 August 21, 2019, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') 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 Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') is filing with the Securities and Exchange Commission

[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).

(''Commission'') a proposed rule change to introduce a new data product on its equity options platform (''BZX Options'') to be known as Open-Close Data. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), 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 introduce a new data product on BZX Options to be known as Open-Close Data, which will be available for purchase to BZX Options Members and Non-Members.[5] Cboe LiveVol, LLC (''LiveVol''), a wholly owned subsidiary of the Exchange's parent company, Cboe Global Markets, Inc., will make the Open-Close Data available for purchase to Members and Non-Members on the LiveVol DataShop website (*datashop.cboe.com*). The Exchange also proposes to amend Exchange Rule 21.15(b) to add a description of the Open-Close Data product.

A description of each market data product offered by the Exchange is described in Exchange Rule 21.15(b). The Exchange proposes to amend Rule 21.15(b) to introduce and add a description of the Open-Close Data product under proposed new subparagraph (5). The Exchange proposes to describe the Open-Close Data as ''a data product that summarizes volume (contracts traded on BZX Options) by origin (customer and firm orders), original order size and the opening or closing position of the order.'' The volume data is also summarized by day and series (symbol, expiration date, strike price, call or put). The Open-Close Data would be available for purchase to both BZX Members and Non-Members on a subscription and ad-hoc basis. The Exchange notes that its affiliate, Cboe Exchange, Inc. (''Cboe Options''), as well as other exchanges, offer a similar data product.[6]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed Open-Close Data would further broaden the availability of U.S. option market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of Open-Close Data. The proposed rule change would benefit investors by providing access to the Open-Close Data, which may promote better informed trading. Moreover, the Exchange's affiliate Cboe Options, along with other exchanges, also offer a similar data product.[9]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will promote competition by permitting the Exchange to offer a data product similar to those offered by other competitor options exchanges.[10] The Exchange is proposing to introduce Open-Close Data for BZX Options in order to keep pace with changes in the industry and evolving customer needs, and believes this proposed rule change would contribute to robust competition among national securities exchanges. As noted, at least three other U.S. options exchanges offer a market data product that is substantially similar to the Open-Close Data. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. Therefore, the Exchange does not believe the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[13] normally does not become operative for 30 days after the date of its

[5] The Exchange intends to submit a rule filing to establish fees for Open-Close Data.

[6] *See* Securities Exchange Act Release No. 55062 (January 8, 2007), 72 FR 2048 (January 17, 2007) (approving SR–CBOE–2006–88); *See also* Securities Exchange Act Release No. 56254 (August 15, 2007), 72 FR 47104 (August 22, 2007) (SR–ISE–2007–70).

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(5).

[9] *See* Securities Exchange Act Release No. 55062 (January 8, 2007), 72 FR 2048 (January 17, 2007) (approving SR–CBOE–2006–088); *See also* Securities Exchange Act Release No. 56254 (August 15, 2007), 72 FR 47104 (August 22, 2007) (SR–ISE–2007–70).

[10] *Id.*

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 17 CFR 240.19b–4(f)(6).

filing. However, Rule 19b–4(f)(6)(iii) [14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the Exchange may implement the proposed rule change on September 1, 2019, the anticipated date upon which the Exchange expects to offer Open-Close Data. The Exchange believes waiver of the operative delay is consistent with the protection of investors and the public interest because the proposed rule change presents no new or novel issues, as other exchanges currently offer a similar data product.[15] For this reason, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal as operative upon filing.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeBZX–2019–079 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–CboeBZX–2019–079. 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–CboeBZX–2019–079 and should be submitted on or before September 26, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–19107 Filed 9–4–19; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] *See supra* note 6.

[16] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86806; File No. SR–CboeEDGX–2019–054]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Introduce a New Data Product on Its Equity Options Platform ("EDGX Options") To Be Known as Open-Close Data

August 29, 2019.

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 August 21, 2019, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') 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 Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to introduce a new data product on its equity options platform (''EDGX Options'') to be known as Open-Close Data. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

[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).

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 introduce a new data product on EDGX Options to be known as Open-Close Data, which will be available for purchase to EDGX Options Members and Non-Members.[5] Cboe LiveVol, LLC (''LiveVol''), a wholly owned subsidiary of the Exchange's parent company, Cboe Global Markets, Inc., will make the Open-Close Data available for purchase to Members and Non-Members on the LiveVol DataShop website (*datashop.cboe.com*). The Exchange also proposes to amend Exchange Rule 21.15(b) to add a description of the Open-Close Data product.

A description of each market data product offered by the Exchange is described in Exchange Rule 21.15(b). The Exchange proposes to amend Rule 21.15(b) to introduce and add a description of the Open-Close Data product under proposed new subparagraph (6). The Exchange proposes to describe the Open-Close Data as ''a data product that summarizes volume (contracts traded on EDGX Options) by origin (customer and firm orders), original order size and the opening or closing position of the order.'' The volume data is also summarized by day and series (symbol, expiration date, strike price, call or put). The Open-Close Data would be available for purchase to both EDGX Members and Non-Members on a subscription and ad-hoc basis. The Exchange notes that its affiliate, Cboe Exchange, Inc. (''Cboe Options''), as well as other exchanges, offer a similar data product.[6]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[7] in general, and furthers the objectives of Section 6(b)(5) of the Act,[8] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed Open-Close Data would further broaden the availability of U.S. option market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of Open-Close Data. The proposed rule change would benefit investors by providing access to the Open-Close Data, which may promote better informed trading. Moreover, the Exchange's affiliate Cboe Options, along with other exchanges, also offer a similar data product.[9]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will promote competition by permitting the Exchange to offer a data product similar to those offered by other competitor options exchanges.[10] The Exchange is proposing to introduce Open-Close Data for EDGX Options in order to keep pace with changes in the industry and evolving customer needs, and believes this proposed rule change would contribute to robust competition among national securities exchanges. As noted, at least three other U.S. options exchanges offer a market data product that is substantially similar to the Open-Close Data. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. Therefore, the Exchange does not believe the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[13] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[14] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the Exchange may implement the proposed rule change on September 1, 2019, the anticipated date upon which the Exchange expects to offer Open-Close Data. The Exchange believes waiver of the operative delay is consistent with the protection of investors and the public interest because the proposed

[5] The Exchange intends to submit a rule filing to establish fees for Open-Close Data.

[6] *See* Securities Exchange Act Release No. 55062 (January 8, 2007), 72 FR 2048 (January 17, 2007) (approving SR–CBOE–2006–88); *See also* Securities Exchange Act Release No. 56254 (August 15, 2007), 72 FR 47104 (August 22, 2007) (SR–ISE–2007–70).

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(5).

[9] *See* Securities Exchange Act Release No. 55062 (January 8, 2007), 72 FR 2048 (January 17, 2007) (approving SR–CBOE–2006–088); *See also* Securities Exchange Act Release No. 56254 (August 15, 2007), 72 FR 47104 (August 22, 2007) (SR–ISE–2007–70).

[10] *Id.*

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

rule change presents no new or novel issues, as other exchanges currently offer a similar data product.[15] For this reason, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal as operative upon filing.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeEDGX–2019–054 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–CboeEDGX–2019–054. 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–CboeEDGX–2019–054 and should be submitted on or before September 26, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–19109 Filed 9–4–19; 8:45 am]

BILLING CODE 8011–01–P

[15] *See supra* note 6.

[16] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Privacy Act of 1974; System of Records

AGENCY: U.S. Small Business Administration.

ACTION: Notice of a New System of Records.

SUMMARY: The U.S. Small Business Administration (SBA) proposes to add a new system of records entitled Small Business Investment Company Information System (SBA # 40) to its inventory of records systems subject to the Privacy Act of 1974, as amended. Publication of this notice complies with the Privacy Act and the Office of Management and Budget (OMB) Circular A–108 requirement for agencies to publish a notice in the **Federal Register** whenever the agency establishes a new system of records. The SBA is in the process of modernizing its technology supporting the Small Business Investment Company (SBIC) program to further enhance the SBA's regulatory oversight and risk management of the SBIC program using modern private equity and alternative investment analytics and tools. The technology includes a Customer Relationship Management (CRM) tool, an investment and risk management tool, an information portal, and a data warehouse with associated Application Programming Interfaces (APIs). Some records may be maintained electronically and in paper format for desktop access or if required for legal purposes.

DATES: This action will be effective without further notice on September 1, 2019 unless comments are received that would result in a contrary determination.

ADDRESSES: Submit written comments to Marja Maddrie, Business Operations Officer, Office of Investment and Innovation, U.S. Small Business Administration, 409 3rd Street SW, Suite 6300, Washington, DC, 20416.

FOR FURTHER INFORMATION CONTACT: Marja Maddrie, Business Operations Officer, Office of Investment and Innovation, U.S. Small Business Administration, 409 3rd Street SW, Suite 6300, Washington, DC, 20416, 202–205–6980.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974 (5 U.S.C. 552a), as amended, embodies fair information practice principles in a statutory framework governing the means by which Federal agencies collect, maintain, use, and disseminate individuals' personal information. The Privacy Act applies to records about individuals that are maintained in a ''system of records.'' A system of records is a group of any records under the control of a Federal agency from which information is retrieved by the name of an individual or by a number, symbol or other identifier assigned to the individual. The Privacy Act requires each Federal agency to publish in the **Federal Register** a System of Records Notice (SORN) identifying and describing each system of records the agency maintains, the purposes for which the Agency uses the Personally Identifiable Information (PII) in the system, the routine uses for which the Agency discloses such information outside the Agency, and how individuals can exercise their rights related to their PII information.

SYSTEM NAME AND NUMBER:

Small Business Investment Company Information System (SBICIS), # 40.

SYSTEM CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

SBA Headquarters, 409 3rd Street SW, Washington, DC, 20416.

SYSTEM MANAGER(S):

Marja Maddrie, Business Operations Officer, Office of Investment and Innovation, U.S. Small Business Administration, 409 3rd Street SW, Suite 6300, Washington, DC, 20416.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Small Business Investment Act of 1958, as amended, 15 U.S.C. 661, *et seq.*

PURPOSES OF THE SYSTEM:

The SBICIS serves a centralized and automated framework for the organization, retrieval, and analysis of SBIC information which supports the SBA's oversight and risk management roles for the SBIC program.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system covers individuals related to current and former (i) prospective SBIC license applicants, (ii) SBIC applicants, and (iii) SBICs. (Solely for the purposes of this SORN, the term ''SBIC'' refers to each of (i), (ii) and (iii) in the preceding sentence.) This includes managers, executives, members, and employees associated or affiliated with an SBIC, and personal and professional references for certain of the foregoing. It also includes SBIC investors, SBIC portfolio companies, certain SBIC portfolio company employees, SBIC service providers, and certain other individuals associated, affiliated or involved with an SBIC.

CATEGORIES OF RECORDS IN THE SYSTEM:

Personal and commercial information (*e.g.,* name, address, credit history, background information, business information, financial information, investor commitments, identifying number or other personal identifiers, regulatory compliance information) on individuals and portfolio companies named in SBIC files.

RECORD SOURCE CATEGORIES:

Information contained within this system is obtained from SBICs, SBIC authorized representatives, SBIC investors, SBIC portfolio companies, SBA employees, and commercial industry and government sources.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the information contained in this system may be disclosed to authorized entities, as is determined to be relevant and necessary, outside SBA as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including offices of the U.S Attorneys, or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is deemed by the SBA to be relevant or necessary to the litigation or the SBA has an interest in such litigation when any of the following are a party to the litigation or have an interest in the litigation: (1) Any employee or former employee of the SBA in his or her official capacity; (2) Any employee or former employee of the SBA in his or her individual capacity when DOJ or SBA has agreed to represent the employee or a party to the litigation or have an interest in the litigation; or (3) The United States or any agency thereof.

B. To a Congressional office from the record of an individual in response to an inquiry from that Congressional office made at the request of the individual. The member's access rights are no greater than those of the individual.

C. To the National Archives and Records Administration (NARA) or General Services Administration (GSA) pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization, including the SBA's Office of Inspector General, for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when: (1) The SBA suspects or has confirmed that the security or confidentiality of information processed and maintained by the SBA has been compromised, (2) the SBA has determined that as a result of the suspected or confirmed compromise, there is a risk of identity theft or fraud, harm to economic or property interests, harm to an individual, or harm to the security or integrity of this system or other systems or programs (whether maintained by SBA or any other agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SBA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To another Federal agency or Federal entity, when the SBA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in: (1) Responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

G. To another agency or agent of a Government jurisdiction within or under the control of the U.S., lawfully engaged in national security or homeland defense when disclosure is undertaken for intelligence, counterintelligence activities (as defined by 50 U.S.C. 3003(3)), counterterrorism, homeland security, or related law enforcement purposes, as authorized by U.S. law or Executive Order.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Information stored by SBICIS is stored electronically and is protected through the implementation of access controls, user permissions, event logging, and monitoring. External media are further protected using encryption.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

SBICIS records are retrieved by SBIC or Portfolio Company Name, affiliation with a particular SBIC personal identifier, SBA identifier, employee identification number, or any other data field that would enable SBA to perform its official duties.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained in accordance with SBA Standard Operating Procedure (SOP) 00 41 2, schedules 65:02 through 65:06. Records maintained as part of the General Records Schedules (GRS) are disposed of in accordance with applicable SBA policies.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access and use are limited to persons with official need to know. Users are evaluated on a recurring basis to ensure need-to-know still exists. Safeguards are implemented in accordance with the Federal Information Security Modernization Act of 2014 (FISMA) and are evaluated on a recurring basis to ensure desired operation.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to records about them should submit a Privacy Act request to the SBA Chief, Freedom of Information and Privacy Act

Office, U.S. Small Business Administration, 409 Third St. SW, Eighth Floor, Washington, DC 20416 or *FOIA@sba.gov.* Individuals must provide their full name, mailing address, personal email address, telephone number, and a detailed description of the records being requested. Individuals requesting access must also follow SBA's Privacy Act regulations regarding verification of identity and access to records (13 CFR part 102 subpart B).

CONTESTING RECORD PROCEDURES:

Individuals wishing to contest information contained in records about them should submit a Privacy Act request to the SBA Chief, Freedom of Information and Privacy Act Office, U.S. Small Business Administration, 409 Third St. SW, Eighth Floor, Washington, DC 20416 or *FOIA@sba.gov.* Individuals must provide their full name, mailing address, personal email address, telephone number, and a detailed description of the records being requested. Requesting individuals must follow SBA's Privacy Act regulations regarding verification of identity and access to records (13 CFR part 102 subpart B).

NOTIFICATION PROCEDURES:

Individuals may make record inquiries in person or in writing to the Systems Manager through the SBA Chief, Freedom of Information and Privacy Act Office, U.S. Small Business Administration, 409 Third St. SW, Eighth Floor, Washington, DC 20416 or *FOIA@sba.gov.*

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Dated: August 26, 2019.

Marja Maddrie,

Business Operations Officer, Office of Investment and Innovation.

[FR Doc. 2019–19153 Filed 9–4–19; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice: 10866]

Notice of Determinations; Culturally Significant Object Imported for Exhibition—Determinations: ''Andy Warhol: From A to B and Back Again'' Exhibition

SUMMARY: On September 25, 2018, notice was published on page 48496 of the **Federal Register** (volume 83, number 186) of determinations pertaining to certain objects to be included in an exhibition entitled ''Andy Warhol: From A to B and Back Again.'' Notice is hereby given of the following determinations: I hereby determine that a certain additional object to be exhibited in the exhibition ''Andy Warhol: From A to B and Back Again,'' imported from abroad for temporary exhibition within the United States, is of cultural significance. The object is imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit object at the Art Institute of Chicago, Chicago, Illinois, from on or about October 20, 2019, until on or about January 26, 2020, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–19186 Filed 9–4–19; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10867]

Notice of Determinations;

Culturally Significant Objects Imported for Exhibition—Determinations: ''Ernst Ludwig Kirchner'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Ernst Ludwig Kirchner,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Neue Gallerie New York, in New York, New York, from on or about October 3, 2019, until on or about January 13, 2020, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–19185 Filed 9–4–19; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10865]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Rachel Harrison Life Hack'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Rachel Harrison Life Hack,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Whitney Museum of American Art, New York, New York, from on or about October 25, 2019, until on or about January 12, 2020, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–19178 Filed 9–4–19; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10870]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Designing the New: Charles Rennie Mackintosh and the Glasgow Style'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Designing the New: Charles Rennie Mackintosh and the Glasgow Style,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Walters Art Museum, Baltimore, Maryland, from on or about October 6, 2019, until on or about January 5, 2020, at the Frist Museum of Art, Nashville, Tennessee, from on or about June 26, 2020, until on or about September 27, 2020, at the Museum of the American Arts & Crafts Movement, St. Petersburg, Florida, from on or about October 29, 2020, until on or about January 24, 2021, at The Richard H. Driehaus Museum, Chicago, Illinois, from on or about February 27, 2021, until on or about May 23, 2021, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–19187 Filed 9–4–19; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10869]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Rayyane Tabet: Alien Property'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Rayyane Tabet: Alien Property,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Metropolitan Museum of Art, New York, New York, from on or about October 30, 2019, until on or about January 18, 2021, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–19180 Filed 9–4–19; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10872]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Alonso Berruguete: First Sculptor of Renaissance Spain'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Alonso Berruguete: First Sculptor of Renaissance Spain,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the National Gallery of Art, Washington, District of Colombia, from on or about October 13, 2019, until on or about February 17, 2020; at the Meadows Museum, Southern Methodist University, Dallas, Texas, from on or about March 29, 2020, until on or about July 26, 2020; and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999,

and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–19181 Filed 9–4–19; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10873]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Sahel: Art and Empires on the Shores of the Sahara'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Sahel: Art and Empires on the Shores of the Sahara,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Metropolitan Museum of Art, New York, New York, from on or about January 27, 2020, until on or about May 10, 2020, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chi D. Tran, Paralegal Specialist, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000.

Marie Therese Porter Royce,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2019–19188 Filed 9–4–19; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2019–39]

Petition for Exemption; Summary of Petition Received; Helinet Aviation Services, LLC

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 25, 2019.

ADDRESSES: Send comments identified by docket number FAA–2019–0463 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 683–7788, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 15, 2019.

John Linsenmeyer,

Acting Deputy Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2019–0463.

Petitioner: Helinet Aviation Services, LLC.

Section(s) of 14 CFR Affected: §§ 61.23(a) & (c); 61.101(e)(4) & (5); 61.113(a); 61.315(a); 91.7(a); 91.119(c); 91.121; 91.151(a)(1); 91.405(a); 91.407(a)(1); 91.409(a)(1) & (2); & 91.417(a) & (b).

Description of Relief Sought: The proposed exemption, if granted, would allow the petitioner to operate the BFD Systems GD40 (110 pounds (lbs.)); DJI Storm/X8 (99 lbs.); and Periscope MK–IV (117 lbs.) unmanned aircraft systems (UAS), in support of closed-set motion picture and television filming operations. The petitioner intends to operate the UAS closer than 200 feet to production personnel and other individuals participating in the intended purposes of the operation who are located on the closed set; however, the UAS will never be operated over people. The operations will take place below 400 feet above ground level and within visual line of sight of the pilot and a visual observer. Operations will occur during daylight hours on private property with permission from the property owner/controller. Operations will be limited to Class G airspace unless an appropriate Air Traffic Organization Certificate of Waiver or Authorization has been obtained that authorizes operations in other classes of airspace.

[FR Doc. 2019–19128 Filed 9–4–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. FAA–2019–53]

Petition for Exemption; Summary of Petition Received; Wing Aviation, LLC

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 20, 2019.

ADDRESSES: Send comments identified by docket number FAA–2018–0835 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nia Daniels, (202) 267–7626, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 21, 2019.

John Linsenmeyer,

Acting Deputy Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2018–0835.

Petitioner: Wing Aviation, LLC.

Sections of 14 CFR Affected: §§ 135.321; 135.323; 135.325; 135.327; 135.329; 135.330; 135.331; 135.335; 135.337; 135.338; 135.339; 135.340; 135.341; 135.343; 135.345; 135.347; 135.351; 135.433; and 135.501(a).

Description of Relief Sought: Wing Aviation, LLC seeks an amendment to its existing exemption to allow it to conduct part 135 air carrier operations using small unmanned aircraft systems (UAS). This amendment would enable Wing to train its personnel- pilots in command, visual observers, and nest managers.

[FR Doc. 2019–19137 Filed 9–4–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2019–44]

Petition for Exemption; Summary of Petition Received; University of Florida Unmanned Aircraft Systems Research Program

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 25, 2019.

ADDRESSES: Send comments identified by docket number FAA–2019–0504 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 683–7788, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 15, 2019.

John Linsenmeyer,

Acting Deputy Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2019–0504.

Petitioner: University of Florida Unmanned Aircraft Systems Research Program.

Section(s) of 14 CFR Affected: § 107.3.

Description of Relief Sought: The proposed exemption, if granted, would permit relief from the definitions of part

107 in order to conduct research on the viability of distributed electric propulsion systems for full scale electric vertical take-off and landing aircraft control by using a sub-scale unmanned aircraft system, weighing 195 pounds, to develop the control schemes that can be used for scaling purposes. Flight operations would take place solely at a remote designated flight test area on University of Florida property.

[FR Doc. 2019–19136 Filed 9–4–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2019–41]

Petition for Exemption; Summary of Petition Received; A-Cam Aerials, LLC

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 25, 2019.

ADDRESSES: Send comments identified by docket number FAA–2019–0477 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 683–7788, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 15, 2019.

John Linsenmeyer,

Acting Deputy Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2019–0477.

Petitioner: A-Cam Aerials, LLC.

Section(s) of 14 CFR Affected: part 45, Subpart C; part 47; §§ 61.3(a)(1); 91.7(a); 91.119(c); 91.121; 91.151(b); 91.405(a); 91.407(a)(1); 91.409(a)(1) & (2); & 91.417(a) & (b).

Description of Relief Sought: The proposed exemption, if granted, would allow the petitioner to operate the Watts Innovations MFD5000 unmanned aircraft system, weighing over 55 pounds (lbs.) but no more than 100 lbs., for aerial photography and cinematography operations. The proposed operation would allow the use of a pilot in command who holds a part 107 remote pilot certificate, rather than an airline transport, commercial, private, recreational, or sport pilot certificate. Additionally, the petitioner proposes to operate within 500 feet (ft.) of consenting individuals and uninvolved individuals. Flights will be limited to a maximum altitude of 400 ft. above ground level or within 400 ft. of a structure.

[FR Doc. 2019–19139 Filed 9–4–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Availability of the Federal Aviation Administration Record of Decision and Adoption of the Portions Specific to the Battle Area Complex Restricted Area R–2201 (BAX R–2201) and the Expand Restricted Area R–2205, Including the Digital Multi-Purpose Training Range (DMPTR R–2205), of the Final Environmental Impact Statement for Modernization and Enhancement of Ranges, Airspace, and Training Areas in the Joint Pacific Alaska Range Complex in Alaska

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of record of decision.

SUMMARY: The Federal Aviation Administration (FAA) announces its decision to adopt the portions specific to the BAX R–2201 and DMPTR R–2205 of the United States Departments of the Army (Army) and Air Force's (USAF) Final Environmental Impact Statement (EIS) for the Modernization and Enhancement of Ranges, Airspace, and Training Areas in the Joint Pacific Alaska Range Complex (JPARC) in Alaska, EIS No. 20130181. In accordance with Section 102 of the National Environmental Policy Act of 1969 (''NEPA''), the Council on Environmental Quality's (''CEQ'') regulations implementing NEPA, and other applicable authorities, including The Federal Aviation Administration (FAA) Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 8–2, and FAA Order JO 7400.2M, ''Procedures for Handling Airspace Matters,'' paragraph 32–2–3, the FAA has conducted an independent review and evaluation of the Army and the USAF's Final EIS for Modernization and Enhancement of Ranges, Airspace, and Training Areas in the JPARC in Alaska, dated June 2013. As a cooperating agency with responsibility for approving special use airspace (SUA), the FAA provided subject matter expertise and coordinated with the USAF and Army during the environmental review process, including preparation of the Draft EIS and the Final EIS. Based on its independent review and evaluation, the FAA has determined the Final EIS, including its supporting documentation, as incorporated by reference, and other supporting documentation incorporated by reference for FAA's Written Re-Evaluation and Adoption of the Final EIS adequately assesses and discloses

the environmental impacts of the for Modernization and Enhancement of Ranges, Airspace, and Training Areas in the JPARC in Alaska. FAA is authorized to adopt the Final EIS, Adoption. Accordingly, the FAA adopts the Final EIS, and takes full responsibility for the scope and content that addresses the proposed changes to SUA for JPARC.

FOR FURTHER INFORMATION CONTACT: Paula Miller, Airspace Policy and Regulations Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; email: *Paula.Miller@faa.gov;* telephone: (202) 267–7378.

SUPPLEMENTARY INFORMATION:

Background

In March 2012, in accordance with NEPA and its implementing regulations, the USAF and Army released a Draft EIS. The Draft EIS presented the potential environmental consequences of the USAF and Army's proposal to modernize and enhance JPARC ranges by analyzing the military training activities at JPARC, Alaska. As a result of the FAA aeronautical review process, and public, agency, and tribal comments during the 111-day public comment period on the Draft EIS, the USAF, FAA, other federal and state agencies, and tribal governments have consulted to mitigate concerns while continuing to meet national defense training requirements. The USAF and Army are the proponents for the JPARC Modernization and were the lead agencies for the preparation of the Final EIS, which was issued in June 2013. The FAA is a cooperating agency responsible for approving SUA as defined in 40 CFR 1508.5.

The FAA has independently evaluated the JPARC Final EIS and the accompanying SUA proposals. FAA previously issued a Record of Decision (ROD) for the USAF SUA proposals because they were ripe for a decision while the Army SUA proposals are currently still undergoing aeronautical processing and development. The Army SUA proposals are now ripe for a decision; therefore, the scope and extent of FAA's ROD is only for the Army SUA proposals.

The USAF and Army issued one ROD. The ROD lists the Army and USAF actions and decisions separately. The ROD includes an Army Decision, signed July 30, 2013, and an USAF Decision signed August 6, 2013. The Army selected the preferred alternatives for BAX R–2201, DMPTR R–2205, and Unmanned Aerial Vehicle (UAV) Access. The Army/USAF ROD also lists mitigation measures by agency and specific action. The FAA has coordinated with the Army on UAV Access on an alternative solution of implementing Certificates of Authorization, since the activity does not qualify for a restricted area.

Implementation

After evaluating the public comments received, the aeronautical studies, and the environmental analysis, the FAA is establishing BAX R–2201and expanding DMPTR R–2205. On March 6, 2017, the FAA published a notice of proposed rulemaking (NPRM) proposing to establish BAX R–2201 in the **Federal Register** (82 FR 12529). In response to public comments expressing concerns over the impact to general aviation aircraft, the FAA subsequently published a Supplemental NPRM in the **Federal Register** on January 11, 2018 (83 FR 1316), that would reduce the overall size of the proposed BAX R–2201 by 50 percent. On March 6, 2019, the FAA published a NRPM (82 FR 12526) to expand DMPTR R–2205. Minor changes to reduce the size of R–2205 were made from what was analyzed in the FEIS to improve aviation safety and reduce the burden on non-participating traffic to help civil pilots remain well clear of hazardous activities while following the river during VFR flights and to avoid the Alaska Pipeline.

FAA. The August 29, 2019 Written Re-Evaluation/Adoption/ROD is available on the FAA website and can be viewed at *https://www.faa.gov/air_traffic/environmental_issues/.*

Right of Appeal

The Written Re-evaluation, Adoption, and ROD for the changes to the JPARC MOAs constitutes a final order of the FAA Administrator and is subject to exclusive judicial review under 49 U.S.C. 46110 by the U.S. Circuit Court of Appeals for the District of Columbia or the U.S. Circuit Court of Appeals for the circuit in which the person contesting the decision resides or has its principal place of business. Any party having substantial interest in this order may apply for review of the decision by filing a petition for review in the appropriate U.S. Court of Appeals no later than 60 days after the date of this notice in accordance with the provisions of 49 U.S.C. 46110.

Issued in Des Moines, WA, on August 26, 2019.

B.G. Chew,

Acting Manager, Operations Support Group, Western Service Center, Federal Aviation Administration.

[FR Doc. 2019–19105 Filed 9–4–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2019–38]

Petition for Exemption; Summary of Petition Received; Helinet Aviation Services, LLC

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 25, 2019.

ADDRESSES: Send comments identified by docket number FAA–2019–0462 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to

http://www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jake Troutman, (202) 683–7788, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on August 15, 2019.

John Linsenmeyer,

Acting Deputy Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2019–0462.

Petitioner: Helinet Aviation Services, LLC.

Section(s) of 14 CFR Affected: §§ 61.23(a) & (c); 61.101(e)(4) & (5); 61.113(a); 61.315(a); 91.7(a); 91.119(c); 91.121; 91.151(a)(1); 91.405(a); 91.407(a)(1); 91.409(a)(1) & (2); & 91.417(a) & (b).

Description of Relief Sought: The proposed exemption, if granted, would allow the petitioner to operate the Shotover U1 unmanned aircraft system (UAS), weighing 88.2 pounds, in support of closed-set motion picture and television filming operations. The petitioner intends to operate the UAS closer than 500 feet to production personnel and other individuals participating in the intended purposes of the operation who are located on the closed-set; however, the UAS will never be operated over people. The operations will take place below 400 feet above ground level and within visual line of sight of the pilot and a visual observer. Operations will occur during daylight hours on private property with permission from the property owner/controller. Operations will be limited to Class G airspace unless an appropriate Air Traffic Organization Certificate of Waiver or Authorization has been obtained that authorizes operations in other classes of airspace.

[FR Doc. 2019–19138 Filed 9–4–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Withdrawal of a Notice of Intent (NOI) To Prepare an Environmental Impact Statement (EIS)

AGENCY: Federal Highway Administration (FHWA), United States Department of Transportation (USDOT).

ACTION: Notice of NOI withdrawal.

SUMMARY: The FHWA is issuing this notice to advise the public of withdrawal of the NOI to prepare an EIS published in the **Federal Register** Vol. 71, No. 128, July 5, 2006 for a proposed combined highway and transit project on 1–285 in Cobb, Fulton, and DeKalb Counties, Georgia.

FOR FURTHER INFORMATION CONTACT: Jennifer Giersch, Environmental Coordinator, Federal Highway Administration, 61 Forsyth Street, Suite 17T100, Atlanta, Georgia 30303, Telephone: (404) 562–3653; email: *JenniferGiersch@fhwa.dot.gov.*

Eric Duff, State Environmental Administrator, Georgia Department of Transportation, One Georgia Center, 16th Floor, Atlanta, Georgia 30308, Telephone: (404) 631–1071; email: *eduff@dot.ga.gov.*

SUPPLEMENTARY INFORMATION: The FHWA in cooperation with the Georgia Department of Transportation (GDOT), published a NOII on July 5, 2006 to prepare an EIS for a proposed combined highway and transit project along 1–285 from I75 in Cobb County to 1–85 in DeKalb County, a length of approximately 17 miles. FHWA hereby advises the public of the rescission of this NOI. This change occurred because part of the project corridor, the interchange of 1–285 and GA 400, advanced as an independent project with its own purpose and need. Additionally, GDOT's Major Mobility Investment Program refocused the purpose and need for improvements along 1–285. FHWA and GDOT anticipate the issuance of a new NOI for the proposed construction of express lanes along the project corridor.

Any future Federal-aided action within this corridor will comply with the environmental review requirements of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), FHWA implementing environmental regulations (23 CFR part 771) and related authorities, as appropriate. Comments and questions concerning this action should be directed to FHWA at the address provided above.

Authority: 23 U.S.C. 315; 49 CFR 1.48.

Issued on: August 21, 2019.

Moises Marrero,

Division Administrator, Federal Highway Administration, Atlanta, Georgia.

[FR Doc. 2019–18512 Filed 9–4–19; 8:45 am]

BILLING CODE M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2019–0055]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this provides the public notice that by letter dated May 22, 2019, the Belt Railway Company of Chicago (BRC) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR 234.309, *ENS signs in general,* and 49 CFR 234.311, *ENS sign placement and maintenance.* FRA assigned the petition Docket Number FRA–2019–0055.

Specifically, BRC requests relief from the requirement to replace signage under §§ 234.309 and 234.311, pending the successful conclusion of two 49 CFR part 236 block signal applications (BSAP) (*see* Docket Numbers FRA–2019–0039 and FRA–2019–0010). Access to the subject track is either over Bridge 710 on Canadian National Railway's (CN) Lakefront Subdivision or via access from BRC's Kenton Line. BSAPs were filed by both BRC and CN based on lack of traffic and upgrades that will render this trackage entirely inaccessible for train traffic. There is currently no rail service on this track, and no plan to restore service.

This single industrial track includes no sidings or auxiliary tracks and runs parallel to Harbor Avenue and South Lake Shore Drive. There are five private highway-rail grade crossings (HRGC) and one public HRGC on the route:

(1) DOT #869205W—milepost (MP) 0.29—Private;

(2) DOT #869206D—MP 0.52—Ewing Avenue;

(3) DOT #869207K—MP 0.53—Private;

(4) DOT #869208S—MP 0.63—Private;

(5) DOT #869209Y—MP 0.65—Private; and

(6) DOT #869210T—MP 0.71—Private.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's

Docket Operations Facility, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by October 21, 2019 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of *regulations.gov.*

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2019–19170 Filed 9–4–19; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2019–0046]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on June 7, 2019, Norfolk Southern Railway Company (NS) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR 225.25, *Recordkeeping.* FRA assigned the petition Docket Number FRA–2019–0046.

Specifically, NS seeks a waiver of compliance from 49 CFR 225.25(h) which states, in part, that except as provided in paragraph (h)(15), a listing of all injuries and occupational illnesses reported to FRA as having occurred at an establishment shall be posted in a conspicuous location at that establishment, within 30 days after the expiration of the month during which the injuries and illnesses occurred, if the establishment has been in continual operation for a minimum of 90 calendar days.

NS requests a waiver regarding the actual posting of the monthly listing of employee reportable injuries, occupational illnesses, and fatalities, as reported to FRA that have occurred during the past 12-month period at each establishment. In lieu of physically posting a ''paper'' copy of the monthly listing at each establishment, NS has developed an electronic version that would be available to its employees by accessing this information on computer terminals located at company facilities and personal devices. NS would notify employees of the electronic establishment log, including instructions for accessing it, by posting information on NS's operations web portals and by their supervisors in job safety briefings and other safety contacts. Where appropriate, the log would be distributed as a paper handout and may be requested from the employee's supervisor at any time.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by October 21, 2019 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov.*

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2019–19171 Filed 9–4–19; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2019–0103]

Privacy Act of 1974; System of Records; DOT/FMCSA–011; Military Under 21 Pilot Program System of Records

AGENCY: Federal Motor Carrier Safety Administration, Department of Transportation.

ACTION: Notice of a New System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Transportation proposes to issue a new Department of Transportation system of records titled, ''Department of Transportation Federal Motor Carrier Safety Administration–011—Military Under 21 Pilot Program System of Records.'' FMCSA is required by Section 5404 of the Fixing America's Surface Transportation Act, 2015 (FAST Act), to conduct a pilot program to allow 18- to 20-year-old persons with military driving experience to operate CMVs in interstate commerce. The pilot program seeks to determine the safety benefits or risks posed by military service members aged 18, 19, and 20 with specialized training in heavy vehicle operations operating a freight-carrying CMV in interstate commerce as compared to current entry-level commercial motor vehicle drivers aged 21–24 when operating a freight-carrying CMV in interstate commerce. The goal of this pilot program is to determine whether the group of under-21 military CDL holders operating in interstate commerce have similar or better safety performance outcomes than the 21–24 year old entry level drivers operating in interstate commerce.

The information collected as part of the pilot program is necessary to: (1) Determine the eligibility of drivers to participate in the pilot program; (2) effectively implement and monitor the pilot program, given that participating under-21 military drivers will be participating with an exemption; (3) contact drivers if necessary throughout the pilot program (*e.g.,* for follow-on questions or clarification on data), and (4) to conduct analysis on the safety performance of the participating drivers and make safety decisions accordingly. Specific details concerning eligibility for pilot program participation were previously published at 81 FR 56745 (September 21, 2016); 83 FR 31631 (July 6, 2018); and 83 FR 60950 (November 27, 2018). Pursuant to 49 U.S.C. 31315(c)(3) and 49 CFR 381.515, the FMCSA Administrator has the authority to immediately revoke the participation of a motor carrier, CMV, or driver in the Under 21 Military Pilot Program for failure to comply with the program's terms and conditions. Participation in the Under 21 Military Pilot Program does not provide for any right, entitlement, or benefit.

DATES: Written comments must be submitted on or before October 7, 2019. The modified system will be effective immediately with the exception of the modified routine use which will be effective October 7, 2019.

ADDRESSES: You may submit comments, identified by docket number DOT–OST–2019–0103 by one of the following methods:

Federal e-Rulemaking Portal: https://www.regulations.gov

Fax: (202) 493–2251.

• *Mail:* Department of Transportation Docket Management, Room W12–140, 1200 New Jersey Ave. SE, Washington, DC 20590.

Instructions: You must include the agency name and docket number, DOT–OST–2019–0057. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* or to the street address listed above. Follow the online instructions for accessing dockets.

FOR FURTHER INFORMATION CONTACT: For system-related questions please contact: Nicole Michel, Program Manager. 1200 New Jersey Ave SE, Washington, DC 20590. Email: *nicole.michel@dot.gov,* Tel. (202) 366–4354.

For general and privacy questions, please contact: Claire W. Barrett, Departmental Chief Privacy Officer, Department of Transportation, S–81, Washington, DC 20590, Email: *privacy@dot.gov,* Tel. (202) 366–8135.

SUPPLEMENTARY INFORMATION:

Background: The U.S. Department of Transportation's (DOT) Federal Motor Carrier Safety Administration (FMCSA) core mission is to reduce commercial motor vehicle-related crashes and fatalities. Pursuant to Section 5404 of the Fixing America's Surface Transportation Act, 2015 (FAST Act), the FMCSA Office of Research will conduct a pilot program to determine the safety benefits or risks posed by allowing military service members aged 18, 19, and 20 with specialized training in heavy vehicle operations to engage in interstate commerce when they are compared to current entry-level commercial motor vehicle (CMV) drivers aged 21–24). The pilot program will also seek to compare the safety benefits or risks of these military licensed drivers under the age of 21 when operating in interstate commerce when compated to current CMV drivers who are also under the age of 21, but who only operate in intrastate commerce. All CMV drivers in the study will be required to meet all Federal Motor Carrier Safety Regulation (FMCSR) requirements (except age) for operating a CMV in interstate commerce (FMCSR part 383, subparts G and J, require that drivers be tested for knowledge and skills, and part 391 includes additional qualifications, including driver medical examinations). FMCSA will grant an exemption from the regulatory requirement that a Commercial Driver's License (CDL) holder to be 21 years of age prior to operating in interstate commerce for participants in the pilot program. The exemption will allow a limited set of individuals aged 18, 19, and 20 who have received specialized military training and experience in heavy vehicle operations to participate in interstate commerce. FMCSA will recruit motor carriers (carriers) to apply to participate in the pilot program as driver sponsors. Once approved by FMCSA, carriers will recruit under-21 drivers to participate in the pilot program as ''covered drivers.'' Covered drivers will be required to carry a copy of a letter from FMCSA to the approved motor carrier and present the letter during inspections or other encounters with law enforcement. In addition to under-21 drivers with special military training, the program will require that carriers provide participants in each of two control groups. The first control group consists of current entry-level CMV drivers (aged 21–24) who operate in interstate commerce. The second control group consists of current CMV drivers under 21 who participate

intrastate in intrastate commerce. Participating motors carriers must be able to supply control group drivers in numbers matching the study group (covered) drivers to be employed. Drivers will be required to submit a background information form, as well as sign an informed consent form to participate in the pilot program to the carrier, who will then provide it to the research team. The driver will provide information about their training and experience, as well as demograpic data. If admitted to the study, drivers agree to allow the carrier to send the records on their driving history and their safety performance to the research team throughout their period of participation. Drivers may choose to leave the pilot program at any time. For participating drivers, the research team will collect safety data from the carrier on a monthly basis, and will perform random checks of participating drivers' license status via FMCSA's Commercial Driver Licensing Information System (CDLIS). The research team will send FMCSA a status report every month highlighting potentially unsafe drivers which FMCSA may use in conjunction with other data maintained by FMCSA to remove a participating driver from the pilot program. Pursuant to 49 U.S.C. 31315(c)(3) and 49 CFR 381.515, the FMCSA Administrator has the authority to immediately revoke the participation of a motor carrier, CMV, or driver in the Under 21 Military Pilot Program for failure to comply with the program's terms and conditions. Participation in the Under 21 Military Pilot Program does not provide for any right, entitlement, or benefit.

Privacy Act: The Privacy Act (5 U.S.C. 552a) governs the means by which the Federal Government collects, maintains, and uses personally identifiable information (PII) in a System of Records. A ''System of Records'' is a group of any records under the control of a Federal agency from which information about individuals is retrieved by name or other personal identifier. The Privacy Act requires each agency to publish in the **Federal Register** a System of Records notice (SORN) identifying and describing each System of Records the agency maintains, including the purposes for which the agency uses PII in the system, the routine uses for which the agency discloses such information outside the agency, and how individuals to whom a Privacy Act record pertains can exercise their rights under the Privacy Act (*e.g.,* to determine if the system contains information about them and to contest inaccurate information). In accordance with 5 U.S.C. 552a(r), DOT has provided a report of this system of records to the OMB and to Congress. More information about the pilot program is also available via the Privacy Impact Assessment for the program. The PIA, entitled ''Military Under-21 Pilot Program'', can be found at: *www.transportation.gov/privacy.*

SYSTEM NAME AND NUMBER:

Department of Transportation (DOT)/ Federal Motor Carrier Safety Administration (FMCSA) 010, Military Under 21 Pilot Program System of Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records in this system are stored electronically by the contractor research team. Contract information is available by contacting the Contracting Officer Representative at: 1200 New Jersey Ave. SE, Washington, DC 20590.

SYSTEM MANAGER(S):

The System Manager is Nicole Michel, Program Manager. 1200 New Jersey Ave. SE, Washington, DC 20590. Email: *Under21Pilot@dot.gov*.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 5404 of the Fixing America's Surface Transportation (FAST) Act (Pub.L. 114–94, Dec. 4, 2015, 49 U.S.C. 31305 note).

PURPOSE(S) OF THE SYSTEM:

The system of records will be used to determine the safety benefits or risks posed by allowing military service members aged 18, 19, and 20 with specialized training in heavy vehicle operations to engage in interstate commerce compared to current entry-level CMV drivers aged 21–24 and CMV drivers under 21 who engage in intrastate commerce. Driver background information will be used to qualify drivers for participation in the study and allow for continued authorization under the carrier's exemption. Demographic and driving history information (miles, hours, shift days, types of vehicles operated, etc.) will be used to analyze and evaluate effects on safety outcomes. Information about Safety-critical events (SCEs), such as hard braking or sudden lane changes that is recorded via an Onboard Monitoring System (OBMS) or electronic control module recording device, as well as crash data, moving violations, violations from inspections will be analyzed for all three groups to determine differences, if any, in safety outcomes of the participating groups. Information in the system of records may also be used to remove unsafe drivers from participation in the pilot program.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system of records will include information about individuals who are 18- to 20-years-old with military driving experience who apply to operate a CMV in interstate commerce as a part of the pilot program; 21 to 24-year-old CMV drivers who participate in interstate commerce and volunteer to participate in the pilot program; and 18- to 20-year-old CMV drivers who participate in intrastate commerce, and agree to participate in the pilot program.

CATEGORIES OF RECORDS IN THE SYSTEM:

The Military Under 21 pilot will collect, process, transmit, and store the following types of information:

Military Drivers between 18- and 20-years-old:

- *From Driver:*
  - *Qualifying Information:* military driver's license number military branch of service and unit Military service dates; and Commanding Officer's contact information (name, duty station, telephone number, email, and physical work address (when available)).

All Drivers:

- *From Driver:*
  - *Contact Information:* Name, email, telephone, home address
  - Commercial driver's license number
  - *Demographic Information:* Driver's date of birth, and gender.
- *From Carrier:*
  - *Carrier Information:* Carrier name, Carrier USDOT number, Carrier address, Carrier phone number, and Carrier email address
  - *Driver's Experience:* Training experience, Driving Experience, Trip-level data on participating drivers (*i.e.,* trip start and end times, miles traveled, total hours driven, type of truck driven, starting and ending location); Number of inspections of participating drivers, and Driver's qualifications (*i.e.,* air brake, air-over-hydraulic braking, or manual transmission)
  - *Driving Safety Data:* Crash summaries and investigative documents on crashes involving participating drivers (to include DOT reportable crashes and non-DOT reportable crashes), Numbers of violations for participating drivers, Safety critical events experienced by participating drivers (when available), Number of motorist incident reports concerning participating drivers.
  - Data from Onboard Monitoring System (OBMS) or electronic control module recording device

○ *Disqualifying events:* Alcohol-related citation, or failed a drug test.

• Created by DOT

○ Randomly-generated participant identification number

RECORD SOURCE CATEGORIES

Records are obtained from motor carriers that volunteer to participate in the pilot program, individuals who volunteer to participate in the pilot program, and records retrieved from CDLIS by the Department.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DOT as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

System-Specific Routine Uses—None.

DOT General Routine Uses

1. In the event that a system of records maintained by DOT to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, State, local or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order issued pursuant thereto.

2. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to a DOT decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

3. A record from this system of records may be disclosed, as a routine use, to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

4. It shall be a routine use of the records in this system of records to disclose them to the Department of Justice or other Federal agency conducting litigation when—(a) DOT, or any agency thereof, or (b) Any employee of DOT or any agency thereof, in his/her official capacity, or (c) Any employee of DOT or any agency thereof, in his/her individual capacity where the Department of Justice has agreed to represent the employee, or (d) The United States or any agency thereof, where DOT determines that litigation is likely to affect the United States, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or other Federal agency conducting the litigation is deemed by DOT to be relevant and necessary in the litigation, provided, however, that in each case, DOT determines that disclosure of the records in the litigation is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

5. It shall be a routine use of records in this system to disclose them in proceedings before any court or adjudicative or administrative body before which DOT or any agency thereof, appears, when—(a) DOT, or any agency thereof, or (b) Any employee of DOT or any agency thereof (including a member of the Coast Guard) in his/her official capacity, or (c) Any employee of DOT or any agency thereof, or (d) The United States or any agency thereof, where DOT determines that the proceeding is likely to affect the United States, is a party to the proceeding or has an interest in such proceeding, and DOT determines that use of such records is relevant and necessary in the proceeding, provided, however, that in each case, DOT determines that disclosure of the records in the proceeding is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

6. Disclosure may be made to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual. In such cases, however, the Congressional office does not have greater rights to records than the individual. Thus, the disclosure may be withheld from delivery to the individual where the file contains investigative or actual information or other materials which are being used, or are expected to be used, to support prosecution or fines against the individual for violations of a statute, or of regulations of the Department based on statutory authority. No such limitations apply to records requested for Congressional oversight or legislative purposes; release is authorized under 49 CFR 10.35(9).

7. One or more records from a system of records may be disclosed routinely to the National Archives and Records Administration in records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

8. DOT may make available to another agency or instrumentality of any government jurisdiction, including State and local governments, listings of names from any system of records in DOT for use in law enforcement activities, either civil or criminal, or to expose fraudulent claims, regardless of the stated purpose for the collection of the information in the system of records. These enforcement activities are generally referred to as matching programs because two lists of names are checked for match using automated assistance. This routine use is advisory in nature and does not offer unrestricted access to systems of records for such law enforcement and related antifraud activities. Each request will be considered on the basis of its purpose, merits, cost effectiveness and alternatives using Instructions on reporting computer matching programs to the Office of Management and Budget, OMB, Congress, and the public, published by the Director, OMB, dated September 20, 1989.

9. DOT may disclose records from this system, as a routine use, to the Office of Government Information Services for the purpose of (a) resolving disputes between FOIA requesters and Federal agencies and (b) reviewing agencies' policies, procedures, and compliance in order to recommend policy changes to Congress and the President.

10. DOT may disclose records from the system, as a routine use, to contractors and their agents, experts, consultants, and others performing or working on a contract, service, cooperative agreement, or other assignment for DOT, when necessary to accomplish an agency function related to this system of records.

11. DOT may disclose records from this system, as a routine use, to an agency, organization, or individual for the purpose of performing audit or oversight operations related to this system of records, but only such records as are necessary and relevant to the audit or oversight activity. This routine use does not apply to intra-agency sharing authorized under Section (b)(1) of the Privacy Act.

12. DOT may disclose from this system, as a routine use, records consisting of, or relating to, terrorism

information (6 U.S.C. 485(a)(5)), homeland security information (6 U.S.C. 482(f)(1)), or Law enforcement information (Guideline 2 Report attached to White House Memorandum, ''Information Sharing Environment, November 22, 2006) to a Federal, State, local, tribal, territorial, foreign government and/or multinational agency, either in response to its request or upon the initiative of the Component, for purposes of sharing such information as is necessary and relevant for the agencies to detect, prevent, disrupt, preempt, and mitigate the effects of terrorist activities against the territory, people, and interests of the United States of America, as contemplated by the Intelligence Reform and Terrorism Prevention Act of 2004 (Pub. L. 108–458) and Executive Order 13388 (October 25, 2005).

13. DOT may disclose records from the system, as a routine use to appropriate agencies, entities, and persons when (1) DOT suspects or has confirmed that there has been a breach of the system of records, (2) DOT has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DOT (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DOT's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

14. DOT may disclose records from the system, as a routine use to another Federal agency or Federal entity, when DOT determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system are stored electronically on a contractor-maintained cloud storage service.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records will be retrived by carrier name, driver name, CDL number, or the randomly generated participant ID assigned by the DOT contractor.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The FMCSA is in the process of developing a Records Control Schedule (RCS) for pilot programs. FMCSA will request disposition authority for the records from NARA to be held for six months after cutoff, and to destroyed after 3 years. Until the RCS is approved by NARA, Military Under 21 CMV Pilot Program records will be retained as permanent.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

DOT safeguards records in this system according to applicable rules and policies, including all applicable DOT IT systems security and access policies. DOT has imposed strict controls to minimize the risk of information being compromised. Access to the records in this system is limited to those individuals who have a need to know the information in furtherance of the performance of their official duties, and who have appropriate clearances or permissions.

RECORD ACCESS PROCEDURES:

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the System Manager at the address identified in ''System Manager and Address'' above. If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Departmental Freedom of Information Act Office, U.S. Department of Transportation, Room W94–122, 1200 New Jersey Ave. SE, Washington, DC 20590, ATTN: FOIA/Privacy Act request.

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy Act regulations set forth in 49 CFR part 10. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Freedom of Information Act Officer, *http://www.dot.gov/foia* or 202.366.4542. In addition you should provide the following:

An explanation of why you believe the Department would have information on you;

- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DOT component agency may have responsive records.

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without this bulleted information the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORD PROCEDURES:

See ''Record Access Procedures'' above.

NOTIFICATION PROCEDURES:

See ''Record Access Procedures'' above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

Not applicable.

Issued in Washington, DC.

Claire W. Barrett,

Departmental Chief Privacy Officer.

[FR Doc. 2019–19135 Filed 9–4–19; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of four 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; 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 (*www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On August 29, 2019, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following four persons are blocked under the relevant sanctions authority listed below.

Entities

1. JAMMAL TRUST BANK S.A.L. (a.k.a. JAMMAL TRUST BANK; a.k.a. ''JTB''), JTB Tower, Elias Hraoui Avenue, Beirut, Lebanon; Jammal Trust Bank SAL Building, Rashid Karame Ave, Beirut, Lebanon; PO Box 11–5640 & 13–5750, Bank's Bldg, Rashid Karameh Ave, Beirut, Lebanon; SCI La Balance, Boulevard Giscard D'estaing, Abidjan, Cote d' Ivoire; 15A Burma Road, Apapa, Lagos State, Nigeria; 3rd Floor, Berkeley Court, 6/7 Pollen St, London W1S 1ND, United Kingdom; Al-Buss, Lebanon; Al Furzol, Lebanon; Baalbeck, Lebanon; Beirut, Lebanon; Bint Jbeil, Lebanon; Bourj El Barajneh, Lebanon; Dora, Lebanon; Ghazieh, Lebanon; Jbeil, Lebanon; Jwaya, Lebanon; Kana, Lebanon; Labwe, Lebanon; Marjeyoun, Lebanon; Nabatieh, Lebanon; Saida, Lebanon; Tibnin, Lebanon; Tripoli, Lebanon; Tyre, Lebanon; Verdun, Lebanon; Abidjan, Cote d' Ivoire; Apapa, Nigeria; London, United Kingdom; SWIFT/BIC JTBKLBBE; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations; All Branches Worldwide [SDGT] (Linked To: HIZBALLAH).

Designated pursuant to section 1(d)(ii) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism'' (E.O. 13224) for assisting in, sponsoring, or providing financial, material, or technological support for, or financial or other services to or in support of, HIZBALLAH, an entity whose property and interests in property are blocked pursuant to E.O. 13224.

2. TRUST INSURANCE S.A.L. (a.k.a. TRUST INSURANCE), JTB Tower, Tahweeta High Way, Elias Hraoui Avenue, Beirut, Lebanon; PO Box 15750, Jammal Trust Bank Building, Rachid Karameh Street, Verdun, Lebanon; Verdun, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: JAMMAL TRUST BANK S.A.L.).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by JAMMAL TRUST BANK S.A.L., an entity whose property and interests in property are blocked pursuant to E.O. 13224.

3. TRUST INSURANCE SERVICES S.A.L., JTB Tower, Tahweeta High Way, Elias Hraoui Avenue, Beirut, Lebanon; Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: JAMMAL TRUST BANK S.A.L.).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by JAMMAL TRUST BANK S.A.L., an entity whose property and interests in property are blocked pursuant to E.O. 13224.

4. TRUST LIFE INSURANCE COMPANY S.A.L. (a.k.a. TRUST LIFE; a.k.a. TRUST LIFE INSURANCE CO SAL), JTB Tower, Tahweeta High Way, Elias Hraoui Avenue, Beirut, Lebanon; Jamal Trust Vabk Building, Beirut, Lebanon; Beirut, Lebanon; Additional Sanctions Information—Subject to Secondary Sanctions Pursuant to the Hizballah Financial Sanctions Regulations [SDGT] (Linked To: JAMMAL TRUST BANK S.A.L.).

Designated pursuant to section 1(c) of E.O. 13224 for being owned or controlled by JAMMAL TRUST BANK S.A.L., an entity whose property and interests in property are blocked pursuant to E.O. 13224.

Dated: August 29, 2019.

Andrea Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2019–19115 Filed 9–4–19; 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, Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of four 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; 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 (*www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On August 29, 2019, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following four persons are blocked under the relevant sanctions authority listed below.

Entities

1. SARUR, Muhammad (a.k.a. SURUR, Muhammad Ibrahim), Baalbek-Hermel Province, Lebanon; DOB 05 Feb 1967; Gender Male (individual) [SDGT] (Linked To: HAMAS).

Designated pursuant to section 1(d)(i) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism'' (E.O. 13224) for assisting in, sponsoring, or providing financial, material, or technological support for, or financial or other services to or in support of, HAMAS, an entity whose property and interests in property are blocked pursuant to E.O. 13224.

2. AWAD, Kamal Abdelrahman Aref (a.k.a. AWAD, Kamal), Gaza, Palestinian; DOB 07 Aug 1978; POB Nablus, West Bank; Gender Male; National ID No. 905037545 (Palestinian) (individual) [SDGT] (Linked To: HAMAS).

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, or technological support for, or financial or other services to or in support of, HAMAS, an entity whose property and interests in property are blocked pursuant to E.O. 13224.

3. NASSER, Fawaz Mahmud Ali (a.k.a. NASIR, Fawwaz), Gaza, Palestinian; DOB 13 Jan 1979; POB Ramallah, West Bank; Gender Male; National ID No. 946045622 (Palestinian) (individual) [SDGT] (Linked To: HAMAS).

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, or technological support for, or financial or other services to or in support of, HAMAS, an entity whose property and interests in property are blocked pursuant to E.O. 13224.

4. AL–AYY, Muhammad Kamal (a.k.a. ALAY, Muhammad Kamal Salamah), Gaza, Palestinian; DOB 22 Dec 1970; Gender Male; National ID No. 912396140 (Palestinian) (individual) [SDGT] (Linked To: HAMAS).

Designated pursuant to section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, or technological support for, or financial or other services to or in support of, HAMAS, an entity whose property and interests in property are blocked pursuant to E.O. 13224.

Dated: August 29, 2019.

Andrea Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2019–19114 Filed 9–4–19; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons and vessels 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 and these vessels are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

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 (*www.treasury.gov/ofac*).

Notice of OFAC Actions

On August 30, 2019, 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. CHEN, Mei Hsiang (Chinese Traditional: 陳美香) (a.k.a. CHEN, Mei-Hsiang), Taiwan; DOB 18 May 1956; nationality Taiwan; Gender Female; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Passport 310422295 expires 06 Jan 2025; National ID No. R222185563 (individual) [DPRK4].

Designated pursuant to section 1(a)(iii) of Executive Order 13810 of September 20, 2017, "Imposing Additional Sanctions With Respect to North Korea" (E.O. 13810), for having engaged in at least one significant importation from or exportation to North Korea of any goods, services, or technology.

2. HUANG, Wang Ken (Chinese Traditional: 黃旺根) (a.k.a. HUANG, Wan Ken; a.k.a. HUANG, Wang-gen; a.k.a. HUANG, Wan-Ken), Taiwan; DOB 18 Jul 1960; nationality Taiwan; Gender Male; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; CEO and Manager of Jui Pang Co., Ltd. (individual) [DPRK4].

Designated pursuant to section 1(a)(iii) of E.O. 13810 for having engaged in at least one significant importation from or exportation to North Korea of any goods, services, or technology.

Entities

1. JUI CHENG SHIPPING COMPANY LIMITED (Chinese Traditional: 瑞誠海運股份有限公司) (a.k.a. JUI CHENG SHIPPING CO LTD; a.k.a. JUI CHENG SHIPPING CO., LIMITED), Care of Jui Zong Ship Management Co Ltd, 5th Floor, 551, Jiuru 1st Road, Sanmin District, Kaohsiung 80764, Taiwan; Room B, 21/F Kaikwong Commercial Building, 332 Lockhart Road, Wan Chai, Hong Kong; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Commercial Registry Number 0925906 (Hong Kong); Company Number IMO 5499198 [DPRK4].

Designated pursuant to section 1(a)(iii) of E.O. 13810 for having engaged in at least one significant importation from or exportation to North Korea of any goods, services, or technology.

2. JUI PANG SHIPPING CO LTD (Chinese Traditional: 瑞邦海運股份有限公司), 5th Floor, 551, Jiuru 1st Road, Sanmin District, Kaohsiung City 80764, Taiwan; 5F-2 No 551 Jiouru 1st Road, Sanmin District, Kaohsiung, Taiwan; 4FL No. 198 Wencheng 2nd Road, Chengde Village, North District, Tainan, Taiwan; 193 San Kuan Rd, Tainan City 70247, Taiwan; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Company Number IMO 1865817; Business Number 16111431 (Taiwan) [DPRK4].

Designated pursuant to section 1(a)(iii) of E.O. 13810 for having engaged in at least one significant importation from or exportation to North Korea of any goods, services, or technology.

3. JUI ZONG SHIP MANAGEMENT CO LTD (Chinese Traditional: 瑞榮船舶管理有限公司) (a.k.a. JUI ZONG SHIP MANAGEMENT CO; a.k.a. JUI ZONG SHIP MANAGEMENT CO., LTD.), 5FL-2 No. 551 Jiouru 1st Road Sanmin Dist., Kaohsiung 80764, Taiwan; 5th Floor, 551, Jiuru 1st Road, Sanmin District, Kaohsiung City 80764, Taiwan; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Company Number IMO 5418446; Business Number 13195014 (Taiwan) [DPRK4].

Designated pursuant to section 1(a)(iii) of E.O. 13810 for having engaged in at least one significant importation from or exportation to North Korea of any goods, services, or technology.

Vessel

1. SHANG YUAN BAO Panama flag; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Vessel Registration Identification IMO 8126070 (vessel) [DPRK4] (Linked To: HUANG, Wang Ken; Linked To: CHEN, Mei Hsiang; Linked To: JUI CHENG SHIPPING COMPANY LIMITED; Linked To: JUI PANG SHIPPING CO LTD; Linked To: JUI ZONG SHIP MANAGEMENT CO LTD).

Identified pursuant to E.O. 13810 as property in which HUANG WANG KEN, CHEN MEI HSIANG, JUI CHENG SHIPPING COMPANY LIMITED, JUI ZONG SHIP MANAGEMENT CO LTD, and JUI PANG SHIPPING CO LTD, persons whose property and interests in property are blocked pursuant to E.O. 13810, have an interest.

Dated: August 30, 2019.

Andrea Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2019–19159 Filed 9–4–19; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Senior Executive Service Performance Review Board

AGENCY: Internal Revenue Service (IRS), Department of the Treasury.

ACTION: Notice.

SUMMARY: To announce a list of senior executives who comprise a standing roster that will serve on IRS's Fiscal Year 2019 Senior Executive Service (SES) Performance Review Boards.

DATES: This list of senior executives is effective September 1, 2019.

FOR FURTHER INFORMATION CONTACT: Sharnetta A. Walton, Director, Office of Executive Services at (202) 317–3817 or Candice I. Jones, Assistant Director, Office of Executive Services at (202) 317–6284, IRS, 1111 Constitution Avenue NW, Washington, DC 20224.

SUPPLEMENTARY INFORMATION: Pursuant to 5 U.S.C. 4314(c)(4), this board shall review and evaluate the initial appraisals of career senior executives' performance and provide recommendations to the appointing authority on performance ratings, pay adjustments and performance awards. The senior executives are as follows:

Jeffrey J. Tribiano, Chair
Sunita Lough
David P Alito
William H. Ankrum
Scott A. Ballint
Robert J. Bedoya
Michael C. Beebe
Jennifer L. Best
Thomas A. Brandt
Linda J. Brown
Carol A. Campbell
John V. Cardone
Robert Choi
Elita I. Christiansen
James P. Clifford
Amalia C. Colbert
Kenneth C. Corbin
Robert S. Cox
Tracy DeLeon
Brenda A. Dial
Joseph Dianto
Donald C. Drake
John C. Duder
Elizabeth A. Dugger
Nikole C. Flax
John D. Fort
Ursula S. Gillis
Linda K. Gilpin
Dietra D. Grant
Darren J. Guillot
Daniel S. Hamilton
Donna C. Hansberry
Barbara L. Harris
Gearl D. Harris
Nancy E. Hauth
Mary R. Hernandez
John E. Hinding
Carrie Y. Holland
David W. Horton
Cecil T. Hua
Eric C. Hylton
Scott E. Irick
Sharon C. James
Tracy A. Keeter
Andrew J. Keyso Jr.
Edward T. Killen
Robert M. Leahy Jr.
James C. Lee
Terry Lemons
William H. Maglin II
Paul J. Mamo
Lee D. Martin
Steven M. Martin
Erick Martinez
Ivy S. McChesney
Kevin Q. McIver
Karen A. Michaels
Kevin M. Morehead
Mary E. Murphy
Frank A. Nolden
Douglas W. O'Donnell
Kaschit D. Pandya
Holly O. Paz
Richard A. Peterson
Robert A. Ragano
Scott D. Reisher
Tamera L. Ripperda
Bridget T. Roberts
Richard L. Rodriguez
Frederick W. Schindler
Theodore D. Setzer
Verline A. Shepherd
Nancy A. Sieger
Susan Simon
Harrison Smith
Tommy A. Smith
Gloria C. Sullivan
John J. Tuzynski
Margaret Von Lienen
Keith A. Walker
Shanna R. Webbers
Lavena B. Williams

This document does not meet the Treasury's criteria for significant regulations.

Kirsten B. Wielobob,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

[FR Doc. 2019–19200 Filed 9–4–19; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 84 Thursday,

No. 172 September 5, 2019

Part II

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 219

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Alaska Fisheries Science Center Fisheries Research; Final Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 219

[Docket No. 170127128–9394–02]

RIN 0648–BG64

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Alaska Fisheries Science Center Fisheries Research

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

ACTION: Final rule.

SUMMARY: NMFS's Office of Protected Resources (OPR), upon request from NMFS's Alaska Fisheries Science Center (AFSC), hereby issues regulations to govern the unintentional taking of marine mammals incidental to fisheries research conducted in multiple specified geographical regions over the course of five years. These regulations, which allow for the issuance of Letters of Authorization (LOA) for the incidental take of marine mammals during the described activities and specified timeframes, prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, as well as requirements pertaining to the monitoring and reporting of such taking.

DATES: Effective from October 7, 2019, through October 7, 2024.

ADDRESSES: A copy of AFSC's application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-noaa-fisheries-afsc-fisheries-and-ecosystem-research.* In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Regulatory Action

These regulations establish a framework under the authority of the MMPA (16 U.S.C. 1361 *et seq.*) to allow for the authorization of take of marine mammals incidental to the AFSC's fisheries research activities in the Gulf of Alaska, Bering Sea, and Arctic Ocean, and, by AFSC's request, also includes fisheries research activities of the International Pacific Halibut Commission (IPHC), which occur in the Bering Sea, Gulf of Alaska, and off of the U.S. west coast.

We received an application from the AFSC requesting five-year regulations and authorization to take multiple species of marine mammals. Take would occur by Level B harassment incidental to the use of active acoustic devices, as well as by visual disturbance of pinnipeds, and by Level A harassment, serious injury, or mortality incidental to the use of fisheries research gear. Please see ''Background'' below for definitions of harassment.

Legal Authority for the Action

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) directs the Secretary of Commerce 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 for up to five years if, after notice and public comment, the agency makes certain findings and issues regulations that set forth permissible methods of taking pursuant to that activity and other means of effecting the ''least practicable adverse impact'' on the affected species or stocks and their habitat (see the discussion below in the ''Mitigation'' section), as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I provide the legal basis for issuing this rule containing five-year regulations, and for any subsequent LOAs. As directed by this legal authority, the regulations contain mitigation, monitoring, and reporting requirements.

Summary of Major Provisions Within the Regulations

Following is a summary of the major provisions of these regulations regarding AFSC fisheries research activities. These measures include:

- Required monitoring of the sampling areas to detect the presence of marine mammals before deployment of certain research gear.
- Required implementation of the mitigation strategy known as the ''move-on rule mitigation protocol'' which incorporates best professional judgment, when necessary during certain research fishing operations.

Background

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1361 *et seq.*) directs 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, regulations are issued, and notice is provided to the public.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

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.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On June 28, 2016, we received an adequate and complete request from AFSC for authorization to take marine

mammals incidental to fisheries research activities. On October 18, 2016 (81 FR 71709), we published a notice of receipt of AFSC's application in the **Federal Register**, requesting comments and information related to the AFSC request for thirty days. We received comments jointly from The Humane Society of the United States and Whale and Dolphin Conservation (HSUS/WDC). Subsequently, AFSC presented substantive revisions to the application, including revisions to the take authorization request as well as incorporation of the IPHC fisheries research activities. We received this revised application, which was determined to be adequate and complete, on September 6, 2017. We then published a notice of its receipt in the **Federal Register**, requesting comments and information for thirty days, on September 14, 2017 (82 FR 43223). We received no comments in response to this second review period. The original comments received from HSUS/WDC are available online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-noaa-fisheries-afsc-fisheries-and-ecosystem-research* and were considered in development of the proposed rule. We published a Notice of Proposed Rulemaking in the **Federal Register** on August 1, 2018 (83 FR 37638) and requested comments and information from the public. Please see ''Comments and Responses,'' below.

AFSC conducts fisheries research using trawl gear used at various levels in the water column, hook-and-line gear (including longlines with multiple hooks), gillnets, and other gear. If a marine mammal interacts with gear deployed by AFSC, the outcome could potentially be Level A harassment, serious injury (*i.e.,* any injury that will likely result in mortality), or mortality. Although any given gear interaction could result in an outcome less severe than mortality or serious injury, we do not have sufficient information to allow parsing these potential outcomes. Therefore, AFSC presents a pooled estimate of the number of potential incidents of gear interaction and, for analytical purposes we assume that gear interactions would result in serious injury or mortality. AFSC also uses various active acoustic devices in the conduct of fisheries research, and use of some devices has the potential to result in Level B harassment of marine mammals. Level B harassment of pinnipeds hauled out may also occur, as a result of visual disturbance from vessels conducting AFSC research.

AFSC requested authorization to take individuals of 19 species by Level A harassment, serious injury, or mortality (hereafter referred to as M/SI) and of 25 species by Level B harassment. These regulations are effective for five years.

Description of the Specified Activity

Overview

The AFSC collects a wide array of information necessary to evaluate the status of exploited fishery resources and the marine environment. AFSC scientists conduct fishery-independent research onboard NOAA-owned and operated vessels or on chartered vessels. Such research may also be conducted by cooperating scientists on non-NOAA vessels when the AFSC helps fund the research. The AFSC plans to administer and conduct approximately 58 survey programs over the five-year period, within three separate research areas (some survey programs are conducted across more than one research area). The gear types used fall into several categories: towed nets fished at various levels in the water column, longline gear, gillnets and seine nets, traps, and other gear. Only use of trawl nets, longlines, and gillnets are likely to result in interaction with marine mammals. Many of these surveys also use active acoustic devices.

The Federal government has a responsibility to conserve and protect living marine resources in U.S. waters and has also entered into a number of international agreements and treaties related to the management of living marine resources in international waters outside the United States. NOAA has the primary responsibility for managing marine finfish and shellfish species and their habitats, with that responsibility delegated within NOAA to NMFS.

In order to direct and coordinate the collection of scientific information needed to make informed fishery management decisions, Congress created six regional fisheries science centers, each a distinct organizational entity and the scientific focal point within NMFS for region-based Federal fisheries-related research. This research is aimed at monitoring fish stock recruitment, abundance, survival and biological rates, geographic distribution of species and stocks, ecosystem process changes, and marine ecological research. The AFSC is the research arm of NMFS in the Alaska region of the United States. The AFSC conducts research and provides scientific advice to manage fisheries and conserve protected species in the geographic research areas described below and provides scientific information to support the North Pacific Fishery Management Council and other domestic and international fisheries management organizations.

The IPHC, established by a convention between the governments of Canada and the United States, is an international fisheries organization mandated to conduct research on and management of the stocks of Pacific halibut (*Hippoglossus stenolepis*) within the Convention waters of both nations. The Northern Pacific Halibut Act of 1982 (16 U.S.C. 773), which amended the earlier Northern Pacific Halibut Act of 1937, is the enabling legislation that gives effect to the Convention in the United States. Although operating in U.S. waters (and, therefore, subject to the MMPA prohibition on ''take'' of marine mammals), the IPHC is not appropriately considered to be a U.S. citizen (as defined by the MMPA) and cannot be issued an incidental take authorization. For purposes of MMPA compliance, the AFSC sponsors the IPHC research activities occurring in U.S. waters, with applicable mitigation, monitoring, and reporting requirements conveyed to the IPHC via Letters of Acknowledgement issued by the AFSC pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (MSA).

Fishery-independent data necessary to the management of halibut stocks is collected using longline gear aboard chartered commercial vessels within multiple IPHC regulatory areas, including within U.S. waters of the Bering Sea, Gulf of Alaska, and off the U.S. west coast. The IPHC plans to conduct two survey programs over the five-year period. IPHC activity and requested take authorization is described in Appendix C of AFSC's application.

Dates and Duration

The specified activity may occur at any time during the five-year period of validity of the regulations. Dates and duration of individual surveys are inherently uncertain, based on congressional funding levels for the AFSC, weather conditions, or ship contingencies. In addition, cooperative research is designed to provide flexibility on a yearly basis in order to address issues as they arise. Some cooperative research projects last multiple years or may continue with modifications. Other projects only last one year and are not continued. Most cooperative research projects go through an annual competitive selection process to determine which projects should be funded based on proposals developed by many independent researchers and fishing industry participants.

Specified Geographical Region

The AFSC conducts research in Alaska within three research areas considered to be distinct specified geographical regions: The Gulf of Alaska Research Area (GOARA), the Bering Sea/Aleutian Islands Research Area (BSAIRA), and the Chukchi Sea and Beaufort Sea Research Area (CSBSRA). Please see Figures 2–1 through 2–3 in the AFSC application for maps of the three research areas. We note here that, while the specified geographical regions within which the AFSC operates may extend outside of the U.S. Exclusive Economic Zone (EEZ), *i.e.,* into the Canadian EEZ (but not including Canadian territorial waters), the MMPA's authority does not extend into foreign territorial waters. IPHC research activities are carried out within the BSAIRA and GOARA but also within a fourth specified geographical region, *i.e.,* off the U.S. west coast (see Figure C–3 of the AFSC application). The IPHC operates from 36°40′ N (approximately Monterey Bay, California) at the southernmost extension northward to the Canadian border, including U.S. waters within Puget Sound. These areas were described in detail in our Notice of Proposed Rulemaking (83 FR 37638; August 1, 2018); please see that document for further detail.

Detailed Description of Activities

A detailed description of AFSC's planned activities was provided in our Notice of Proposed Rulemaking (83 FR 37638; August 1, 2018) and is not repeated here. No changes have been made to the specified activities described therein.

Comments and Responses

We published a Notice of Proposed Rulemaking in the **Federal Register** on August 1, 2018 (83 FR 37638), and requested comments and information from the public. During the thirty-day comment period, we received letters from the Marine Mammal Commission (Commission), the Ecological Sciences Communication Initiative (ECO–SCI), and from three private citizens. Of the latter, one comment expressed general opposition, one expressed general support, and one was not relevant to the proposed rulemaking. The remaining comments and our responses are provided here, and the comments have been posted online at: *https://www.fisheries.noaa.gov/action/incidental-take-authorization-noaa-fisheries-afsc-fisheries-and-ecosystem-research.* Please see the Commission's comment letter for full rationale behind the recommendations we respond to below. No changes were made to the proposed rule as a result of these comments.

Comment 1: The Commission provides general recommendations—not specific to the proposed AFSC rulemaking—that NMFS develop criteria and guidance for determining when prospective applicants should request taking by Level B harassment from the use of echosounders, other sonars, and sub-bottom profilers and that NMFS formulate a strategy for updating its generic behavioral harassment thresholds for all types of sound sources as soon as possible.

Response: We thank the Commission for its continued interest in these issues. Generally speaking, there has been a lack of information and scientific consensus regarding the potential effects of scientific sonars on marine mammals, which may differ depending on the system and species in question as well as the environment in which the system is operated. We will continue to evaluate the need for applicant guidance specific to the types of acoustic sources mentioned by the Commission.

With regard to revision of existing behavioral harassment criteria, NMFS agrees that this is necessary. NMFS is continuing our examination of the effects of noise on marine mammal behavior and is focused on developing guidance regarding the effects of anthropogenic sound on marine mammal behavior. Behavioral response is a complex question, and NMFS will take the time that is necessary to research and address it appropriately.

Comment 2: The Commission recommends that OPR require AFSC to estimate the numbers of marine mammals taken by Level B harassment incidental to use of active acoustic sources (*e.g.,* echosounders) based on the 120-decibel (dB) rather than the 160-dB root mean square (rms) sound pressure level (SPL) threshold.

Response: Please see our Notice of Proposed Rulemaking (83 FR 37638; August 1, 2018) for discussion related to acoustic terminology and thresholds. The Commission repeats a recommendation made in prior letters concerning proposed authorization of take incidental to use of scientific sonars (such as echosounders). As we have described in responding to those prior comments (*e.g.,* 83 FR 36370), our evaluation of the available information leads us to disagree with this recommendation. After review of the Commission's recommendation in this case, our assessment is unchanged. While the Commission presents certain valid points in attempting to justify their recommendation (*e.g.,* certain sensitive species are known to respond to sound exposures at lower levels), these points do not ultimately support the recommendation.

First, we provide some necessary background on implementation of acoustic thresholds. NMFS has historically used generalized acoustic thresholds based on received levels to predict the occurrence of behavioral harassment, given the practical need to use a relatively simple threshold based on information that is available for most activities. Thresholds were selected in consideration largely of measured avoidance responses of mysticete whales to airgun signals and to industrial noise sources, such as drilling. The selected thresholds of 160 dB rms SPL and 120 dB rms SPL, respectively, have been extended for use since then for estimation of behavioral harassment associated with noise exposure from sources associated with other common activities as well.

Separately, NMFS and the U.S. Navy have historically worked closely together to develop appropriate criteria specific to use of low- and mid-frequency active sonar and underwater explosives. The Commission's reference to the Navy's use of different acoustic harassment criteria is not relevant, as those criteria were developed, and have evolved over time in reflection of available science, with specific reference to military sonar or underwater detonations.

The Commission misinterprets how NMFS characterizes scientific sonars, so we provide clarification here. Sound sources can be divided into broad categories based on various criteria or for various purposes. As discussed by Richardson *et al.* (1995), source characteristics include strength of signal amplitude, distribution of sound frequency and, importantly in context of these thresholds, variability over time. With regard to temporal properties, sounds are generally considered to be either continuous or transient (*i.e.,* intermittent). Continuous sounds, which are produced by the industrial noise sources for which the 120-dB behavioral harassment threshold was selected, are simply those whose sound pressure level remains above ambient sound during the observation period (ANSI, 2005). Intermittent sounds are defined as sounds with interrupted levels of low or no sound (NIOSH, 1998). Simply put, a continuous noise source produces a signal that continues over time, while an intermittent source produces signals of relatively short duration having an obvious start and end with predictable patterns of bursts of sound and silent periods (*i.e.,* duty

cycle) (Richardson and Malme, 1993). It is this fundamental temporal distinction that is most important for categorizing sound types in terms of their potential to cause a behavioral response. For example, Gomez *et al.* (2016) found a significant relationship between source type and marine mammal behavioral response when sources were split into continuous (*e.g.,* shipping, icebreaking, drilling) versus intermittent (*e.g.,* sonar, seismic, explosives) types. In addition, there have been various studies noting differences in responses to intermittent and continuous sound sources for other species (*e.g.,* Neo *et al.,* 2014; Radford *et al.,* 2016; Nichols *et al.,* 2015).

Sound sources may also be categorized based on their potential to cause physical damage to auditory structures and/or result in threshold shifts. In contrast to the temporal distinction discussed above, the most important factor for understanding the differing potential for these outcomes across source types is simply whether the sound is impulsive or not. Impulsive sounds, such as those produced by airguns, are defined as sounds which are typically transient, brief (< 1 sec), broadband, and consist of a high peak pressure with rapid rise time and rapid decay (ANSI, 1986; NIOSH, 1998). These sounds are generally considered to have greater potential to cause auditory injury and/or result in threshold shifts. Non-impulsive sounds can be broadband, narrowband or tonal, brief or prolonged, continuous or intermittent, and typically do not have the high peak pressure with rapid rise/decay time that impulsive sounds do (ANSI, 1995; NIOSH, 1998). Because the selection of the 160-dB behavioral threshold was focused largely on airgun signals, it has historically been commonly referred to as the ''impulse noise'' threshold (including by NMFS). However, this longstanding confusion in terminology—*i.e.,* the erroneous impulsive/continuous dichotomy—presents a narrow view of the sound sources to which the thresholds apply, and inappropriately implies a limitation in scope of applicability for the 160-dB behavioral threshold in particular.

An impulsive sound is by definition intermittent; however, not all intermittent sounds are impulsive. Many sound sources for which it is generally appropriate to consider the authorization of incidental take are in fact either impulsive (and intermittent) (*e.g.,* impact pile driving) or continuous (and non-impulsive) (*e.g.,* vibratory pile driving). However, scientific sonars present a less common case where the sound produced is considered intermittent but non-impulsive. Herein lies the crux of the Commission's argument, *i.e.,* that because scientific sonars used by NMFS's science centers are not impulsive sound sources, they must be assessed using the 120-dB behavioral threshold appropriate for continuous noise sources. However, given the existing paradigm—dichotomous thresholds appropriate for generic use in evaluating the potential for behavioral harassment resulting from exposure to continuous or intermittent sound sources—the Commission does not adequately explain why potential harassment from an intermittent sound source should be evaluated using a threshold developed for use with continuous sound sources. As we have stated in prior responses to this recommendation, consideration of the preceding factors leads to a conclusion that the 160-dB threshold is more appropriate for use than is the 120-dB threshold.

As noted above, the Commission first claims generically that we are using an incorrect threshold, because scientific sonars do not produce impulse noise. However, in bridging the gap from this generic assertion to their specific recommendation that the 120-dB continuous noise threshold should be used, the Commission makes several leaps of logic that we address here. The Commission's justification is in large part seemingly based on citation to examples in the literature of the most sensitive species responding at lower received levels to sources dissimilar to those considered here. There are three critical errors in this approach.

First, the citation of examples of animals ''responding to sound'' does not equate to behavioral harassment, as defined by the MMPA. As noted above under ''Background,'' the MMPA defines Level B harassment as acts with the potential to disturb a marine mammal by causing *disruption of behavioral patterns.* While it is possible that some animals do in fact experience Level B harassment upon exposure to intermittent sounds at received levels less than the 160-dB threshold, this is not in and of itself adequate justification for using a lower threshold. Implicit in the use of a step function for quantifying behavioral harassment is the realistic assumption, due to behavioral context and other factors, that some animals exposed to received levels below the threshold will in fact experience harassment, while others exposed to levels above the threshold will not. Moreover, a brief, transient behavioral response should not necessarily be considered as having the potential to disturb by disrupting behavioral patterns.

Many of the examples given by the Commission demonstrate mild responses, but not behavioral changes more likely to indicate Level B harassment. For example, the Commission discusses two studies (Quick *et al.,* 2017; Cholewiak *et al.,* 2017) that describe responses to one of the same sources considered here (the EK60 echosounder). We addressed Quick *et al.* (2017) in our Notice of Proposed Rulemaking, describing the authors' findings that, while tagged pilot whales increased heading variance during exposure to the EK60, tag data did not show an overt response to the echosounder or a change to foraging behavior. (Digital acoustic recording tags were attached to study animals; EK60 signals were within audible range for the animals with received levels ranging from 117–125 dB). Similarly, the authors report that visual observations of behavior did not indicate any dramatic response, unusual behaviors, changes in heading, or cessation of biologically important behavior such as feeding. No evidence is presented that could be reasonably construed as Level B harassment. Cholewiak *et al.* (2017) describe responses of beaked whales to the EK60 echosounder, finding that they were significantly less likely to be detected acoustically while echosounders were active. However, it is not clear that this response should be considered as Level B harassment when considered in context of what is likely a brief, transient effect given the mobile nature of the surveys and the fact that some beaked whale populations are known to have high site fidelity. (We note that the Commission cites these studies as support for Lurton and DeRuiter (2011)'s suggestion of 130 dB as a reasonable behavioral response threshold. Given that a ''behavioral response threshold'' does not equate to a behavioral harassment threshold, we are unsure about the intended implication. In addition, Lurton and DeRuiter casually offer this threshold as a result of a ''conservative approach'' using ''response thresholds of the most sensitive species studied to date.'' NMFS does not agree with any suggestion that this equates to an appropriate behavioral harassment threshold). Watkins and Schevill (1975) note that sperm whales ''temporarily interrupted'' sound production in response to sound from pingers. No avoidance behavior was observed, and the authors note that ''there appeared to be no startle reactions, no sudden movements, or changes in the activity of the whales.'' Kastelein *et al.* (2006a)

describe the response of harbor porpoise to an experimental acoustic alarm (discussed below; power averaged source level of 145 dB), while also noting that a striped dolphin showed no reaction to the alarm, despite both species being able to clearly detect the signal.

Second, unlike the studies discussed above which relate to echosounders, many of the cited studies do not present a relevant comparison. These studies discuss sources that are not appropriately or easily compared to the sources considered here and/or address responses of animals in experimental environments that are not appropriately compared to the likely exposure context here. For example, aside from the well-developed literature concerning ''acoustic harassment'' or ''acoustic deterrent'' devices—which are obviously designed for the express purpose of harassing marine mammals (usually specific species or groups)—Kastelein *et al.* (2006b) describe harbor seal responses to signals used as part of an underwater data communication network. In this case, seals in a pool were exposed to signals of relatively long duration (1–2 seconds) and high duty cycle for 15 minutes, with experimental signals of continuously varying frequency, three different sound blocks, or frequency sweeps. These seals swam away from the sound (though they did not attempt to reduce exposure by putting their heads out of the water), but this result is of questionable relevance to understanding the likely response of seals in the wild that may be exposed to a 1-ms single-frequency signal from an echosounder moving past the seal as a transient stimulus.

Some studies do not provide a relevant comparison not only because of differences in the source, but because they address sources (in some cases multiple sources) that are stationary (for extended periods of time in some cases), whereas AFSC surveys are infrequent and transient in any given location. Morton (2000) presents only brief speculation that an observed decline in abundance of Pacific white-sided dolphin coincided with introduction of 194-dB (source level) acoustic deterrent devices—an observation that is not relevant to consideration of a single mobile source that would be transient in space and time relevant to a receiver. Morton and Symonds (2002) similarly address displacement from a specific area due to a profusion of ''high-powered'' deterrent devices (the same 194-dB system discussed briefly in Morton (2000)) placed in restricted passages for extended time periods (6 years).

Third, the Commission relies heavily on the use of examples pertaining to the most sensitive species, which does not support an argument that the 120-dB threshold should be applied to all species. NMFS has acknowledged that the scientific evidence indicates that certain species are, in general, more acoustically sensitive than others. In particular, harbor porpoise and beaked whales are considered to be behaviorally sensitive, and it may be appropriate to consider use of lower behavioral harassment thresholds for these species. NMFS is considering this issue in its current work of developing new guidelines for assessing behavioral harassment; however, until this work is completed and new guidelines are identified (if appropriate), the existing generic thresholds are retained. Moreover, as is discussed above for other reasons, the majority of examples cited by the Commission are of limited relevance in terms of comparison of sound sources. In support of their statement that numerous researchers have observed marine mammals responding to sound from sources claimed to be similar to those considered herein, the Commission indeed cites numerous studies; however, the vast majority of these address responses of harbor porpoise or beaked whales to various types of acoustic alarms or deterrent devices.

We acknowledge that the Commission presents legitimate points in support of defining a threshold specific to non-impulsive, intermittent sources and that, among the large number of cited studies, there are a few that show relevant results of individual animals responding to exposure at lower received levels in ways that could be considered harassment. As noted in a previous comment response, NMFS is currently engaged in an ongoing effort towards developing updated guidance regarding the effects of anthropogenic sound on marine mammal behavior. However, prior to conclusion of this effort, NMFS will continue using the historical Level B harassment thresholds (or derivations thereof) and will appropriately evaluate behavioral harassment due to intermittent sound sources relative to the 160-dB threshold.

Comment 3: The Commission notes that NMFS has delineated two categories of acoustic sources, largely based on frequency, with those sources operating at frequencies greater than the known hearing ranges of any marine mammal (*i.e.,* >180 kilohertz (kHz)) lacking the potential to disturb marine mammals by causing disruption of behavioral patterns. The Commission describes the recent scientific literature on acoustic sources with frequencies above 180 kHz (*i.e.,* Deng *et al.,* 2014; Hastie *et al.,* 2014) and recommends that we estimate numbers of takes associated with those acoustic sources (or similar acoustic sources) with frequencies above 180 kHz that have been shown to elicit behavioral responses above the 120-dB threshold.

Response: As the Commission acknowledges, we considered the cited information in our Notice of Proposed Rulemaking. NMFS's response regarding the appropriateness of the 120-dB versus 160-dB rms thresholds was provided above in the response to Comment #2. In general, the referenced literature indicates only that sub-harmonics could be detectable by certain species at distances up to several hundred meters. As we have noted in previous responses, behavioral response to a stimulus does not necessarily indicate that Level B harassment, as defined by the MMPA, has occurred. Source levels of the secondary peaks considered in these studies—those within the hearing range of some marine mammals—mean that these sub-harmonics would either be below the threshold for behavioral harassment or would attenuate to such a level within a few meters. Beyond these important study details, these high-frequency (*i.e.,* Category 1) sources and any energy they may produce below the primary frequency that could be audible to marine mammals would be dominated by a few primary sources (*e.g.,* EK60) that are operated near-continuously—much like other Category 2 sources considered in our assessment of potential incidental take from AFSC's use of active acoustic sources—and the potential range above threshold would be so small as to essentially discount them. Further, recent sound source verification testing of these and other similar systems did not observe any sub-harmonics in any of the systems tested under controlled conditions (Crocker and Fratantonio, 2016). While this can occur during actual operations, the phenomenon may be the result of issues with the system or its installation on a vessel rather than an issue that is inherent to the output of the system. There is no evidence to suggest that Level B harassment of marine mammals should be expected in relation to use of active acoustic sources at frequencies exceeding 180 kHz.

Comment 4: ECO–SCI appears to suggest that we failed to use the best scientific evidence available in developing our proposed rulemaking and in making our preliminary determinations under the MMPA.

Response: As explained in detail in our Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638), NMFS did use the best scientific evidence available. In cases where population abundance estimates are not presented in NMFS' Stock Assessment Reports, either due to lack of available data or because the available data are considered outdated, we carefully described the data that are available, how those data support our assessment of the size and health of affected populations, and the process by which we evaluated the effects of the specified activity on the affected marine mammal species and stocks. The ECO–SCI comment letter evidences a limited understanding of the available data and confusion regarding relevant statutory and regulatory processes; and, ultimately, the commenter's apparent claims are not supported.

Description of Marine Mammals in the Area of the Specified Activity

We have reviewed AFSC's species descriptions—which summarize available information regarding status and trends, distribution and habitat preferences, behavior and life history, and auditory capabilities of the potentially affected species—for accuracy and completeness and refer the reader to Sections 3 and 4 of AFSC's application (and Sections 3 and 4 of Appendix C, which specifically addresses the IPHC activities), instead of reprinting the information here. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SAR; *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 (*www.fisheries.noaa.gov/find-species*).

Table 1 lists all species with expected potential for occurrence in the specified geographical regions where AFSC and IPHC plan to conduct the specified activities and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2018). PBR, 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, is discussed in greater detail later in this document (see ''Negligible Impact Analysis'').

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 the specified geographical regions are assessed in either NMFS's U.S. Alaska SARs or U.S. Pacific SARs. All values presented in Table 1 are the most recent available at the time of writing and are available in the 2017 SARs (Carretta *et al.,* 2018; Muto *et al.,* 2018) or draft 2018 SARs (available online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*).

Forty species (with 88 managed stocks) are considered to have the potential to co-occur with AFSC and IPHC activities. Species that could potentially occur in the research areas but are not expected to have the potential for interaction with AFSC research gear or that are not likely to be harassed by AFSC's use of active acoustic devices are described briefly but omitted from further analysis. These include extralimital species, which are species that do not normally occur in a given area but for which there are one or more occurrence records that are considered beyond the normal range of the species. Species considered to be extralimital here are the narwhal (*Monodon monoceros;* CSBSRA only), Bryde's whale (*Balaenoptera edeni brydei;* IPHC U.S. west coast research area only), and the Western North Pacific stock of the gray whale (see our Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638) for additional discussion of the gray whale). In addition, the sea otter is found in coastal waters—with the northern (or eastern) sea otter (*Enhydra lutris kenyoni*) found in Alaska—and the Pacific walrus (*Odobenus rosmarus divergens*) and polar bear (*Ursus maritimus*) may also occur in AFSC research areas. However, these species are managed by the U.S. Fish and Wildlife Service and are not considered further in this document.

BILLING CODE 3510–22–P

Table 1. Marine Mammals Potentially Present in the Vicinity of AFSC Research Activities

Common name	Scientific name	Stock	Occurrence[1]				ESA/ MMPA status; Strategic (Y/N)[2]	Stock abundance (CV, N_{min}, most recent abundance survey)[3]	PBR	Annual M/SI[4]
			WC	GOA	BSAI	CSBS				
Order Cetartiodactyla – Cetacea – Superfamily Mysticeti (baleen whales)										
Family Balaenidae										
North Pacific right whale	*Eubalaena japonica*	Eastern North Pacific (ENP)		X	X		E/D; Y	31 (0.226; 26; 2015)	0.05	0
Bowhead whale	*Balaena mysticetus*	Western Arctic			X	X	E/D; Y	16,820 (0.052; 16,100; 2011)	161	46
Family Eschrichtiidae										
Gray whale	*Eschrichtius robustus*	ENP	X	X	X	X	-; N	26,960 (0.05; 25,849; 2016)	801	138
Family Balaenopteridae (rorquals)										
Humpback whale	*Megaptera novaeangliae kuzira*	California/ Oregon/ Washington (CA/OR/WA)*	X				E/D; Y	2,900 (0.03; 2,784; 2014)	16.7[12]	≥38.6
		Central North Pacific (CNP)*		X	X		E/D; Y	10,103 (0.3; 7,891; 2006)	83	26
		Western North Pacific*		X	X	X	E/D; Y	1,107 (0.3; 865; 2006)	3	3
Minke whale	*Balaenoptera acutorostrata scammoni*	CA/OR/WA	X				-; N	636 (0.72; 369; 2014)	3.5	≥1.3
		Alaska*		X	X	X	-; N	Unknown	n/a	0
Sei whale	*B. borealis borealis*	ENP	X	X	X		E/D; Y	519 (0.4; 374; 2014)	0.75	≥0.2
Fin whale	*B. physalus physalus*	CA/OR/WA	X				E/D; Y	9,029 (0.12; 8,127; 2014)	81	≥43.5
		Northeast Pacific*		X	X	X	E/D; Y	Unknown	n/a	0.6
Blue whale	*B. musculus musculus*	ENP	X	X	X		E/D; Y	1,647 (0.07; 1,551; 2011)	2.3[12]	≥19
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)										
Family Physeteridae										
Sperm whale	*Physeter macrocephalus*	CA/OR/WA	X				E/D; Y	1,997 (0.57; 1,270; 2014)	2.5	0.9
		North Pacific*		X	X		E/D; Y	Unknown	n/a	4.4
Family Kogiidae										
Pygmy sperm whale	*Kogia breviceps*	CA/OR/WA	X				-; N	4,111 (1.12; 1,924; 2014)	19.2	0
Dwarf sperm whale	*K. sima*	CA/OR/WA[6]	X				-; N	Unknown	n/a	0
Family Ziphiidae (beaked whales)										

Cuvier's beaked whale	*Ziphius cavirostris*	CA/OR/WA	X				-; N	3,274 (0.67; 2,059; 2014)	21	<0.1
		Alaska		X	X		-; N	Unknown	n/a	0
Baird's beaked whale	*Berardius bairdii*	CA/OR/WA	X				-; N	2,697 (0.6; 1,633; 2014)	16	0
		Alaska		X	X		-; N	Unknown	n/a	0
Stejneger's beaked whale	*Mesoplodon stejnegeri*	Alaska		X	X		-; N	Unknown	n/a	0
Hubbs' beaked whale	*M. carlhubbsi*	CA/OR/WA[7]	X				-; N	3,044 (0.54; 1,967; 2014)	20	0.1
Blainville's beaked whale	*M. densirostris*		X							
Ginkgo-toothed beaked whale	*M. ginkgodens*		X							
Perrin's beaked whale	*M. perrini*		X							
Lesser (pygmy) beaked whale	*M. peruvianus*		X							
Stejneger's beaked whale	*M. stejnegeri*		X							
Family Monodontidae										
Beluga whale	*Delphinapterus leucas*	Beaufort Sea[9]			X	X	-; N	39,258 (0.229; 32,453; 1992)	n/a	139
		Eastern Chukchi Sea			X	X	-; N	20,752 (0.7; 12,194; 2012)	244	67
		Eastern Bering Sea[9]			X		-; N	6,994 (0.37; 5,173; 2000)	n/a	206
		Bristol Bay[9]			X		-; N	1,926 (0.25; 1,565; 2005)	n/a	25
		Cook Inlet[10]		X			E/D; Y	327 (0.06; 311; 2016)	n/a	0
Family Delphinidae										
Common bottlenose dolphin	*Tursiops truncatus truncatus*	CA/OR/WA Offshore	X				-; N	1,924 (0.54; 1,255; 2014)	11	≥1.6
		California Coastal	X				-; N	453 (0.06; 346; 2011)	2.7	≥2.0
Striped dolphin	*Stenella coeruleoalba*	CA/OR/WA	X				-; N	29,211 (0.2; 24,782; 2014)	238	≥0.8
ENP long-beaked common dolphin	*Delphinus delphis bairdii*	California	X				-; N	101,305 (0.49; 68,432; 2014)	657	≥35.4
Common	*D. d. delphis*	CA/OR/WA	X				-; N	969,861	8,393	≥40

dolphin								(0.17; 839,325; 2014)		
Pacific white-sided dolphin	*Lagenorhynchus obliquidens*	CA/OR/WA	X				-; N	26,814 (0.28; 21,195; 2014)	191	7.5
		North Pacific[9]		X	X		-; N	26,880 (n/a; 26,880; 1990)	n/a	0
Northern right whale dolphin	*Lissodelphis borealis*	CA/OR/WA	X				-; N	26,556 (0.44; 18,608; 2014)	179	3.8
Risso's dolphin	*Grampus griseus*	CA/OR/WA	X				-; N	6,336 (0.32; 4,817; 2014)	46	≥3.7
Killer whale	*Orcinus orca*[5]	ENP Offshore	X	X	X		-; N	300 (0.1; 276; 2012)	2.8	0
		West Coast Transient[8]	X	X			-; N	243 (n/a; 2009)	2.4	0
		AT1 Transient		X			D; Y	7 (n/a; 2017)	0.01	0
		ENP Gulf of Alaska, Aleutian Islands, and Bering Sea Transient		X	X	X	-; N	587 (n/a; 2012)	5.9	1
		ENP Southern Resident	X				E/D; Y	77 (n/a; 2017)	0.13	0
		ENP Northern Resident	X	X			-; N	261 (n/a; 2011)	1.96	0
		ENP Alaska Resident		X	X		-; N	2,347 (n/a; 2012)	24	1
Short-finned pilot whale	*Globicephala macrorhynchus*	CA/OR/WA	X				-; N	836 (0.79; 466; 2014)	4.5	1.2
Family Phocoenidae (porpoises)										
Harbor porpoise	*Phocoena phocoena vomerina*	Morro Bay	X				-; N	2,917 (0.41; 2,102; 2012)	21	≥0.6
		Monterey Bay	X				-; N	3,715 (0.51; 2,480; 2011)	25	0
		San Francisco-Russian River	X				-; N	9,886 (0.51; 6,625; 2011)	66	0
		Northern CA/Southern OR	X				-; N	35,769 (0.52; 23,749; 2011)	475	≥0.6
		Northern OR/WA Coast	X				-; N	21,487 (0.44; 15,123; 2011)	151	≥3
		Washington Inland Waters	X				-; N	11,233 (0.37; 8,308; 2015)	66	≥7.2
		Southeast Alaska*		X			-; Y	Unknown	n/a	34
		Gulf of Alaska[9]		X			-; Y	31,046	n/a	72

								(0.21; 26,064; 1998)		
		Bering Sea[9]			X	X	-; Y	48,215 (0.22; 40,150; 1999)	n/a	0.4
Dall's porpoise	*Phocoenoides dalli dalli*	CA/OR/WA	X				-; N	25,750 (0.45; 17,954; 2014)	172	0.3
		Alaska[9]		X	X		-; N	83,400 (0.097; n/a; 1991)	n/a	38
Order Carnivora – Superfamily Pinnipedia										
Family Otariidae (eared seals and sea lions)										
Guadalupe fur seal	*Arctocephalus philippii townsendi*	Mexico to California	X				T/D; Y	20,000 (n/a; 15,830; 2010)	542	≥3.2[13]
Northern fur seal	*Callorhinus ursinus*	Pribilof Islands/Eastern Pacific	X	X	X		D; Y	620,660 (0.2; 525,333; 2016)	11,295	457
		California	X	X			-; N	14,050 (n/a; 7,524; 2013)	451	1.8
California sea lion	*Zalophus californianus*	United States	X				-; N	257,606 (n/a; 233,515; 2014)	14,011	≥319
Steller sea lion	*Eumetopias jubatus monteriensis*	Eastern U.S.	X	X			-; N	41,638 (n/a; 2015)	2,498	108
	E. j. jubatus	Western U.S.		X	X		E/D; Y	54,267 (n/a; 2017)	326	252
Family Phocidae (earless seals)										
Bearded seal	*Erignathus barbatus nauticus*	Alaska (Beringia DPS)*			X	X	T/D; Y	273,676*	8,210*	557
Harbor seal	*Phoca vitulina richardii*	California	X				-; N	30,968 (n/a; 27,348; 2012)	1,641	43
		OR/WA Coast[9]	X				-; N	24,732 (0.12; 22,380; 1999)	n/a	10.6
		Washington Northern Inland Waters[9]	X				-; N	11,036 (0.15; 7,213; 1999)	n/a	9.8
		Southern Puget Sound[9]	X				-; N	1,568 (0.15; 1,025; 1999)	n/a	3.4
		Hood Canal[9]	X				-; N	1,088 (0.15; 711; 1999)	n/a	0.2
		Clarence Strait[11]		X			-; N	31,634 (4,518; 29,093; 2011)	1,222	41
		Dixon/Cape Decision[11]		X			-; N	18,105 (1,614;	703	69

								16,727; 2011)		
		Sitka/Chatham Strait[11]		X			-; N	14,855 (2,106; 13,212; 2011)	555	77
		Lynn Canal/ Stephens Passage[11]		X			-; N	9,478 (1,467; 8,605; 2011)	155	50
		Glacier Bay/Icy Strait[11]		X			-; N	7,210 (1,866; 5,647; 2011)	169	104
		Cook Inlet/ Shelikof Strait[11]		X			-; N	27,386 (3,328; 25,651; 2011)	770	234
		Prince William Sound[11]		X			-; N	29,889 (13,846; 27,936; 2011)	838	279
		South Kodiak[11]		X			-; N	19,199 (2,429; 17,479; 2011)	314	128
		North Kodiak[11]		X			-; N	8,321 (1,619; 7,096; 2011)	298	37
		Bristol Bay[11]			X		-; N	32,350 (6,882; 28,146; 2011)	1,182	142
		Pribilof Islands[11]			X		-; N	232 (n/a; 2010)	7	0
		Aleutian Islands[11]			X		-; N	6,431 (882; 5,772; 2011)	173	90
Spotted seal	*P. largha*	Alaska			X	X	-; N	461,625 (n/a; 423,237; 2013)	12,697	329
Ringed seal	*Pusa hispida hispida*	Alaska*			X	X	T/D; N	Unknown	n/a	1,054
Ribbon seal	*Histriophoca fasciata*	Alaska			X	X	-; N	184,000 (n/a; 163,086; 2013)	9,785	3.9
Northern elephant seal	*Mirounga angustirostris*	California Breeding	X	X	X		-; N	179,000 (n/a; 81,368; 2010)	4,882	8.8

*Stocks marked with an asterisk were addressed in further detail in our Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638).

[1]WC: west coast (including Puget Sound); GOA: Gulf of Alaska; BSAI: Bering Sea/Aleutian Islands; CSBS: Chukchi Sea/Beaufort Sea

[2]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.

[3]NMFS marine mammal stock assessment reports at: *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. For most stocks of killer whales, the abundance values represent direct counts of individually identifiable animals; therefore there is only a single abundance estimate with no associated CV. For certain stocks of pinnipeds, abundance estimates are based upon observations of animals (often pups) ashore multiplied by some correction factor derived from knowledge of the species' (or similar species') life history to arrive at a best abundance estimate; therefore, there is no associated CV. In these cases, the minimum abundance may represent actual counts of all animals ashore.

[4]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, subsistence hunting, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value. All M/SI values are as presented in the draft 2018 SARs.

[5]Transient and resident killer whales are considered unnamed subspecies (Committee on Taxonomy, 2018).

[6]No information is available to estimate the population size of dwarf sperm whales off the U.S. west coast, as no sightings of this species have been documented despite numerous vessel surveys of this region (Carretta *et al*., 2017). Dwarf and pygmy sperm whales are difficult to differentiate at sea but, based on previous sighting surveys and historical stranding data, it is thought that recent ship survey sightings were of pygmy sperm whales.

[7]The six species of Mesoplodont beaked whales occurring in the CA/OR/WA region are managed as a single stock due to the rarity of records and the difficulty in distinguishing these animals to species in the field. Based on bycatch and stranding records, it appears that *M. carlhubbsi* is the most commonly encountered of these species (Carretta *et al*., 2008; Moore and Barlow, 2013).

[8]The abundance estimate for this stock includes only animals from the "inner coast" population occurring in inside waters of southeastern Alaska, British Columbia, and Washington—excluding animals from the "outer coast" subpopulation, including animals from California—and therefore should be considered a minimum count. For comparison, the previous abundance estimate for this stock, including counts of animals from California that are now considered outdated, was 354.

[9]Abundance estimates for these stocks are not considered current. PBR is therefore considered undetermined for these stocks, as there is no current minimum abundance estimate for use in calculation. We nevertheless present the most recent abundance estimates, as these represent the best available information for use in this document.

[10]Despite current abundance information for the Cook Inlet stock of beluga whales, a PBR cannot be calculated because the stock does not meet the assumptions inherent to the use of the PBR equation, *i.e.*, despite low abundance relative to historical estimates and low known levels of human-caused mortality since 1999, the stock is not increasing (for unknown reasons).

[11]For harbor seal stocks in Alaska, abundance estimates are based on aerial survey data with survey counts adjusted to account for the influence of external conditions (*e.g.*, tide, time of day, day of year) on the number of seals hauled out on shore, and counted, during the surveys. Corrections are also made to account for the proportion of seals in the water and not counted. The minimum population estimate is calculated as the lower bound of the 80 percent credible interval obtained from the posterior distribution of abundance estimates. For these stocks, an estimate of standard error associated with the abundance estimate is provided rather than CV. For the Pribilof Islands stock, the abundance estimate represents a complete count of individuals in the stock.

[12]These stocks are known to spend a portion of their time outside the U.S. EEZ. Therefore, the PBR presented here is the allocation for U.S. waters only and is a portion of the total. The total PBR for blue whales is 9.3 (one-quarter allocation for U.S. waters), and the total for CA/OR/WA humpback whales is 33.4 (one half allocation for U.S. waters). Annual M/SI presented for these species is for U.S. waters only.

[13]This represents annual M/SI in U.S. waters. However, the vast majority of M/SI for this stock—the level of which is unknown—would likely occur in Mexican waters.

BILLING CODE 3510–22–C

Additional detail regarding the affected species and stocks was provided in our Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638) and is not repeated here.

Take Reduction Planning—Take reduction plans are designed to help recover and prevent the depletion of strategic marine mammal stocks that interact with certain U.S. commercial fisheries, as required by Section 118 of the MMPA. The immediate goal of a take reduction plan is to reduce, within

six months of its implementation, the M/SI of marine mammals incidental to commercial fishing to less than the PBR level. The long-term goal is to reduce, within five years of its implementation, the M/SI of marine mammals incidental to commercial fishing to insignificant levels, approaching a zero serious injury and mortality rate, taking into account the economics of the fishery, the availability of existing technology, and existing state or regional fishery management plans. Take reduction teams are convened to develop these plans.

There are no take reduction plans currently in effect for Alaskan fisheries. For marine mammals off the U.S. west coast, there is currently one take reduction plan in effect (Pacific Offshore Cetacean Take Reduction Plan). The goal of this plan is to reduce M/SI of several marine mammal stocks incidental to the California thresher shark/swordfish drift gillnet fishery (CA DGN). A team was convened in 1996 and a final plan produced in 1997 (62 FR 51805; October 3, 1997). Marine mammal stocks of concern initially included the California, Oregon, and Washington stocks for beaked whales, short-finned pilot whales, pygmy sperm whales, sperm whales, and humpback whales. The most recent five-year averages of M/SI for these stocks are below PBR. More information is available online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/pacific-offshore-cetacean-take-reduction-plan.* Of the stocks of concern, the AFSC requested the authorization of incidental M/SI for the short-finned pilot whale only (on behalf of IPHC; see ''Estimated Take'' later in this document). The most recent reported average annual human-caused mortality for short-finned pilot whales (2010–14) is 1.2 animals. The IPHC does not use drift gillnets in its fisheries research program; therefore, take reduction measures applicable to the CA DGN fisheries are not relevant.

Unusual Mortality Events (UME)—A UME is defined under the MMPA as a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response. From 1991 to the present, there have been 19 formally recognized UMEs on the U.S. west coast or in Alaska involving species under NMFS' jurisdiction. The only currently ongoing investigations involve Guadalupe fur seals and California sea lions along the west coast. Increased strandings of Guadalupe fur seals (up to eight times the historical average) have occurred along the entire coast of California. These increased strandings were reported beginning in January 2015 and peaked from April through June 2015, but have remained well above average through 2018. Findings from the majority of stranded animals include malnutrition with secondary bacterial and parasitic infections. Beginning in January 2013, elevated strandings of California sea lion pups were observed in southern California, with live sea lion strandings nearly three times higher than the historical average. Findings to date indicate that a likely contributor to the large number of stranded, malnourished pups was a change in the availability of sea lion prey for nursing mothers, especially sardines. These UMEs are occurring in the same areas and the causes and mechanisms of this remain under investigation (*www.fisheries.noaa.gov/national/marine-life-distress/2015-2019-guadalupe-fur-seal-unusual-mortality-event-california; www.fisheries.noaa.gov/national/marine-life-distress/2013-2017-california-sea-lion-unusual-mortality-event-california*; accessed March 18, 2019).

Another recent, notable UME involved large whales and occurred in the western Gulf of Alaska and off of British Columbia, Canada. Beginning in May 2015, elevated large whale mortalities (primarily fin and humpback whales) occurred in the areas around Kodiak Island, Afognak Island, Chirikof Island, the Semidi Islands, and the southern shoreline of the Alaska Peninsula. Although most carcasses have been non-retrievable as they were discovered floating and in a state of moderate to severe decomposition, the UME is likely attributable to ecological factors, *i.e.,* the 2015 El Niño, ''warm water blob,'' and the Pacific Coast domoic acid bloom. The dates of the UME are considered to be from May 22 through December 31, 2015 (western Gulf of Alaska) and from April 23, 2015, through April 16, 2016 (British Columbia). More information is available online at *www.fisheries.noaa.gov/national/marine-life-distress/2015-2016-large-whale-unusual-mortality-event-western-gulf-alaska.*

Additional UMEs in the past ten years include those involving ringed, ribbon, spotted, and bearded seals (collectively ''ice seals'') (2011; disease); harbor porpoises in California (2008; cause determined to be ecological factors); Guadalupe fur seals in the Northwest (2007; undetermined); large whales in California (2007; human interaction); cetaceans in California (2007; undetermined); and harbor porpoises in the Pacific Northwest (2006; undetermined). For more information on UMEs, please visit: *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-unusual-mortality-events.*

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2016) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 dB threshold from the normalized composite audiograms, with an exception for lower limits for low-frequency cetaceans where the result was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. The functional groups and the associated frequencies are indicated below (note that these frequency ranges correspond to the range for the composite group, with the entire range not necessarily reflecting the capabilities of every species within that group):

- Low-frequency cetaceans (mysticetes): Generalized hearing is estimated to occur between approximately 7 Hz and 35 kHz, with best hearing estimated to be from 100 Hz to 8 kHz;
- Mid-frequency cetaceans (larger toothed whales, beaked whales, and most delphinids): Generalized hearing is estimated to occur between approximately 150 Hz and 160 kHz, with best hearing from 10 to less than 100 kHz;
- High-frequency cetaceans (porpoises, river dolphins, and members of the genera *Kogia* and *Cephalorhynchus;* including two members of the genus *Lagenorhynchus,*

on the basis of recent echolocation data and genetic data): Generalized hearing is estimated to occur between approximately 275 Hz and 160 kHz;

• Pinnipeds in water; Phocidae (true seals): Functional hearing is estimated to occur between approximately 50 Hz to 86 kHz, with best hearing between 1–50 kHz;

• Pinnipeds in water; Otariidae (eared seals): Functional hearing is estimated to occur between 60 Hz and 39 kHz for Otariidae, with best hearing between 2–48 kHz.

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Forty marine mammal species (30 cetacean and ten pinniped (four otariid and six phocid) species) have the potential to co-occur with AFSC and IPHC research activities. Please refer to Table 1. Of the 30 cetacean species that may be present, eight are classified as low-frequency cetaceans (*i.e.,* all mysticete species), eighteen are classified as mid-frequency cetaceans (*i.e.,* all delphinid and ziphiid species and the sperm whale), and four are classified as high-frequency cetaceans (*i.e.,* porpoises and *Kogia* spp.).

Potential Effects of the Specified Activity on Marine Mammals and Their Habitat

We provided discussion of the potential effects of the specified activity on marine mammals and their habitat in our **Federal Register** Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638). Therefore, we do not reprint the information here but refer the reader to that document. That document included a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The ''Estimated Take'' section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The ''Negligible Impact Analysis and Determination'' section considers the content of this section and the material it references, the ''Estimated Take'' section, and the ''Mitigation'' section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization, which will inform both NMFS's consideration of whether the number of takes is ''small'' and the negligible impact determination.

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).

Take of marine mammals incidental to AFSC research activities could occur as a result of (1) injury or mortality due to gear interaction (Level A harassment, serious injury, or mortality); (2) behavioral disturbance resulting from the use of active acoustic sources (Level B harassment only); or (3) behavioral disturbance of pinnipeds resulting from incidental approach of researchers (Level B harassment only). Below we describe how the potential take is estimated.

Estimated Take Due to Gear Interaction

In order to estimate the number of potential incidents of take that could occur through gear interaction, we first consider AFSC's and IPHC's record of past such incidents, and then consider in addition other species that may have similar vulnerabilities to AFSC trawl and IPHC longline gear as those species for which we have historical interaction records. Historical interactions with research gear are described in Table 2, and we anticipate that all species that interacted with AFSC or IPHC fisheries research gear historically could potentially be taken in the future. Available records are for the years 2004 through present (AFSC) and 1998 through present (IPHC). All historical AFSC interactions have taken place in the GOARA, and have occurred during use of either the Cantrawl surface trawl net or with a bottom trawl. Historical IPHC interactions have occurred during use of bottom longlines and were located in the GOARA (southeast Alaska) or west coast (offshore Oregon). AFSC has no historical interactions for any longline or gillnet gear, and there are no historical interactions in the BSAIRA or CSBSRA. Please see Figures 6–1 and C–6 in the AFSC request for authorization for specific locations of these incidents.

TABLE 2—HISTORICAL INTERACTIONS WITH RESEARCH GEAR

Gear	Survey	Date	Location [1]	Species	Number killed	Number released alive	Total
Bottom longline	IPHC setline	7/17/1999	West coast	Harbor seal	1		1
Bottom longline	IPHC setline	7/23/2003	SE Alaska	Steller sea lion	1		1
Bottom longline	IPHC setline	7/16/2007	SE Alaska	Steller sea lion	1		1
Bottom trawl	Gulf of Alaska Biennial Shelf and Slope Bottom Trawl Groundfish Survey.	6/13/2009	GOARA	Northern fur seal [2].	1		1
Bottom longline	IPHC setline	7/31/2011	West coast	Harbor seal	1		1
Surface trawl (Cantrawl)	Gulf of Alaska Assessment	9/10/2011	GOARA	Dall's porpoise	1		1
Surface trawl (Cantrawl)	Gulf of Alaska Assessment	9/21/2011	GOARA	Dall's porpoise	1		1
Bottom trawl	ADFG Large Mesh Trawl Survey	9/5/2014	GOARA	Harbor seal	1		1
Bottom longline	IPHC setline	7/22/2016	SE Alaska	Steller sea lion	1		1
Bottom longline	Longline Stock Assessment Survey.	8/18/2019	GOARA	Steller sea lion	1		1
Total individuals captured				Northern fur seal	1		1
				Dall's porpoise	2		2
				Harbor seal	3		3
				Steller sea lion	4		4

[1] AFSC interactions are described by research area. IPHC research programs are not distributed according to AFSC research areas and so are described by geographic location. Specific locations of all interactions are shown in Figures 6–1 and C–6 of the application.

[2] Based on the location of this incident, the captured animal was believed to be from the eastern Pacific stock of northern fur seal.

In order to use these historical interaction records as the basis for the take estimation process, and because we have no specific information to indicate whether any given future interaction might result in M/SI versus Level A harassment, we conservatively assume that all interactions equate to mortality for these fishing gear interactions. AFSC and IPHC have historically had only infrequent interactions with marine mammals, *e.g.,* from 2004–2015 AFSC conducted at least 1,250 trawl tows per year, with only three (a fourth occurred during a survey conducted by the Alaska Department of Fish and Game) marine mammal interactions (Table 2). However, we assume that any of the historically-captured species (northern fur seal, Dall's porpoise, harbor seal, Steller sea lion) could be captured in any year.

We consider all of the interaction records available to us. In consideration of these data, we assume that one individual of each of the historically-captured species (Table 2) could be captured per year over the course of the five-year period of validity for these regulations, specific to relevant survey operations where the species occur (*e.g.,* one harbor seal taken per year specific to IPHC longline survey operations, one Dall's porpoise taken per year specific to AFSC trawl survey operations in GOARA, one Dall's porpoise taken per year specific to AFSC trawl survey operations in BSAIRA). Table 3 shows the projected five-year total captures of the historically-captured species for this rule, as described above, for AFSC trawl gear and IPHC longline gear only. Although more than one individual Dall's porpoise has been captured in a single year, interactions have historically occurred only infrequently. Therefore, we believe that the above assumption appropriately reflects the likely total number of individuals involved in research gear interactions over a five-year period and that the assumption is precautionary in that it separately accounts for potential vulnerability of species to gear interaction in the different research areas. Harbor seals are expected to have less frequency of interaction than the fur seal or Steller sea lion due to their more inshore and coastal distribution. AFSC requested authorization of one take per harbor seal stock in each relevant research area over the 5-year period (note that these takes are not included in Table 3 but are incorporated in Table 5). These estimates are based on the assumption that annual effort (*e.g.,* total annual trawl tow time) over the five-year authorization period will be approximately equivalent to the annual effort during prior years for which we have interaction records.

TABLE 3—PROJECTED FIVE-YEAR TOTAL TAKE FOR HISTORICALLY CAPTURED SPECIES [1]

Gear	Species	AFSC GOARA average annual take (total)	AFSC BSAIRA average annual take (total)	IPHC average annual take (total) [2]	Projected 5-year total
Trawl	Northern fur seal [3]	1 (5)	1 (5)		10
	Dall's porpoise	1 (5)	1 (5)		10
Longline	Harbor seal			1 (5)	5
	Steller sea lion [4]			1 (5)	5

[1] Projected takes based on species interaction records in analogous commercial fisheries (versus historical records) are incorporated in Table 5 below, as are all projected takes within the CSBSRA.

[2] IPHC activities are not defined by the three AFSC research areas and may occur anywhere within the IPHC research areas off the U.S. west coast or in the Gulf of Alaska and Bering Sea. Projected IPHC harbor seal takes could occur to any stock of harbor seal. Historical IPHC takes of Steller sea lion have been of the eastern DPS (based on geographic location), but potential future takes could occur to either eastern or western DPS.

[3] Referring to expected potential future takes of eastern Pacific stock northern fur seals in AFSC trawl gear on basis of historical record. Additional take of California stock northern fur seals, inferred based on vulnerability and geographic overlap, are incorporated in Table 5 below.

[4] Immediately prior to publication of this final rule, a Steller sea lion take occurred in AFSC longline operations in the GOARA (Table 2). However, this incident does not affect our overall evaluation of the likelihood for Steller sea lion take due to AFSC longline operations, and we retain the analytical structure discussed herein.

As background to the process of determining which species not historically taken may have sufficient vulnerability to capture in AFSC gear to justify inclusion in the take authorization request (or whether species historically taken may have vulnerability to gears in which they have not historically been taken or additional vulnerability not reflected above due to activity in other areas such as the CSBSRA), we note that the AFSC is NMFS' research arm in Alaska and may be considered as a leading source of expert knowledge regarding marine mammals (*e.g.,* behavior, abundance, density) in the areas where they operate. The species for which the take request was formulated were selected by the AFSC, and we have concurred with these decisions. We also note that, in addition to consulting NMFS's List of Fisheries (LOF; described below), the historical interaction records described above for the IPHC informed our consideration of risk of interaction due to AFSC's use of longline gear (for which there are no historical interaction records).

In order to estimate the total potential number of incidents of takes that could occur incidental to the AFSC's use of trawl, longline, and gillnet gear, and IPHC's use of longline gear, over the five-year period of validity for these regulations (*i.e.,* takes additional to those described in Table 3), we first consider whether there are additional species that may have similar vulnerability to capture in trawl or longline gear as the five species described above that have been taken historically and then evaluate the potential vulnerability of these and other species to additional gears.

We believe that the Pacific white-sided dolphin likely has similar vulnerability to capture in trawl gear as the Dall's porpoise, given similar habitat preferences and with documented vulnerability to capture in both commercial and research trawls. The harbor porpoise is also considered vulnerable to capture in trawl gear, but likely with less frequency of interaction given its inshore and coastal distribution. The Steller sea lion is considered to have similar vulnerability to capture in trawl gear as the northern fur seal, given similar habitat preferences and with documented vulnerability to capture in commercial trawls. In addition to the one northern fur seal per year from the eastern Pacific stock that could be captured in each

relevant research area (Table 3), we assume that one additional northern fur seal from the California stock could be taken in trawl gear over the 5-year period. The assumed lesser frequency of interaction is due to presumed lower occurrence of California stock fur seals in AFSC research areas. Only approximately half of this relatively small stock of fur seals ranges to the eastern GOARA. Similar to the harbor porpoise, spotted seals are expected to have similar vulnerability to capture in trawl gear as historically captured pinnipeds, but with less frequency of interaction due to its more inshore and coastal distribution. AFSC requested authorization of one take of spotted seal in each relevant research area over the 5-year period. This assumption is supported by LOF records (Table 5).

Historical IPHC take records also illustrate likely similar vulnerabilities to capture by AFSC longline gear (as demonstrated by a recent take by AFSC longline gear in the GOARA; Table 2). However, due to reduced use of longline gear by AFSC relative to IPHC activity, we expect that one Steller sea lion from each DPS could be taken over the 5-year period in each relevant research area. Despite IPHC records of harbor seal capture in longline gear, we do not believe that AFSC use of longline gear presents similar risk, in part due to the relative infrequency of use but also because of a lack of expected geographic overlap between AFSC longline sets and harbor seal occurrence. IPHC conducts many more longline sets per year but also conducts survey effort further inshore than does AFSC (water depths of 18 m). No take of harbor seals incidental to AFSC longline survey effort is authorized. Northern fur seals and California sea lions are considered analogous to Steller sea lions due to similar vulnerability to capture in longline gear. AFSC has requested authorization of one take over the 5-year period for each fur seal stock in each research area where fur seals are found and, on behalf of IPHC, requested authorization of one fur seal per year (which could be from either stock) and one California sea lion over the 5-year period. Finally, the spotted seal may have similar vulnerability to interaction with longline gear as the harbor seal, but likely with less frequency given the limited overlap between the species range and survey effort. We authorize one take over the 5-year period for IPHC survey effort, but none for AFSC given very little expected overlap. These assumptions are supported by LOF records (Table 5).

In order to evaluate the potential vulnerability of additional species to trawl and longline and of all species to gillnet gear, we first consulted the LOF, which classifies U.S. commercial fisheries into one of three categories according to the level of incidental marine mammal M/SI that is known to occur on an annual basis over the most recent five-year period (generally) for which data has been analyzed: Category I, frequent incidental M/SI; Category II, occasional incidental M/SI; and Category III, remote likelihood of or no known incidental M/SI. We provide summary information, as presented in the 2018 LOF (83 FR 5349; February 7, 2018), in Table 4. In order to simplify information presented, and to encompass information related to other similar species from different locations, we group marine mammals by genus (where there is more than one member of the genus found in U.S. waters). Where there are documented incidents of M/SI incidental to relevant commercial fisheries, we note whether we believe those incidents provide sufficient basis upon which to infer vulnerability to capture in AFSC or IPHC research gear. For a listing of all Category I, II, and II fisheries using relevant gears, associated estimates of fishery participants, and specific locations and fisheries associated with the historical fisheries takes indicated in Table 4 below, please see the 2018 LOF. For specific numbers of marine mammal takes associated with these fisheries, please see the relevant SARs. More information is available online at *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-protection-act-list-fisheries* and *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.*

TABLE 4—U.S. COMMERCIAL FISHERIES INTERACTIONS FOR TRAWL, LONGLINE, AND GILLNET GEAR FOR RELEVANT SPECIES

Species [1]	Trawl [2]	Vulnerability inferred?	Longline [2]	Vulnerability inferred?	Gillnet [2]	Vulnerability inferred?
North Pacific right whale	N	N	N	N	N	N
Bowhead whale	N	N	N	N	N	N
Gray whale	Y	N	N	N	Y	N
Humpback whale	Y	N	Y	N	Y	N
Balaenoptera spp	Y	N	Y	N	Y	N
Sperm whale	N	N	Y	Y	Y	N
Kogia spp	n/a	n/a	Y	N	n/a	n/a
Cuvier's beaked whale	N	N	Y	N	N	N
Baird's beaked whale	N	N	N	N	N	N
Mesoplodon spp	N	N	Y	N	N	N
Beluga whale	N	Y	N	N	Y	N
Common bottlenose dolphin	n/a	n/a	Y	Y	n/a	n/a
Stenella spp	n/a	n/a	Y	N	n/a	n/a
Delphinus spp	n/a	n/a	Y	Y	n/a	n/a
Lagenorhynchus spp	Y	Y	N	N	Y	Y
Northern right whale dolphin	n/a	n/a	N	N	n/a	n/a
Risso's dolphin	n/a	n/a	Y	Y	n/a	n/a
Killer whale	Y	N	Y	Y	N	N
Globicephala spp	n/a	n/a	Y	Y	n/a	n/a
Harbor porpoise	Y	Y	Y	N	Y	Y
Dall's porpoise [3]	n/a	n/a	Y	Y	Y	Y
Guadalupe fur seal [4]	n/a	n/a	N	N	n/a	n/a
Northern fur seal [3]	n/a	n/a	Y	Y	Y	Y
California sea lion [5]	n/a	n/a	Y	Y	n/a	n/a
Steller sea lion [3]	Y	Y	n/a	n/a	Y	Y
Bearded seal	Y	Y	N	N	N	N
Phoca spp [3]	Y	Y	n/a	n/a	Y	Y

TABLE 4—U.S. COMMERCIAL FISHERIES INTERACTIONS FOR TRAWL, LONGLINE, AND GILLNET GEAR FOR RELEVANT SPECIES—Continued

Species [1]	Trawl [2]	Vulnerability inferred?	Longline [2]	Vulnerability inferred?	Gillnet [2]	Vulnerability inferred?
Ringed seal	Y	Y	Y	Y	N	N
Ribbon seal	Y	Y	N	N	N	N
Northern elephant seal	Y	Y	Y	N	Y	N

[1] Please refer to Table 1 for taxonomic reference.
[2] Indicates whether any member of the genus has documented incidental M/SI in a U.S. fishery using that gear in the most recent five-year timespan for which data is available. For those species not expected to occur in Alaskan waters, trawl and gillnet gear are not applicable (these gears would only be used in Alaskan waters).
[3] This exercise is considered ''not applicable'' for those species historically captured by AFSC or IPHC gear. Historical record, rather than analogy, is considered the best information upon which to base a take estimate.
[4] It is likely that Guadalupe fur seals are taken in Mexican fisheries, but there are no available records.
[5] There are no records of take for California sea lions in commercial longline fisheries, but there have been multiple takes of California sea lions in longline surveys conducted by NMFS's Southwest Fisheries Science Center. We therefore infer vulnerability for the species to research longline gear.

Information related to incidental M/SI in relevant commercial fisheries is not, however, the sole determinant of whether it may be appropriate to authorize take incidental to AFSC survey operations. A number of factors (*e.g.,* species-specific knowledge regarding animal behavior, overall abundance in the geographic region, density relative to AFSC survey effort, feeding ecology, propensity to travel in groups commonly associated with other species historically taken) were taken into account by the AFSC to determine whether a species may have a similar vulnerability to certain types of gear as historically taken species. In some cases, we have determined that species without documented M/SI may nevertheless be vulnerable to capture in AFSC research gear. Similarly, we have determined that some species groups with documented M/SI are not likely to be vulnerable to capture in AFSC gear. In these instances, we provide further explanation below. Those species with no records of historical interaction with AFSC research gear and no documented M/SI in relevant commercial fisheries, and for which the AFSC has not requested the authorization of incidental take, are not considered further in this section. The AFSC believes generally that any sex or age class of those species for which take authorization is requested could be captured.

In order to estimate a number of individuals that could potentially be captured in AFSC research gear for those species not historically captured, we first determine which species may have vulnerability to capture in a given gear. Of those species, we then determine whether any may have similar propensity to capture in a given gear as a historically captured species. For these species, we assume it is possible that take could occur while at the same time contending that, absent significant range shifts or changes in habitat usage, capture of a species not historically captured would likely be a very rare event. Therefore, we assume that capture would be a rare event such that authorization of a single take over the five-year period, for each region where the gear is used and the species is present, is likely sufficient to capture the risk of interaction.

Trawl—From the 2018 LOF, we infer vulnerability to trawl gear for the bearded seal, ringed seal, ribbon seal, and northern elephant seal. This is in addition to the species for which vulnerability is indicated by historical AFSC interactions (described above).

For the beluga whale, we believe that there is a reasonable likelihood of incidental take in trawl gear although there are no records of incidental M/SI in relevant commercial fisheries. Commercial fisheries using trawl gear have largely been absent from areas where beluga whales occur and, in particular, there are no commercial trawl fisheries in the CSBSRA. AFSC examined the potential for incidental take of beluga whales by evaluating the areas of overlap between their planned fisheries research activities and beluga whale distribution, considering the seasonality of both the research activities and the species distributions as well as other factors that may influence the degree of potential overlap such as sea and shorefast ice occurrence. In considering the possible take of beluga whales, the AFSC considered that beluga whales show behavior similar to large dolphins and porpoises. While no belugas have been taken in AFSC research or commercial trawl fisheries, there have been takes of large dolphins elsewhere in trawls. Beluga whales may occur in summer periods within the Chukchi and Beaufort Sea regions where the AFSC may be conducting trawl surveys. Thus, AFSC requested authorization of one take each from two stocks of beluga whale (eastern Chukchi stock and Beaufort Sea stock) in fisheries research trawl surveys over the 5-year authorization period. Potential spatiotemporal overlap between AFSC trawl survey activities and other beluga whale stocks was evaluated and determined to not support a take authorization request for other stocks of beluga whale.

It is also possible that a captured animal may not be able to be identified to species with certainty. Certain pinnipeds and small cetaceans are difficult to differentiate at sea, especially in low-light situations or when a quick release is necessary. For example, a captured delphinid that is struggling in the net may escape or be freed before positive identification is made. Therefore, the AFSC requested the authorization of incidental take for one unidentified pinniped and one unidentified small cetacean in trawl gear for each research area over the course of the five-year period of authorization. One exception is for small cetaceans in the CSBSRA, as no cetacean interactions with trawl gear are expected in that region (other than the aforementioned potential beluga whale interactions), as small cetaceans occur only rarely in this region.

Longline—The process is the same as is described above for trawl gear. From the 2018 LOF, we infer vulnerability to longline gear for the Dall's porpoise, Risso's dolphin, bottlenose dolphin, common dolphin, short-finned pilot whale, and ringed seal. This is in addition to the species for which vulnerability is indicated by historical AFSC interactions (described above).

Based on the 2018 LOF and historical observations of sperm whale and killer whale interactions with research longline gear, we also infer vulnerability

to interaction with longline gear for killer whales (Alaska resident stock only) and sperm whales (North Pacific stock only). Although we generally believe that, despite records of interaction with analogous commercial fisheries, the potential for incidental take of any large whale (*i.e.,* baleen whales or sperm whale), beaked whale, or killer whale in research gear is so unlikely as to be discountable, there is a long history of attempted depredation of longline gear by animals from these stocks in Alaska, with take of these species having occurred in commercial fisheries. Between 2010 and 2014, five sperm whales are recorded as having been seriously injured in the Gulf of Alaska sablefish longline fishery, while there have been two instances of killer whale M/SI in BSAI longline fisheries (Helker *et al.,* 2016). Cetaceans have never been caught or entangled in AFSC or IPHC longline research gear. If interactions occur, marine mammals depredate hooked fish from the gear, but typically leave the hooks attached although occasionally bent or broken (*i.e.,* evidence of the interaction). Certain species, particularly killer whales in the Bering Sea and sperm whales in the Gulf of Alaska, are commonly attracted to longline fishing operations and are adept at removing fish from longline gear as it is retrieved. Although we consider it unlikely that AFSC or IPHC research activities would result in any takes of either sperm whales or killer whales, AFSC requested the authorization of such take as a precautionary measure, given the observed interactions of these species with research longline gear. Since longline depredation by sperm whales is known to occur only in Alaskan waters, requested take is limited to the North Pacific stock. Commercial fishery takes have been reported for both transient and resident stocks of killer whale. However, the Alaska resident stock consumes fish (*e.g.,* Herman *et al.,* 2005) and is most likely to be involved in depredation of research catch. In contrast, transient killer whales feed on marine mammals and are less likely to interact with research longline gears, and the limited effort for AFSC and IPHC research surveys compared to commercial fisheries does not justify take authorization for transient whales.

Although there are LOF interaction records in longlines for stenellid dolphin species, the harbor porpoise, and the northern elephant seal, we do not authorize take of these species through use of longline. No take is anticipated for the striped dolphin or for the long-beaked stock of common dolphin and coastal stock of bottlenose dolphin because of their expected pelagic and southerly distributions (respectively) relative to expected IPHC survey effort. Harbor porpoise have only been recorded as taken in commercial fisheries through use of pelagic longline in the Atlantic Ocean; there are no records of incidental take of harbor porpoise in longline fisheries in Alaska or off the U.S. west coast. Similarly, the LOF indicates that elephant seal interaction occurred only in a Hawaiian pelagic longline fishery.

As described for trawl gear, it is also possible that a captured animal may not be able to be identified to species with certainty. Although we expect that cetaceans would likely be able to be identified when captured in longline gear, pinnipeds are considered more likely to escape before the animal may be identified. Therefore, the AFSC requested the authorization of incidental take for one unidentified pinniped for each relevant research area, in addition to one unidentified pinniped captured in IPHC surveys, over the course of the five-year period of authorization.

Gillnet—The process is the same as is described above for trawl gear. From the 2018 LOF, we infer vulnerability to gillnet gear for the Pacific white-sided dolphin, harbor porpoise, Dall's porpoise, harbor seal, northern fur seal, and Steller sea lion. Gillnets are used only in Prince William Sound and at Little Port Walter in southeast Alaska. Therefore, only one take is authorized for relevant stocks of the vulnerable species over the 5-year period. This includes both the eastern Pacific and California stocks of northern fur seal and the Prince William Sound and Sitka/Chatham Strait stocks of harbor seal. Although there are LOF interaction records in gillnets for the sperm whale, beluga whale, and the northern elephant seal, we do not expect these species to be present in areas where AFSC plans to use gillnet research gear and no take of these species through use of gillnet is authorized.

AFSC also expects that there may be an interaction resulting in escape of an unidentified cetacean in gillnet gear, and requested the authorization of incidental take for one unidentified cetacean over the course of the five-year period of authorization.

TABLE 5—TOTAL ESTIMATED TAKE DUE TO GEAR INTERACTION, 2019–24 [1]

Species	Estimated 5-year total, trawl	Estimated 5-year total, longline (AFSC)	Estimated 5-year total, longline (IPHC) [2]	Estimated 5-year total, gillnet	Total, all gears
Sperm whale (North Pacific)		1 (GOARA)	1		2
Beluga whale (eastern Chukchi)	1 (CSBSRA)				1
Beluga whale (Beaufort Sea)	1 (CSBSRA)				1
Bottlenose dolphin (offshore)			1		1
Common dolphin			1		1
Pacific white-sided dolphin	5 (GOARA)			1	6
Risso's dolphin			1		1
Killer whale (Alaska resident)		1 (BSAIRA)	1		2
Short-finned pilot whale			1		1
Harbor porpoise (Southeast Alaska) [3]					1
Harbor porpoise (Gulf of Alaska)	1			1	2
Harbor porpoise (Bering Sea)	1				1
Dall's porpoise	10 (5 GOARA/5 BSAIRA)	2 (1 GOARA/1 BSAIRA)	1	1	14
Northern fur seal (eastern Pacific)	10 (5 GOARA/5 BSAIRA)	2 (1 GOARA/1 BSAIRA)	5	1	13–18
Northern fur seal (California)	1 (GOARA)	1 (GOARA)		1	3–8
California sea lion			1		1
Steller sea lion (eastern)	5	1	5	1	7–12
Steller sea lion (western)	10 (5 GOARA/5 BSAIRA)	2 (1 GOARA/1 BSAIRA)	1	13–18	
Bearded seal	2 (1 BSAIRA/1 CSBSRA)				2
Harbor seal [4]	12		5	2	19
Spotted seal	2 (1 BSAIRA/1 CSBSRA)		1		3
Ringed seal	2 (1 BSAIRA/1 CSBSRA)	1	1		4
Ribbon seal	2 (1 BSAIRA/1 CSBSRA)				2
Northern elephant seal	1				1

TABLE 5—TOTAL ESTIMATED TAKE DUE TO GEAR INTERACTION, 2019–24 [1]—Continued

Species	Estimated 5-year total, trawl	Estimated 5-year total, longline (AFSC)	Estimated 5-year total, longline (IPHC) [2]	Estimated 5-year total, gillnet	Total, all gears
Unidentified pinniped [5]	3	2	1		6
Unidentified small cetacean [6]	2			1	3

[1] Please see Table 4 and preceding text for derivation of take estimates. Takes numbers are informed by area- and gear-specific vulnerability. However, IPHC longline takes are considered separately. AFSC use of gillnets occurs only in the GOARA. Only trawl gear is used in the CSBSRA.

[2] Potential IPHC takes are not specific to any area or stock. For example, the one expected take of Dall's porpoise could occur to an individual of either the CA/OR/WA or Alaska stocks. For harbor seals, although five total takes may occur over the 5-year period of the regulations, no more than one take is anticipated from any given stock.

[3] For harbor porpoise in southeast Alaska, we authorize take of one animal in all gears combined (*i.e.,* trawl and gillnet) over the 5-year period. In general, harbor porpoise would be expected to have the same vulnerability to particular gears regardless of stock. However, AFSC plans to use acoustic pingers on surface trawl nets in southeast Alaska, reducing the likelihood of porpoise interaction with that gear. Use of acoustic pingers is planned for gillnets in both southeast Alaska and in the Gulf of Alaska.

[4] For trawl gear, the numbers include one take during the 5-year period for each Alaskan harbor seal stock (three stocks in BSAIRA and nine stocks in GOARA). For gillnet gear, the numbers include one take during the 5-year period for the Prince William Sound and Sitka/Chatham Strait stocks. For IPHC longline surveys, the five takes could occur for any harbor seal stock, though no more than one take would be expected to occur over the 5-year period for any given stock.

[5] Includes one unidentified pinniped in each research area (trawl) and one unidentified pinniped in the GOARA and BSAIRA and for IPHC surveys (longline).

[6] Includes one unidentified small cetacean in the GOARA and BSAIRA (trawl) and one unidentified cetacean in the GOARA (gillnet). This is not anticipated to apply to harbor porpoise in southeast Alaska, as the already low probability of gear interaction is further reduced through use of additional mitigation (described in footnote 3).

Whales—For large whales (baleen whales and sperm whales) and small whales (considered here to be beaked whales, *Kogia* spp., and killer whales), observed M/SI is extremely rare for trawl and gillnet gear and, for most of these species, only slightly more common in longline gear. Furthermore, with the exception of sperm whales and killer whales (who attempt to depredate longline gear), most of these species longline interactions are with pelagic gear. Baleen whale interactions with longline gear represent entanglements in pelagic mainlines, while beaked whales and *Kogia* spp. typically have a pelagic distribution resulting in a lack of spatial overlap with bottom longline fisheries. Although whale species could become captured or entangled in AFSC gear, the probability of interaction is extremely low considering the lower level of effort relative to that of commercial fisheries. For example, there were estimated to be three total incidents of sperm whale M/SI in the Hawaii deep-set longline fishery over a five-year period. This fishery has 129 participants, and the fishery as a whole exerts substantially greater effort in a given year than does the AFSC. In a very rough estimate, we can say that these three estimated incidents represent an insignificant per-participant interaction rate of 0.005 per year, despite the greater effort. Similarly, there were zero documented interactions over a five-year period in the Atlantic Ocean, Caribbean, Gulf of Mexico large pelagics longline fishery, despite a reported fishing effort of 8,044 sets and 5,955,800 hooks in 2011 alone (Garrison and Stokes, 2012). With an average soak time of ten to fourteen hours, this represents an approximate minimum of almost sixty million hook hours. AFSC and IPHC effort is a small fraction of this per year. Other large whales and small whales have similarly low rates of interaction with commercial fisheries, despite the significantly greater effort. In addition, most large whales and small whales generally have, with few exceptions, very low densities in areas where AFSC and IPHC research occurs relative to other species (see Tables 6–8). With exceptions for sperm whales and killer whales that are known to depredate research longline gear in particular locations, we believe it extremely unlikely that any large whale or small whale would be captured or entangled in AFSC research gear.

Estimated Take Due to Acoustic Harassment

As described in our Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638; ''Potential Effects of the Specified Activity on Marine Mammals and Their Habitat''), we believe that AFSC use of active acoustic sources has, at most, the potential to cause Level B harassment of marine mammals. In order to attempt to quantify the potential for Level B harassment to occur, NMFS (including the AFSC and acoustics experts from other parts of NMFS) developed an analytical framework considering characteristics of the active acoustic systems described in our Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638) under ''Description of Active Acoustic Sound Sources,'' their expected patterns of use, and characteristics of the marine mammal species that may interact with them. We believe that this quantitative assessment benefits from its simplicity and consistency with current NMFS acoustic guidance regarding Level B harassment but caution that, based on a number of deliberately precautionary assumptions, the resulting take estimates are likely an overestimate of the potential for behavioral harassment to occur as a result of the operation of these systems. Additional details on the approach used and the assumptions made that result in these estimates are described below.

As discussed in in our Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638), available information suggests that the likelihood of auditory injury occurring is exceedingly small. Therefore, potential auditory injury is not considered further in this analysis.

The assessment paradigm for active acoustic sources used in AFSC fisheries research is relatively straightforward and has a number of key simplifying assumptions. NMFS's current acoustic guidance requires in most cases that we assume Level B harassment occurs when a marine mammal receives an acoustic signal at or above a simple step-function threshold. Estimating the number of exposures at the specified received level (160 dB rms) requires several determinations, each of which is described sequentially below:

(1) A detailed characterization of the acoustic characteristics of the effective sound source or sources in operation;

(2) The operational areas exposed to levels at or above those associated with Level B harassment when these sources are in operation;

(3) A method for quantifying the resulting sound fields around these sources; and

(4) An estimate of the average density for marine mammal species in each area of operation.

Quantifying the spatial and temporal dimension of the sound exposure footprint (or ''swath width'') of the active acoustic devices in operation on moving vessels and their relationship to the average density of marine mammals enables a quantitative estimate of the number of individuals for which sound

levels exceed the relevant threshold for each area. The number of potential incidents of Level B harassment is ultimately estimated as the product of the volume of water ensonified at 160 dB rms or higher (to a maximum depth of 500 m) and the volumetric density of animals determined from simple assumptions about their vertical stratification in the water column. Specifically, reasonable assumptions based on what is known about diving behavior across different marine mammal species were made to segregate those that predominately remain in the upper 200 m of the water column versus those that regularly dive deeper during foraging and transit. Because depths range dramatically along the margin of the continental slope that define the outer edge of the survey areas, but deeper surveyed depths rarely range over 500 m in practice, the depth range for determining volumes was set at 500 m for deep diving species. We described the approach used (including methods for estimating each of the calculations described above) and the assumptions made that result in conservative estimates in significant detail in our Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638). There have been no changes made to the approach, the informational inputs, or the results. Therefore, we do not repeat the discussion here and refer the reader to the Notice of Proposed Rulemaking. Summaries of the results are provided in Table 6–8 below. Note that the IPHC does not use active acoustic systems for data acquisition purposes; therefore, potential Level B harassment is only considered for AFSC survey operations in the GOARA, BSAIRA, and CSBSRA.

TABLE 6—DENSITIES AND ESTIMATED SOURCE-, STRATUM-, AND SPECIES-SPECIFIC ANNUAL ESTIMATES OF LEVEL B HARASSMENT IN THE GOARA

Species	Shallow	Deep	Area density (animals/km^2) [1]	Volumetric density (animals/km^3) [2]	Estimated Level B harassment, 0–200 m		Estimated Level B harassment, >200 m		Total
					EK60	ES60	EK60	ES60	
North Pacific right whale	X		0.005	0.027	0.1				1
Gray whale	X		1.700	8.500	4,649.4				4,650
Humpback whale (CNP)	X		0.065	0.327	115.4				116
Humpback whale (WNP)	X		0.001	0.004	1.2				2
Minke whale	X		0.001	0.006	2.1				3
Sei whale	X		0.000	0.000	0.01				1
Fin whale	X		0.020	0.100	35.3				36
Blue whale	X		0.000	0.001	0.2				1
Sperm whale		X	0.001	0.002	0.7	0.2	1.3	0.2	3
Cuvier's beaked whale		X	0.000	0.000	0.1	0	0.1	0	1
Baird's beaked whale		X	0.002	0.003	1.2	0.3	2.1	0.3	4
Stejneger's beaked whale		X	0.005	0.010	3.6	0.8	6.4	0.8	12
Beluga whale (Cook Inlet) [3]	X		0.200	1.000		2.5			3
Pacific white-sided dolphin	X		0.015	0.075	26.5	5.9			33
Killer whale (offshore)	X		0.011	0.055	19.4	4.3			24
Killer whale (west coast transient)	X		0.006	0.028	9.9	2.2			13
Killer whale (AT1 transient)	X		0.001	0.004	1.2	0.3			2
Killer whale (GOA/BSAI transient)	X		0.001	0.004	1.2	0.3			2
Killer whale (northern resident)	X		0.003	0.013	4.4	1.0			6
Killer whale (AK resident)	X		0.009	0.045	15.9	3.5			20
Harbor porpoise (GOA)	X		0.200	1.000	547.0	102.9			650
Harbor porpoise (SEAK)	X		0.110	0.550	300.8	56.6			358
Dall's porpoise	X		1.600	8.000	4,375.9	823.3			5,200
Northern fur seal (CA) [4]	X		0.044	0.219	119.5	22.5			143
Northern fur seal (EP—winter) [5]	X		0.377	1.883	458.0				459
Northern fur seal (EP—summer)	X		0.116	0.582	176.7	59.9			237
Steller sea lion (eastern; GOA-wide)	X		0.059	0.294	160.8	30.3			192
Steller sea lion (eastern; E144)	X		0.221	1.103	603.3	113.5			717
Steller sea lion (eastern; W144)	X		0.001	0.006	3.3	0.6			4
Steller sea lion (western; GOA-wide)	X		0.035	0.176	96.0	18.1			115
Steller sea lion (western; E144)	X		0.003	0.015	7.9	1.5			10
Steller sea lion (western; W144)	X		0.048	0.239	130.7	24.6			156
Harbor seal (Clarence Strait)	X		0.099	0.494	174.6	38.7			214
Harbor seal (Dixon/Cape Decision)	X		0.057	0.283	99.9	22.1			123
Harbor seal (Sitka/Chatham Strait)	X		0.046	0.232	82.0	18.2			101
Harbor seal (Lynn Canal/Stephens Passage)	X		0.030	0.148	52.3	11.6			64
Harbor seal (Glacier Bay/Icy Strait)	X		0.022	0.113	39.8	8.8			49
Harbor seal (Cook Inlet/Shelikof Strait)	X		0.031	0.156	54.9	12.2			68
Harbor seal (Prince William Sound)	X		0.061	0.303	107.2	23.7			131
Harbor seal (South Kodiak)	X		0.022	0.109	38.6	8.5			48
Harbor seal (North Kodiak)	X		0.009	0.472	16.7	3.7			21
Northern elephant seal		X	0.020	0.045	15.9	3.5	28.3	3.6	52

[1] Sources and derivation of marine mammal density information are provided in Table 6–10d of AFSC's application.

[2] Volumetric density estimates derived by dividing area density estimates by 0.2 km (for shallow species) or 0.5 km (for deep species), corresponding with defined depth strata.

[3] The EK60 is not used in areas of Cook Inlet where beluga whales may be present.

[4] Individuals from the California stock of northern fur seals are assumed to occur only east of 144° W.

[5] The EK60 is not used in winter in areas where the northern fur seal may be present.

TABLE 7—DENSITIES AND ESTIMATED SOURCE-, STRATUM-, AND SPECIES-SPECIFIC ANNUAL ESTIMATES OF LEVEL B HARASSMENT IN THE BSAIRA

Species	Shallow	Deep	Area density (animals/km²) [1]	Volumetric density (animals/km³) [2]	Estimated Level B harassment, 0–200 m			Estimated Level B harassment, >200 m		Total
					EK60	ES60	7111	EK60	ES60	
North Pacific right whale	X		0.000	0.002	0.1					1
Bowhead whale	X		0.017	0.085	41.5					42
Gray whale	X		0.380	1.900	928.5					929
Humpback whale (CNP)	X		0.018	0.092	45.0					45
Humpback whale (WNP)	X		0.002	0.008	3.9					4
Minke whale	X		0.002	0.011	4.3					5
Sei whale	X		0.000	0.001	0.4					1
Fin whale	X		0.001	0.007	3.4					4
Sperm whale		X	0.008	0.016	6.5	5.5	0.3	4.2	1.9	19
Cuvier's beaked whale		X	0.000	0.000	0.1	0.1	0	0	0	1
Baird's beaked whale		X	0.002	0.003	1.4	1.2	0.1	0.9	0.4	4
Stejneger's beaked whale		X	0.001	0.002	1.0	0.8	0	0.6	0.3	3
Beluga whale (Bristol Bay) [3]	X		0.700	3.500						0
Beluga whale (eastern Bering Sea)	X		0.242	0.484	493.7	419.5	24.9			939
Pacific white-sided dolphin	X		0.005	0.027	11.0	9.4	0.6			21
Killer whale (offshore)	X		0.011	0.055	22.4	19.1	1.1			43
Killer whale (GOA/BSAI transient)	X		0.003	0.013	5.3	4.5	0.3			11
Killer whale (AK resident)	X		0.001	0.005	2.0	1.7	0.1			4
Harbor porpoise (Bering Sea)	X		0.450	2.250	918.1	780.1	46.3			1,745
Dall's porpoise	X		0.033	0.164	79.9	58.8	3.4			143
Northern fur seal (EP—winter) [4]	X		0.075	0.377	18.2					19
Northern fur seal (EP—summer)	X		0.215	1.075	473.6	386.6				861
Steller sea lion (eastern)	X		0.000	0.001	0.2	0.2				1
Steller sea lion (western)	X		0.012	0.060	29.1	21.4				51
Bearded seal	X		0.394	1.968	961.5	707.4				1,669
Harbor seal (Aleutian Islands)	X		0.003	0.014	5.9	5.0				11
Harbor seal (Pribilof Islands)	X		0.000	0.001	0.2	0.2				1
Harbor seal (Bristol Bay)	X		0.015	0.072	29.5	25.1				55
Spotted seal	X		0.601	3.006	1,125.1	827.8				1,953
Ringed seal	X		0.349	1.746	853.3	627.7				1,481
Ribbon seal	X		0.241	1.204	450.5	331.4				782

[1] Sources and derivation of marine mammal density information are provided in Table 6–10d of AFSC's application.
[2] Volumetric density estimates derived by dividing area density estimates by 0.2 km (for shallow species) or 0.5 km (for deep species), corresponding with defined depth strata.
[3] Acoustic sources considered in this analysis are not used in areas of Bristol Bay where beluga whales may occur.
[4] The ES60 is not used during winter in BSAIRA.

TABLE 8—DENSITIES AND ESTIMATED SOURCE-, STRATUM-, AND SPECIES-SPECIFIC ANNUAL ESTIMATES OF LEVEL B HARASSMENT IN THE CSBSRA

Species	Shallow	Deep	Area density (animals/km²) [1]	Volumetric density (animals/km³) [2]	Estimated Level B harassment, 0–200 m	Total
					ES60	
Bowhead whale	X		2.270	11.350		0
Gray whale	X		0.010	0.050		0
Humpback whale (CNP)	X		0.000	0.001		0
Humpback whale (WNP)	X		0.000	0.000		0
Minke whale	X		0.000	0.001		0
Fin whale	X		0.000	0.001		0
Beluga whale (Beaufort Sea)	X		0.008	0.040	3.0	3
Beluga whale (eastern Chukchi Sea)	X		0.008	0.040	3.0	3
Killer whale (GOA/BSAI transient)	X		0.000	0.000	0.003	1
Harbor porpoise (Bering Sea)	X		0.000	0.001	0.03	1
Bearded seal	X		0.175	0.875	58.0	58
Spotted seal	X		0.460	2.302	152.5	153
Ringed seal	X		1.765	8.825	584.6	585
Ribbon seal	X		0.184	0.922	75	62

[1] Sources and derivation of marine mammal density information are provided in Table 6–10d of AFSC's application.
[2] Volumetric density estimates derived by dividing area density estimates by 0.2 km.

Estimated Take Due to Physical Disturbance

Take due to physical disturbance could potentially happen, as it is likely that some pinnipeds will move or flush from known haul-outs into the water in response to the presence or sound of AFSC vessels or researchers. Such events could occur as a result of unintentional approach during survey activity, in the GOARA or BSAIRA only. Physical disturbance would result in no greater than Level B harassment. Behavioral responses may be considered according to the scale shown in Table 9 and based on the method developed by Mortenson (1996). We consider responses corresponding to Levels 2–3 to constitute Level B harassment.

TABLE 9—PINNIPED RESPONSE TO DISTURBANCE

Level	Type of response	Definition
1	Alert	Seal head orientation or brief movement in response to disturbance, which may include turning head towards the disturbance, craning head and neck while holding the body rigid in a u-shaped position, changing from a lying to a sitting position, or brief movement of less than twice the animal's body length.
2	Movement	Movements away from the source of disturbance, ranging from short withdrawals at least twice the animal's body length to longer retreats over the beach, or if already moving a change of direction of greater than 90 degrees.
3	Flight	All retreats (flushes) to the water.

The AFSC estimated potential incidents of Level B harassment due to physical disturbance (Table 10) by considering the number of seals believed to potentially be present at affected haul-outs or rookeries and the number of visits within a certain distance of the haul-out expected to be made by AFSC researchers. The take estimation method was described in detail in our Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638). AFSC does not believe that any research activities would result in physical disturbance of pinnipeds other than Steller sea lions or harbor seals. Similarly, no disturbance is expected of eastern Steller sea lions due to a lack of overlap between known haul-outs or rookeries and research activities.

Although not all individuals on ''disturbed'' haul-outs would necessarily actually be disturbed, and some haul-outs may experience some disturbance at distances greater than expected, we believe that this approach is a reasonable effort towards accounting for this potential source of disturbance. The results are likely overestimates, because some activities may only be one-time, sporadic, or biennial activities, but are assumed to happen on an annual basis.

TABLE 10—ESTIMATED ANNUAL LEVEL B HARASSMENT OF PINNIPEDS ASSOCIATED WITH DISTURBANCE BY RESEARCHERS

Species	Stock	Estimated annual Level B harassment
Harbor seal	Clarence Strait	28
	Dixon/Cape Decision	30
	Sitka/Chatham Strait	864
	Lynn Canal/Stephens Passage	45
	Glacier Bay/Icy Strait	20
	Cook Inlet/Shelikof Strait	2,554
	Prince William Sound	3,063
	South Kodiak	3,761
	North Kodiak	885
	Bristol Bay	132
	Pribilof Islands	28
	Aleutian Islands	290
Steller sea lion	Western DPS (GOARA)	3,082
	Western DPS (BSAIRA)	112

Effects of Specified Activities on Subsistence Uses of Marine Mammals

The availability of the affected marine mammal stocks or species for subsistence uses may be impacted by this activity. The subsistence uses that may be affected and the potential impacts of the activity on those uses are described in section 8 of the AFSC's application. Measures included in this rulemaking to reduce the impacts of the activity on subsistence uses are described in Appendix B of the AFSC's application. For full details, please see those documents. Last, the information from this section and the Mitigation section is analyzed to determine whether the necessary findings may be made in the Unmitigable Adverse Impact Analysis and Determination section.

Mitigation

Under Section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (''least practicable adverse impact''). NMFS does not have a regulatory definition for ''least practicable adverse impact.'' However, NMFS's implementing 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 such 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, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, implementation of the measure(s) is expected to reduce impacts to marine mammal species or stocks, their habitat, and their availability for subsistence uses. This analysis will consider such things as the nature of the potential adverse impact (such as likelihood, scope, and range), the likelihood that the measure will be effective if implemented, and the likelihood of successful implementation.

(2) The practicability of the measure for applicant implementation. Practicability of implementation may consider such things as cost, impact on operations, personnel safety, and practicality of implementation.

The following suite of mitigation measures and procedures, *i.e.,* measures taken to monitor, avoid, or minimize the encounter and potential take of marine mammals, will be employed by the AFSC during research cruises and activities. These procedures are the same whether the survey is conducted AFSC, IPHC, or is an AFSC-supported survey, which may be conducted onboard a variety of vessels, *e.g.,* on board a NOAA vessel or charter vessel. The procedures described are based on protocols used during previous research surveys and/or best practices developed for commercial fisheries using similar gear. The AFSC conducts a large variety of research operations, but only activities using trawl, longline, and gillnet gears are expected to present a reasonable likelihood of resulting in incidental take of marine mammals. AFSC's past survey operations have resulted in marine mammal interactions. These protocols are designed to continue the past record of few interactions while providing credible, documented, and safe encounters with observed or captured animals. Mitigation procedures will be focused on those situations where mammals, in the best professional judgement of the vessel operator and Chief Scientist (CS), pose a risk of incidental take. In many instances, the AFSC will use streamlined protocols and training for protected species developed in collaboration with the North Pacific Groundfish and Halibut Observer Program.

The AFSC has invested significant time and effort in identifying technologies, practices, and equipment to minimize the impact of the proposed activities on marine mammal species and stocks and their habitat. These efforts have resulted in the consideration of many potential mitigation measures, including those the AFSC has determined to be feasible and has implemented in recent years as a standard part of sampling protocols. These measures include the move-on rule mitigation protocol (also referred to in the preamble as the move-on rule), protected species visual watches and use of acoustic pingers on gillnet gear and on surface trawls in southeast Alaska.

Effective monitoring is a key step in implementing mitigation measures and is achieved through regular marine mammal watches. Marine mammal watches are a standard part of conducting AFSC fisheries research activities, particularly those activities that use gears that are known to or potentially interact with marine mammals. Marine mammal watches and monitoring occur during daylight hours prior to deployment of gear (*e.g.,* trawls, gillnets, and longline gear), and they continue until gear is brought back on board. If marine mammals are sighted in the area and are considered to be at risk of interaction with the research gear, then the sampling station is either moved or canceled or the activity is suspended until the marine mammals are no longer in the area. On smaller vessels, the CS and the vessel operator are typically those looking for marine mammals and other protected species. When marine mammal researchers are on board (distinct from marine mammal observers dedicated to monitoring for potential gear interactions), they will record the estimated species and numbers of animals present and their behavior using protocols similar or adapted from the North Pacific Groundfish and Halibut Observer Program. If marine mammal researchers are not on board or available, then the CS in cooperation with the vessel operator will monitor for marine mammals and provide training as practical to bridge crew and other crew to observe and record such information. Because marine mammals are frequently observed in Alaskan waters, marine mammal observations may be limited to those animals that directly interact with or are near to the vessel or gear. NOAA vessels, chartered vessels, and affiliated vessels or studies are required to monitor interactions with marine mammals but are limited to reporting direct interactions, dead animals, or entangled whales.

General Measures

Coordination and Communication—When AFSC survey effort is conducted aboard NOAA-owned vessels, there are both vessel officers and crew and a scientific party. Vessel officers and crew are not composed of AFSC staff but are employees of NOAA's Office of Marine and Aviation Operations (OMAO), which is responsible for the management and operation of NOAA fleet ships and aircraft and is composed of uniformed officers of the NOAA Commissioned Corps as well as civilians. The ship's officers and crew provide mission support and assistance to embarked scientists, and the vessel's Commanding Officer (CO) has ultimate responsibility for vessel and passenger safety and, therefore, decision authority. When AFSC survey effort is conducted aboard cooperative platforms (*i.e.,* non-NOAA vessels), ultimate responsibility and decision authority again rests with non-AFSC personnel (*i.e.,* vessel's master or captain). Decision authority includes the implementation of mitigation measures (*e.g.,* whether to stop deployment of trawl gear upon observation of marine mammals). The scientific party involved in any AFSC survey effort is composed, in part or whole, of AFSC staff and is led by a CS. Therefore, because the AFSC—not OMAO or any other entity that may have authority over survey platforms used by AFSC—is the applicant to whom any incidental take authorization issued under the authority of these regulations would be issued, we require that the AFSC take all necessary measures to coordinate and communicate in advance of each specific survey with OMAO, or other relevant parties, to ensure that all mitigation measures and monitoring requirements described herein, as well as the specific manner of implementation and relevant event-contingent decision-making processes, are clearly understood and agreed-upon. This may involve description of all required measures when submitting cruise instructions to OMAO or when completing contracts with external entities. AFSC will coordinate and conduct briefings at the outset of each survey and as necessary between ship's crew (CO/master or designee(s), as appropriate) and scientific party in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures. The CS will be responsible for coordination with the Officer on Deck (OOD; or equivalent on non-NOAA platforms) to ensure that requirements, procedures, and decision-

making processes are understood and properly implemented.

As described previously, for IPHC longline survey operations, applicable mitigation, monitoring, and reporting requirements would be conveyed from the AFSC to the IPHC via Letters of Acknowledgement issued by the AFSC pursuant to the MSA. Although IPHC survey effort is not conducted aboard NOAA platforms, the same communication and coordination requirements would apply to IPHC surveys.

Vessel Speed—Vessel speed during active sampling rarely exceeds 5 kn, with typical speeds being 2–4 kn. Transit speeds vary from 6–14 kn but average 10 kn. These low vessel speeds minimize the potential for ship strike (see ''Potential Effects of the Specified Activity on Marine Mammals and Their Habitat'' in our Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638) for an in-depth discussion of ship strike). In addition, when research vessels are operating in areas and times where greater risk is expected due to marine mammal presence, *e.g.,* Seguam Pass during humpback whale migration, additional crew are brought up to the bridge to monitor for whales. In such cases vessel captains may also reduce speed to improve the chances of observing whales and avoiding them. At any time during a survey or in transit, if a crew member or designated marine mammal observer standing watch sights marine mammals that may intersect with the vessel course that individual will immediately communicate the presence of marine mammals to the bridge for appropriate course alteration or speed reduction, as possible, to avoid incidental collisions.

Other Gears—The AFSC deploys a wide variety of gear to sample the marine environment during all of their research cruises. Many of these types of gear (*e.g.,* plankton nets, video camera and ROV deployments) are not considered to pose any risk to marine mammals and are therefore not subject to specific mitigation measures. However, at all times when the AFSC is conducting survey operations at sea, the OOD and/or CS and crew will monitor for any unusual circumstances that may arise at a sampling site and use best professional judgment to avoid any potential risks to marine mammals during use of all research equipment.

Handling Procedures—Handling procedures are those taken to return a live animal to the sea or process a dead animal. The AFSC will implement a number of handling protocols to minimize potential harm to marine mammals that are incidentally taken during the course of fisheries research activities. In general, protocols have already been prepared for use on commercial fishing vessels; these have been adapted from the North Pacific Fishery Observer Manual. These procedures are expected to increase post-release survival and, in general, following a ''common sense'' approach to handling captured or entangled marine mammals will present the best chance of minimizing injury to the animal and of decreasing risks to scientists and vessel crew. Handling or disentangling marine mammals carries inherent safety risks, and using best professional judgment and ensuring human safety is paramount.

Captured live or injured marine mammals are released from research gear and returned to the water as soon as possible with no gear or as little gear remaining on the animal as possible. Animals are released without removing them from the water if possible and data collection is conducted in such a manner as not to delay release of the animal(s) or endanger the crew. AFSC staff will be instructed on how to identify different species; handle and bring marine mammals aboard a vessel; assess the level of consciousness; remove fishing gear; and return marine mammals to water. For further information regarding handling procedures, please see section 11.7 of AFSC's application.

Other Measures—AFSC scientists are aware of the need to prevent or minimize disturbance of marine mammals when operating vessels nearshore around pinniped rookeries and haul-outs, and other places where marine mammals are aggregated. Minimum approaches shall be not less than 1 km from the aggregation area.

Trawl Survey Visual Monitoring and Operational Protocols

Visual monitoring protocols, described above, are an integral component of trawl mitigation protocols. Observation of marine mammal presence and behaviors in the vicinity of AFSC trawl survey operations allows for the application of professional judgment in determining the appropriate course of action to minimize the incidence of marine mammal gear interactions. The OOD, CS or other designated member of the scientific party, and crew standing watch on the bridge visually scan surrounding waters with the naked eye and rangefinding binoculars (or monocular) for marine mammals prior to, during, and until all trawl operations are completed. Some sets may be made at night or other limited visibility conditions, when visual observation may be conducted using the naked eye and available vessel lighting with limited effectiveness.

Most research vessels engaged in trawling will have their station in view for 15 minutes or 2 nmi prior to reaching the station, depending upon the sea state and weather. Many vessels will inspect the tow path before deploying the trawl gear, adding another 15 minutes of observation time and gear preparation prior to deployment. Lookouts immediately alert the OOD and CS as to their best estimate of the species and number of animals observed and any observed animal's distance, bearing, and direction of travel relative to the ship's position. If any marine mammals are sighted around the vessel before setting gear, the vessel may be moved away from the animals to a different section of the sampling area if the animals appear to be at risk of interaction with the gear. This is what is referred to as the ''move-on'' rule.

If marine mammals are observed at or near the station, the CS and the vessel operator will determine the best strategy to avoid potential takes based on the species encountered, their numbers and behavior, their position and vector relative to the vessel, and other factors. For instance, a whale transiting through the area and heading away from the vessel may not require any move, or may require only a short move from the initial sampling site, while a pod of dolphins gathered around the vessel may require a longer move from the initial sampling site or possibly cancellation of the station if the dolphins follow the vessel. After moving on, if marine mammals are still visible from the vessel and appear to be at risk, the CS may decide, in consultation with the vessel operator, to move again or to skip the station. In many cases, the survey design can accommodate sampling at an alternate site. In most cases, gear is not deployed if marine mammals have been sighted from the ship in its approach to the station unless those animals do not appear to be in danger of interactions with the gear, as determined by the judgment of the CS and vessel operator. The efficacy of the ''move-on'' rule is limited during night time or other periods of limited visibility; although operational lighting from the vessel illuminates the water in the immediate vicinity of the vessel during gear setting and retrieval. In these cases, it is again the judgment of the CS as based on experience and in consultation with the vessel operator to exercise due diligence and to decide on appropriate course of

action to avoid unintentional interactions.

Once the trawl net is in the water, the OOD, CS or other designated scientist, and/or crew standing watch continue to monitor the waters around the vessel and maintain a lookout for marine mammals as environmental conditions allow (as noted previously, visibility can be limited for various reasons). If marine mammals are sighted before the gear is fully retrieved, the most appropriate response to avoid incidental take is determined by the professional judgment of the OOD, in consultation with the CS and vessel operator as necessary. These judgments take into consideration the species, numbers, and behavior of the animals, the status of the trawl net operation (net opening, depth, and distance from the stern), the time it would take to retrieve the net, and safety considerations for changing speed or course. If marine mammals are sighted during haul-back operations, there is the potential for entanglement during retrieval of the net, especially when the trawl doors have been retrieved and the net is near the surface and no longer under tension. The risk of catching an animal may be reduced if the trawling continues and the haul-back is delayed until after the marine mammal has lost interest in the gear or left the area. The appropriate course of action to minimize the risk of incidental take is determined by the professional judgment of the OOD, vessel operator, and the CS based on all situation variables, even if the choices compromise the value of the data collected at the station. We recognize that it is not possible to dictate in advance the exact course of action that the OOD or CS should take in any given event involving the presence of marine mammals in proximity to an ongoing trawl tow, given the sheer number of potential variables, combinations of variables that may determine the appropriate course of action, and the need to prioritize human safety in the operation of fishing gear at sea. Nevertheless, we require a full accounting of factors that shape both successful and unsuccessful decisions, and these details will be fed back into AFSC training efforts and ultimately help to refine the best professional judgment that determines the course of action taken in any given scenario (see further discussion in ''Monitoring and Reporting'').

If trawling operations have been suspended because of the presence of marine mammals, the vessel will resume trawl operations (when practicable) only when the animals are believed to have departed the area. This decision is at the discretion of the OOD/CS and is dependent on the situation.

Standard survey protocols that are expected to lessen the likelihood of marine mammal interactions include standardized tow durations and distances. Standard bottom trawl tow durations of not more than 15–30 minutes at the target depth will typically be implemented, excluding deployment and retrieval time, to reduce the likelihood of attracting and incidentally taking marine mammals. Short tow durations, and the resulting short tow distances (typically 1–2 nmi), decrease the opportunity for marine mammals to find the vessel and investigate. The scientific crew will avoid dumping previous catches when the net is being retrieved, especially when the net is at the surface at the trawl alley. This practice of dumping fish when the net is near the vessel may train marine mammals to expect food when the net is retrieved and may capture the protected species.

In operations in areas of southeast Alaska deploying surface nets, several additional measures have been employed to minimize the likelihood of marine mammal encounters, including no offal discard prior to or during the trawling at a station, trawling of short duration and seldom at night, no trawling less than one kilometer from pinniped rookeries or haul-outs, and deployment of acoustic pingers attached on the trawl foot or head ropes. Pingers are acoustic deterrents that are intended to deter the presence of marine mammals and therefore decrease the probability of entanglement or unintended capture of marine mammals.

Acoustic Deterrent Devices—Acoustic deterrent devices (pingers) are underwater sound-emitting devices that have been shown to decrease the probability of interactions with certain species of marine mammals when fishing gear is fitted with the devices. Multiple studies have reported large decreases in harbor porpoise mortality (approximately eighty to ninety percent) in bottom-set gillnets (nets composed of vertical panes of netting, typically set in a straight line and either anchored to the bottom or drifting) during controlled experiments (*e.g.,* Kraus *et al.,* 1997; Trippel *et al.,* 1999; Gearin *et al.,* 2000; Palka *et al.,* 2008). Pingers (10 kHz, 132 dB, 300 ms every 4 s) would be deployed on surface trawl nets deployed in southeast Alaska. Pingers would also be deployed on gillnets. Please see ''Marine Mammal Hearing'' for reference to functional and best hearing ranges for marine mammals.

Longline Survey Visual Monitoring and Operational Protocols

Visual monitoring requirements for all longline surveys are similar to the general protocols described above for trawl surveys. Please see that section for full details of the visual monitoring protocol and the move-on rule mitigation protocol. In summary, requirements for longline surveys are to: (1) Conduct visual monitoring prior to arrival on station; (2) implement the move-on rule if marine mammals are observed within the area around the vessel and may be at risk of interacting with the vessel or gear; (3) deploy gear as soon as possible upon arrival on station (depending on presence of marine mammals); and (4) maintain visual monitoring effort throughout deployment and retrieval of the longline gear. As was described for trawl gear, the OOD, CS, or watch leader will use best professional judgment to minimize the risk to marine mammals from potential gear interactions during deployment and retrieval of gear. If marine mammals are detected during setting operations and are considered to be at risk, immediate retrieval or suspension of operations may be warranted. If operations have been suspended because of the presence of marine mammals, the vessel will resume setting (when practicable) only when the animals are believed to have departed the area. If marine mammals are detected during retrieval operations and are considered to be at risk, haul-back may be postponed. These decisions are at the discretion of the OOD/CS and are dependent on the situation.

As for trawl surveys, some standard survey protocols are expected to minimize the potential for marine mammal interactions. Soak times are typically short relative to commercial fishing operations, measured from the time the last hook is in the water to when the first hook is brought out of the water. AFSC longline protocols specifically prohibit chumming (releasing additional bait to attract target species to the gear). Spent bait and offal are discarded away from the longline retrieval area but not retained until completion of longline retrieval. Due to the volume of fish caught with each set and the length of time it takes to retrieve the longline (up to eight hours), the retention of spent bait and offal until the gear is completely retrieved is not possible.

Whales, particularly killer whales in the Bering Sea and sperm whales in the Gulf of Alaska, are commonly attracted to longline fishing operations and have learned how to remove fish from

longline gear as it is retrieved. Such depredation of fish off the longline by whales can significantly affect catch rate and species composition of data collected by the survey. The effect of depredation activity on survey results has been a research subject for many years and many aspects are therefore recorded as part of normal survey protocols, including the amount of catch potentially depredated (percent of empty hooks or damaged fish), number of whales visible, behavior of whales, whale proximity to the vessel, and any whale/vessel interactions. Sperm whale depredation can be difficult to determine because they can alternate between diving deep to depredate the line and swimming at the surface eating offal (see below). The presence of sperm whales at the surface does not mean they are actively depredating the line.

The Alaska Longline Survey uses bottom longline gear with a 16-km mainline. Sets are made in the morning if no killer whales or sperm whales are present and the longline gear is allowed to soak for three hours before haul-back begins. Due to the length of the mainline and numbers of hooks involved, it takes up to eight hours to complete the haul-back. Whales have learned to associate particular sounds with longline operations and typically arrive on scene as the gear is being retrieved. Efforts have been made to avoid depredation by allowing the line to sink back down but such strategies have proved impractical as whales can wait in the area for days and fish caught on the line are then eaten by other demersal marine organisms. The only practical way to minimize depredation if whales find the vessel is to continue retrieving the gear as quickly as possible. As killer whales may also follow the survey vessel between stations, the station order has been altered to disrupt the survey pattern as a means to dissuade the animals from this behavior and to avoid continued interactions.

Gillnet Survey Visual Monitoring and Operational Protocols

Visual monitoring and operational protocols for gillnet surveys are similar to those described previously for trawl surveys, with a focus on visual observation in the survey area and avoidance of marine mammals that may be at risk of interaction with survey vessels or gear. Gillnets are not deployed if marine mammals have been sighted on arrival at the sample site. The exception is for animals that, because of their behavior, travel vector or other factors, do not appear to be at risk of interaction with the gillnet gear. If no marine mammals are present, the gear is set and monitored continuously during the soak. If a marine mammal is sighted during the soak and appears to be at risk of interaction with the gear, then the gear is pulled immediately. As noted above, pingers would be deployed on gillnets, which are used only at the Little Port Walter Research Station in southeast Alaska and in Prince William Sound.

We have carefully evaluated the AFSC's planned mitigation measures and considered a range of other measures in the context of ensuring that we prescribed the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Based on our evaluation of these measures, we have determined that the mitigation measures provide the means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for subsistence uses.

Monitoring and Reporting

In order to issue an LOA for an activity, Section 101(a)(5)(A) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of the authorized taking. NMFS's MMPA implementing regulations further describe the information that an applicant should provide when requesting an authorization (50 CFR 216.104(a)(13)), including the means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and the level of taking or impacts on populations of marine mammals.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of significant interactions with marine mammal species in action area (*e.g.,* animals that came close to the vessel, contacted the gear, or are otherwise rare or displaying unusual behavior).
- 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 important physical components of marine mammal habitat).
- Mitigation and monitoring effectiveness.

AFSC plans to make more systematic its training, operations, data collection, animal handling and sampling protocols, etc. in order to improve its ability to understand how mitigation measures influence interaction rates and ensure its research operations are conducted in an informed manner and consistent with lessons learned from those with experience operating these gears in close proximity to marine mammals. It is in this spirit that we require the monitoring requirements described below.

Visual Monitoring

Marine mammal watches are a standard part of conducting fisheries research activities, and are implemented as described previously in ''Mitigation.'' Dedicated marine mammal visual monitoring occurs as described (1) for some period prior to deployment of most research gear; (2) throughout deployment and active fishing of all research gears; (3) for some period prior to retrieval of longline gear; and (4) throughout retrieval of all research gear. This visual monitoring is performed by trained AFSC personnel or other trained crew during the monitoring period. Observers record the species and estimated number of animals present and their behaviors, which may be valuable information towards an understanding of whether certain species may be attracted to vessels or certain survey gears. Separately, marine mammal watches are conducted by watch-standers (those navigating the vessel and other crew; these will typically not be AFSC personnel) at all times when the vessel is being operated. The primary focus for this type of watch is to avoid striking marine mammals and to generally avoid navigational hazards. These watch-standers typically have other duties associated with navigation and other vessel operations and are not required to record or report

to the scientific party data on marine mammal sightings, except when gear is being deployed or retrieved.

AFSC will also monitor disturbance of hauled-out pinnipeds resulting from the presence of researchers, paying particular attention to the distance at which different species of pinniped are disturbed. Disturbance will be recorded according to the three-point scale, representing increasing seal response to disturbance, shown in Table 9.

Training

AFSC anticipates that additional information on practices to avoid marine mammal interactions can be gleaned from training sessions and more systematic data collection standards. The AFSC will conduct annual trainings for all chief scientists and other personnel who may be responsible for conducting marine mammal visual observations or handling incidentally captured marine mammals to explain mitigation measures and monitoring and reporting requirements, mitigation and monitoring protocols, marine mammal identification, recording of count and disturbance observations, completion of datasheets, and use of equipment. Some of these topics may be familiar to AFSC staff, who may be professional biologists; the AFSC shall determine the agenda for these trainings and ensure that all relevant staff have necessary familiarity with these topics. The AFSC will work with the North Pacific Fisheries Groundfish and Halibut Observer Program to customize a new training program. The first such training will include three primary elements: (1) An overview of the purpose and need for the authorization, including mandatory mitigation measures by gear and the purpose for each, and species that AFSC is authorized to incidentally take; (2) detailed descriptions of reporting, data collection, and sampling protocols; and (3) discussion of best professional judgment (which is recognized as an integral component of mitigation implementation; see ''Mitigation'').

The second topic will include instruction on how to complete new data collection forms such as the marine mammal watch log, the incidental take form (*e.g.,* specific gear configuration and details relevant to an interaction with protected species), and forms used for species identification and biological sampling.

The third topic will include use of professional judgment in any incidents of marine mammal interaction and instructive examples where use of best professional judgment was determined to be successful or unsuccessful. We recognize that many factors come into play regarding decision-making at sea and that it is not practicable to simplify what are inherently variable and complex situational decisions into rules that may be defined on paper. However, it is our intent that use of best professional judgment be an iterative process from year to year, in which any at-sea decision-maker (*i.e.,* responsible for decisions regarding the avoidance of marine mammal interactions with survey gear through the application of best professional judgment) learns from the prior experience of all relevant AFSC personnel (rather than from solely their own experience). The outcome should be increased transparency in decision-making processes where best professional judgment is appropriate and, to the extent possible, some degree of standardization across common situations, with an ultimate goal of reducing marine mammal interactions. It is the responsibility of the AFSC to facilitate such exchange.

Handling Procedures and Data Collection

Improved standardization of handling procedures were discussed previously in ''Mitigation.'' In addition to the benefits implementing these protocols are believed to have on the animals through increased post-release survival, AFSC believes adopting these protocols for data collection will also increase the information on which ''serious injury'' determinations (NMFS, 2012a, 2012b) are based and improve scientific knowledge about marine mammals that interact with fisheries research gears and the factors that contribute to these interactions. AFSC personnel will be provided standard guidance and training regarding handling of marine mammals, including how to identify different species, bring an individual aboard a vessel, assess the level of consciousness, remove fishing gear, return an individual to water and log activities pertaining to the interaction.

AFSC will record interaction information on their own standardized forms. To aid in serious injury determinations and comply with the current NMFS Serious Injury Guidelines (NMFS, 2012a, 2012b), researchers will also answer a series of supplemental questions on the details of marine mammal interactions.

Finally, for any marine mammals that are killed during fisheries research activities, scientists will collect data and samples pursuant to Appendix D of the AFSC EA, ''Protected Species Mitigation and Handling Procedures for AFSC Fisheries Research Vessels.''

Reporting

As is normally the case, AFSC will coordinate with the relevant stranding coordinators for any unusual marine mammal behavior and any stranding, beached live/dead, or floating marine mammals that are encountered during field research activities. The AFSC will follow a phased approach with regard to the cessation of its activities and/or reporting of such events, as described in the regulatory texts following this preamble. In addition, Chief Scientists (or cruise leader, CS) will provide reports to AFSC leadership and to the Office of Protected Resources (OPR). As a result, when marine mammals interact with survey gear, whether killed or released alive, a report provided by the CS will fully describe any observations of the animals, the context (vessel and conditions), decisions made and rationale for decisions made in vessel and gear handling. The circumstances of these events are critical in enabling AFSC and OPR to better evaluate the conditions under which takes are most likely occur. We believe in the long term this will allow the avoidance of these types of events in the future.

The AFSC will submit annual summary reports to OPR including: (1) Annual line-kilometers surveyed during which the EK60, ME70, ES60, 7111 (or equivalent sources) were predominant (see ''Estimated Take by Acoustic Harassment'' for further discussion), specific to each region; (2) summary information regarding use of all longline, gillnet, and trawl gear, including number of sets, tows, etc., specific to each research area and gear; (3) accounts of all incidents of marine mammal interactions, including circumstances of the event and descriptions of any mitigation procedures implemented or not implemented and why; (4) summary information related to any disturbance of pinnipeds, including event-specific total counts of animals present, counts of reactions according to the three-point scale shown in Table 9, and distance of closest approach; and (5) a written evaluation of the effectiveness of AFSC mitigation strategies in reducing the number of marine mammal interactions with survey gear, including best professional judgment and suggestions for changes to the mitigation strategies, if any. The period of reporting will be annually, beginning one year post-issuance of any LOA, and the report must be submitted not less than ninety days following the end of a given year. Submission of this information is in service of an adaptive management framework allowing NMFS to make

appropriate modifications to mitigation and/or monitoring strategies, as necessary, during the five-year period of validity for these regulations.

NMFS has established a formal incidental take reporting system, the Protected Species Incidental Take (PSIT) database, requiring that incidental takes of protected species be reported within 48 hours of the occurrence. The PSIT generates automated messages to NMFS leadership and other relevant staff, alerting them to the event and to the fact that updated information describing the circumstances of the event has been inputted to the database. The PSIT and CS reports represent not only valuable real-time reporting and information dissemination tools but also serve as an archive of information that may be mined in the future to study why takes occur by species, gear, region, etc.

AFSC will also collect and report all necessary data, to the extent practicable given the primacy of human safety and the well-being of captured or entangled marine mammals, to facilitate serious injury (SI) determinations for marine mammals that are released alive. AFSC will require that the CS complete data forms and address supplemental questions, both of which have been developed to aid in SI determinations. AFSC understands the critical need to provide as much relevant information as possible about marine mammal interactions to inform decisions regarding SI determinations. In addition, the AFSC will perform all necessary reporting to ensure that any incidental M/SI is incorporated as appropriate into relevant SARs.

Negligible Impact Analysis and Determination

Introduction—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'' by mortality, serious injury, and Level A or Level B harassment, we consider other factors, such as the likely nature of any behavioral responses (*e.g.,* intensity, duration), the context of any such responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of 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, and specific consideration of take by M/SI previously authorized for other NMFS research activities).

We note here that the takes from potential gear interactions enumerated below could result in non-serious injury, but their worse potential outcome (mortality) is analyzed for the purposes of the negligible impact determination. We discuss here the connection between the mechanisms for authorizing incidental take under section 101(a)(5) for activities, such as AFSC's research activities, and for authorizing incidental take from commercial fisheries. In 1988, Congress amended the MMPA's provisions for addressing incidental take of marine mammals in commercial fishing operations. Congress directed NMFS to develop and recommend a new long-term regime to govern such incidental taking (see MMC, 1994). The need to develop a system suited to the unique circumstances of commercial fishing operations led NMFS to suggest a new conceptual means and associated regulatory framework. That concept, Potential Biological Removal (PBR), and a system for developing plans containing regulatory and voluntary measures to reduce incidental take for fisheries that exceed PBR were incorporated as sections 117 and 118 in the 1994 amendments to the MMPA.

PBR is defined in the MMPA (16 U.S.C. 1362(20)) 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, and is a measure to be considered when evaluating the effects of M/SI on a marine mammal species or stock. Optimum sustainable population (OSP) is defined by the MMPA (16 U.S.C. 1362(9)) as the number of animals which will result in the maximum productivity of the population or the species, keeping in mind the carrying capacity of the habitat and the health of the ecosystem of which they form a constituent element. A primary goal of the MMPA is to ensure that each species or stock of marine mammal is maintained at or returned to its OSP.

PBR values are calculated by NMFS as the level of annual removal from a stock that will allow that stock to equilibrate within OSP at least 95 percent of the time, and is the product of factors relating to the minimum population estimate of the stock (N_{min}); the productivity rate of the stock at a small population size; and a recovery factor. Determination of appropriate values for these three elements incorporates significant precaution, such that application of the parameter to the management of marine mammal stocks may be reasonably certain to achieve the goals of the MMPA. For example, calculation of N_{min} incorporates the precision and variability associated with abundance information and is intended to provide reasonable assurance that the stock size is equal to or greater than the estimate (Barlow *et al.,* 1995). In general, the three factors are developed on a stock-specific basis in consideration of one another in order to produce conservative PBR values that appropriately account for both imprecision that may be estimated as well as potential bias stemming from lack of knowledge (Wade, 1998).

PBR can be used as a consideration of the effects of M/SI on a marine mammal stock but was applied specifically to work within the management framework for commercial fishing incidental take. PBR cannot be applied appropriately outside of the section 118 regulatory framework for which it was designed without consideration of how it applies in section 118 and how other statutory management frameworks in the MMPA differ. PBR was not designed as an absolute threshold limiting commercial fisheries, but rather as a means to evaluate the relative impacts of those activities on marine mammal stocks. Even where commercial fishing is causing M/SI at levels that exceed PBR, the fishery is not suspended. When M/SI exceeds PBR, NMFS may develop a take reduction plan, usually with the assistance of a take reduction team. The take reduction plan will include measures to reduce and/or minimize the taking of marine mammals by commercial fisheries to a level below the stock's PBR. That is, where the total annual human-caused M/SI exceeds PBR, NMFS is not required to halt fishing activities contributing to total M/SI but rather utilizes the take reduction process to further mitigate the effects of fishery activities via additional bycatch

reduction measures. PBR is not used to grant or deny authorization of commercial fisheries that may incidentally take marine mammals.

Similarly, to the extent consideration of PBR may be relevant to considering the impacts of incidental take from activities other than commercial fisheries, using it as the sole reason to deny incidental take authorization for those activities would be inconsistent with Congress's intent under section 101(a)(5) and the use of PBR under section 118. The standard for authorizing incidental take under section 101(a)(5) continues to be, among other things, whether the total taking will have a negligible impact on the species or stock. When Congress amended the MMPA in 1994 to add section 118 for commercial fishing, it did not alter the standards for authorizing non-commercial fishing incidental take under section 101(a)(5), acknowledging that negligible impact under section 101(a)(5) is a separate standard from PBR under section 118. In fact, in 1994 Congress also amended section 101(a)(5)(E) (a separate provision governing commercial fishing incidental take for species listed under the Endangered Species Act) to add compliance with the new section 118 but kept the requirement for a negligible impact finding, showing that the determination of negligible impact and application of PBR may share certain features but are different.

Since the introduction of PBR, NMFS has used the concept almost entirely within the context of implementing sections 117 and 118 and other commercial fisheries management-related provisions of the MMPA. The MMPA requires that PBR be estimated in stock assessment reports and that it be used in applications related to the management of take incidental to commercial fisheries (*i.e.,* the take reduction planning process described in section 118 of the MMPA and the determination of whether a stock is ''strategic'' (16 U.S.C. 1362(19))), but nothing in the MMPA requires the application of PBR outside the management of commercial fisheries interactions with marine mammals.

Nonetheless, NMFS recognizes that as a quantitative metric, PBR may be useful in certain instances as a consideration when evaluating the impacts of other human-caused activities on marine mammal stocks. Outside the commercial fishing context, and in consideration of all known human-caused mortality, PBR can help inform the potential effects of M/SI caused by activities authorized under 101(a)(5)(A) on marine mammal stocks. As noted by NMFS and the USFWS in our implementation regulations for the 1986 amendments to the MMPA (54 FR 40341, September 29, 1989), the Services consider many factors, when available, in making a negligible impact determination, including, but not limited to, the status of the species or stock relative to OSP (if known), whether the recruitment rate for the species or stock is increasing, decreasing, stable, or unknown, the size and distribution of the population, and existing impacts and environmental conditions. To specifically use PBR, along with other factors, to evaluate the effects of M/SI, we first calculate a metric for each species or stock that incorporates information regarding ongoing anthropogenic M/SI into the PBR value (*i.e.,* PBR minus the total annual anthropogenic mortality/serious injury estimate), which is called ''residual PBR'' (Wood *et al.,* 2012). We then consider how the anticipated potential incidental M/SI from the activities being evaluated compares to residual PBR. Anticipated or potential M/SI that exceeds residual PBR is considered to have a higher likelihood of adversely affecting rates of recruitment or survival, while anticipated M/SI that is equal to or less than residual PBR has a lower likelihood (both examples given without consideration of other types of take, which also factor into a negligible impact determination). In such cases where the anticipated M/SI is near, at, or above residual PBR, consideration of other factors, including those outlined above as well as mitigation and other factors (positive or negative), is especially important to assessing whether the M/SI will have a negligible impact on the stock. As described above, PBR is a conservative metric and is not intended to be used as a solid cap on mortality—accordingly, impacts from M/SI that exceed residual PBR may still potentially be found to be negligible in light of other factors that offset concern, especially when robust mitigation and adaptive management provisions are included.

Alternately, for a species or stock with incidental M/SI less than 10 percent of residual PBR, we consider M/SI from the specified activities to represent an insignificant incremental increase in ongoing anthropogenic M/SI that alone (*i.e.,* in the absence of any other take) cannot affect annual rates of recruitment and survival. In a prior incidental take rulemaking and in the commercial fishing context, this threshold is identified as the significance threshold, but it is more accurately an insignificance threshold outside commercial fishing because it represents the level at which there is no need to consider other factors in determining the role of M/SI in affecting rates of recruitment and survival. Assuming that any additional incidental take by harassment would not exceed the negligible impact level, the anticipated M/SI caused by the activities being evaluated would have a negligible impact on the species or stock. This 10 percent was identified as a workload simplification consideration to avoid the need to provide unnecessary additional information when the conclusion is relatively obvious; but as described above, values above 10 percent have no particular significance associated with them until and unless they approach residual PBR.

Our evaluation of the M/SI for each of the species and stocks for which mortality could occur follows. In addition, all mortality authorized for some of the same species or stocks over the next several years pursuant to our final rulemakings for the NMFS Southwest Fisheries Science Center and the NMFS Northwest Fisheries Science Center has been incorporated into the residual PBR.

We first consider maximum potential incidental M/SI for each stock (Table 4) in consideration of NMFS's threshold for identifying insignificant M/SI take (10 percent of residual PBR (69 FR 43338; July 20, 2004)). By considering the maximum potential incidental M/SI in relation to PBR and ongoing sources of anthropogenic mortality, we begin our evaluation of whether the potential incremental addition of M/SI through AFSC research activities may affect the species' or stock's annual rates of recruitment or survival. We also consider the interaction of those mortalities with incidental taking of that species or stock by harassment pursuant to the specified activity.

Summary of Estimated Incidental Take

Here we provide a summary of the total incidental take authorization on an annual basis, as well as other information relevant to the negligible impact analysis. Table 11 shows information relevant to our negligible impact analysis concerning the total annual taking that could occur for each stock from NMFS' scientific research activities when considering incidental take previously authorized for SWFSC (80 FR 58982; September 30, 2015) and NWFSC (83 FR 36370; July 27, 2018) and AFSC. Scientific research activities conducted by the SWFSC and/or NWFSC may impact the same populations of marine mammals expected to be impacted by IPHC survey

activities occurring off of the U.S. west coast. We authorize take by M/SI over the five-year period of validity for these regulations as indicated in Table 11 below. For the purposes of the negligible impact analysis, we assume that all of these takes could potentially be in the form of M/SI; PBR is not appropriate for direct assessment of the significance of harassment.

For some stocks, a range is provided in the ''Total M/SI Authorization'' columns of Table 11 (below). In these cases, the worst case potential outcome is used to derive the value presented in the ''Estimated Maximum Annual M/SI'' column (Table 11, below). For example, we present ranges of 13–18 and 3–8 as the total take authorization over five years for the eastern Pacific and California stocks of northern fur seal, respectively. These ranges reflect that, as part of the overall take authorization for AFSC, a total of five takes of northern fur seals are expected to occur as a result specifically of IPHC longline operations. These five takes are considered as potentially accruing to either stock; therefore, we assess the consequences of the take authorization for these stocks as though the maximum could occur to both. The ten total takes expected to potentially occur as a result of SWFSC and/or NWFSC survey operations could also occur to individuals from either stock. Similarly, we assume that IPHC survey operations specifically could result in incidental take of up to five harbor seals over the five years, and that these takes could occur for any stock of harbor seal (but that no more than one take would be expected from any given stock). Therefore, although only five takes are expected from IPHC activities, we assume that one take accrues to each of the 17 harbor seal stocks that may overlap with the IPHC surveys. For the NWFSC, we assumed that nine total takes of harbor seal could occur over five years, and that these takes could occur to either the California or Oregon/Washington coast stocks. Over five years, six total takes were expected to result from NWFSC/SWFSC survey operations within Washington inland waters—potentially occurring to any of the three stocks of harbor seals occurring in those waters. The value presented for ''Estimated Maximum Annual M/SI'' for each stock reflects these considerations. Similar considerations result in the ranges given for Steller sea lions (Table 11). This stock-specific accounting does not change our expectations regarding the combined total number of takes that would actually occur for each stock, but informs our stock-specific negligible impact analysis.

We previously authorized take of marine mammals incidental to fisheries research operations conducted by the SWFSC (see 80 FR 58982 and 80 FR 68512), and NWFSC (see 81 FR 38516 and 83 FR 36370). This take would occur to some of the same stocks for which we authorize take incidental to AFSC fisheries research operations. Therefore, in order to evaluate the likely impact of the take by M/SI in this rule, we consider not only other ongoing sources of human-caused mortality but the potential mortality authorized for SWFSC/NWFSC. As used in this document, other ongoing sources of human-caused (anthropogenic) mortality refers to estimates of realized or actual annual mortality reported in the SARs and does not include authorized or unknown mortality. Below, we consider the total taking by M/SI for AFSC and previously authorized for SWFSC/NWFSC together to produce a maximum annual M/SI take level (including take of unidentified marine mammals that could accrue to any relevant stock) and compare that value to the stock's PBR value, considering ongoing sources of anthropogenic mortality (as described in footnote 4 of Table 11 and in the following discussion). PBR and annual M/SI values considered in Table 11 reflect the most recent information available (*i.e.,* draft 2018 SARs).

TABLE 11—SUMMARY INFORMATION RELATED TO AFSC ANNUAL TAKE AUTHORIZATION, 2019–24

Species [1]	Stock	Total annual Level B harassment authorization [2]	Percent of estimated population abundance	AFSC/IPHC total M/SI authorization, 2019–24 [3]	SWFSC/NWFSC total M/SI authorization	Estimated maximum annual M/SI [4]	PBR minus annual M/SI (%) [5]	Stock trend [6]
North Pacific right whale	ENP	2	6.5	0	0	0	n/a	?
Bowhead whale	Western Arctic	42	0.2	0	0	0	n/a	↑
Gray whale	ENP	5,579	21.7	0	0	0	n/a	→
Humpback whale	CNP	161	1.6	0	0	0	n/a	↑
	WNP	6	0.5	0	0	0	n/a	↑
Minke whale	Alaska	8	0.2 [8]	0	0	0	n/a	?
Sei whale	ENP	2	0.4	0	0	0	n/a	↑
Fin whale	Northeast Pacific	40	3.9 [8]	0	0	0	n/a	↑
Blue whale	ENP	1	0.1	0	0	0	n/a	→
Sperm whale	North Pacific	22	Unknown	2	0	0.4	?	?
Cuvier's beaked whale	Alaska	2	Unknown	0	0	0	n/a	?
Baird's beaked whale	Alaska	8	Unknown	0	0	0	n/a	?
Stejneger's beaked whale	Alaska	15	Unknown	0	0	0	n/a	?
Beluga whale	Beaufort Sea	3	0.0	1	0	0.2	?	↑ or →
	Eastern Chukchi Sea	3	0.1	1	0	0.2	?	?
	Eastern Bering Sea	939	13.4	0	0	0	n/a	?
	Bristol Bay	0	n/a	0	0	0	n/a	↑
	Cook Inlet	3	0.9	0	0	0	n/a	↓
Bottlenose dolphin	CA/OR/WA Offshore	0	n/a	1	11	2.8	9.4 (29.8)	?
Common dolphin	CA/OR/WA	0	n/a	1	15	3.6	8,353 (0.0)	↑
Pacific white-sided dolphin	NP	54	0.2	6	0	1.6	?	?
Risso's dolphin	CA/OR/WA	0	n/a	1	20	4.6	42.3 (10.9)	?
Killer whale	ENP Offshore	67	22.3	0	0	n/a	n/a	?
	West Coast Transient	13	5.3	0	0	n/a	n/a	↑
	AT1 Transient	2	28.6	0	0	n/a	n/a	↓
	ENP Gulf of Alaska, Aleutian Islands, and Bering Sea Transient.	14	2.4	0	0	n/a	n/a	→
	ENP Northern Resident	6	2.3	0	0	n/a	n/a	↑
	ENP Alaska Resident	24	1.0	2	0	0.4	23 (1.7)	↑
Short-finned pilot whale	CA/OR/WA	0	n/a	1	2	0.6	3.3 (18.2)	?
Harbor porpoise	Southeast Alaska	358	12.4 [8]	1	0	0.2	?	↓ or →
	Gulf of Alaska	650	2.1	2	0	0.8	?	?

TABLE 11—SUMMARY INFORMATION RELATED TO AFSC ANNUAL TAKE AUTHORIZATION, 2019–24—Continued

Species [1]	Stock	Total annual Level B harassment authorization [2]	Percent of estimated population abundance	AFSC/IPHC total M/SI authorization, 2019–24 [3]	SWFSC/ NWFSC total M/SI authorization	Estimated maximum annual M/SI [4]	PBR minus annual M/SI (%) [5]	Stock trend [6]
	Bering Sea	1,746	3.6	1	0	0.4	?	?
Dall's porpoise	CA/OR/WA	0	n/a	1	8	2.2	171.7 (1.3)	?
	Alaska	5,343	6.4	14	0	3.4	?	?
Northern fur seal	Pribilof Islands/Eastern Pacific.	1,576	0.3	13–18	10	7.0	10,838 (0.1)	↓
	California	143	1.0	3–8		4.6	449.2 (1.0)	↑
California sea lion	United States	0	n/a	1	35	8.0	13,692 (0.1)	↑
Steller sea lion	Eastern U.S.	914	2.2	7–12	19	7.4	2,390 (0.3)	↑
	Western U.S.	3,526	6.5	13–18	0	4.6	74 (6.2)	[7] ?
Bearded seal	Alaska (Beringia DPS)	1,727	0.6	2	0	0.8	7,653 (0.0)	?
Harbor seal	California	0	n/a	1	5–14	3.6	1,598 (0.2)	→
	OR/WA Coast	0	n/a	1	2–11	2.2	?	→
	Washington Inland Waters	0	n/a	1	6	1.6	?	→
	Clarence Strait	242	0.8	2	0	0.8	1,181 (0.1)	↑
	Dixon/Cape Decision	153	0.8	2	0	0.8	634 (0.1)	↑
	Sitka/Chatham Strait	965	6.5	3	0	1.0	483 (0.2)	↑
	Lynn Canal/Stephens Passage.	109	1.2	2	0	0.8	105 (0.8)	↓
	Glacier Bay/Icy Strait	69	1.0	2	0	0.8	65 (1.2)	↑
	Cook Inlet/Shelikof Strait	2,622	9.6	2	0	0.8	536 (0.1)	↑
	Prince William Sound	3,194	10.7	3	0	1.0	559 (0.2)	↓
	South Kodiak	3,809	19.8	2	0	0.8	186 (0.4)	↓
	North Kodiak	906	10.9	2	0	0.8	261 (0.3)	↑
	Bristol Bay	187	0.6	2	0	0.8	1,040 (0.1)	↑
	Pribilof Islands	29	12.5	2	0	0.8	7 (11.4)	→
	Aleutian Islands	301	4.7	2	0	0.8	83 (1.0)	↑
Spotted seal	Alaska	2,106	0.5	3	0	1.2	12,368 (0.0)	?
Ringed seal	Alaska	2,066	1.2 [8]	4	0	1.6	?	?
Ribbon seal	Alaska	1,404	0.8	2	0	0.8	9,781.1 (0.0)	?
Northern elephant seal	California Breeding	52	0.0	1	10	2.6	4,873.2 (0.1)	↑

Please see Tables 5, 6, 7, 8, and 10 and preceding text for details.

[1] For some species with multiple stocks, indicated level of take could occur to individuals from any stock (as indicated in table). For some stocks, a range is presented.

[2] Level B harassment totals include estimated take due to acoustic harassment and, for harbor seals and Steller sea lions, estimated take due to physical disturbance. Active acoustic devices are not used for data acquisition by IPHC; therefore, no takes by acoustic harassment are expected for stocks that occur entirely outside of Alaskan waters.

[3] As explained earlier in this document, gear interaction could result in mortality, serious injury, or Level A harassment. Because we do not have sufficient information to enable us to parse out these outcomes, we present such take as a pool. For purposes of this negligible impact analysis we assume the worst case scenario (that all such takes incidental to research activities result in mortality).

[4] This column represents the total number of incidents of M/SI that could potentially accrue to the specified species or stock as a result of NMFS's fisheries research activities and is the number carried forward for evaluation in the negligible impact analysis (later in this document). To reach this total, we add one to the total for each pinniped that may be captured in trawl gear in each of the three AFSC research areas; one to the total for each pinniped that may be captured in AFSC longline gear in the GOARA and BSAIRA; and one to the total for each pinniped that may be captured in IPHC longline gear. We also add one to the total of each small cetacean that may be captured in trawl gear in the GOARA and BSAIRA and one to the total of each small cetacean that may be captured in gillnet gear (GOARA only). This represents the potential that the take of an unidentified pinniped or small cetacean could accrue to any given stock captured in that gear in that area. The take authorization is formulated as a five-year total; the annual average is used only for purposes of negligible impact analysis. We recognize that portions of an animal may not be taken in a given year.

[5] This value represents the calculated PBR less the average annual estimate of ongoing anthropogenic mortalities (*i.e.,* total annual human-caused M/SI, which is presented in the SARs) (see Table 1). In parentheses, we provide the estimated maximum annual M/SI expressed as a percentage of this value. For some stocks, a minimum population abundance value (and therefore PBR) is unavailable. In these cases, the proportion of estimated population abundance represented by the Level B harassment total and/or the proportion of residual PBR represented by the estimated maximum annual M/SI cannot be calculated.

[6] See relevant SARs for more information regarding stock status and trends. Interannual increases may not be interpreted as evidence of a trend. Based on the most recent abundance estimates, harbor seal stocks may have reached carrying capacity and appear stable. A time series of stock-specific abundance estimates for harbor porpoise shows either increasing or stable estimates, but it is not statistically valid to infer a trend.

[7] For western Steller sea lions, it is not appropriate to identify a single trend. Using data collected through 2017, there is strong evidence that non-pup and pup counts increased at ~2 percent per year between 2002 and 2017. However, there are strong regional differences across the range in Alaska, with positive trends east of Samalga Pass (~170° W) in the Gulf of Alaska and eastern Bering Sea and negative trends to the west in the Aleutian Islands. For more information, please see the draft 2018 SAR.

[8] No official abundance estimate is provided for these stocks; however, we use the best available information regarding population abundance for comparison with the total annual Level B harassment authorization. For the minke whale, surveys covering portions of the stock range provide a partial abundance estimate of 2,020 (CV = 0.73) + 1,233 (CV = 0.34) whales. For the fin whale, we use the minimum abundance estimate provided for a portion of the stock range (1,036 whales). Surveys in 2010–2012 provide an abundance estimate of 398 (CV = 0.12) + 577 (CV = 0.14) harbor porpoises in southeast Alaska. However, the resulting total of 975 is not corrected for observer perception bias and porpoise availability at the surface, which is particularly influential for estimates of porpoise abundance. Therefore, we apply a previously estimated correction factor of 2.96 (Hobbs and Waite, 2010) to this estimate for a provisional abundance estimate of 2,886. For the ringed seal, a partial abundance estimate (that does not account for availability bias) of 170,000 seals is given. For more information, please see the relevant SARs.

Analysis—The majority of stocks that may potentially be taken by M/SI (25 of 41) fall below the insignificance threshold (*i.e.,* 10 percent of residual PBR), while an additional 11 stocks do not have current PBR values and therefore are evaluated using other factors. We first consider stocks expected to be affected only by behavioral harassment and those stocks that fall below the insignificance threshold. Next, we consider those stocks above the insignificance threshold (*i.e.,* the offshore stock of bottlenose dolphin, Risso's dolphin, short-finned pilot whale, and the Pribilof Islands stock of harbor seal) and those without PBR values (harbor seal stocks along the Oregon and Washington coasts and in Washington inland waters; two stocks of beluga whale; three stocks of harbor porpoise; sperm whale; Pacific white-sided dolphin; the Alaska stock of Dall's porpoise; and the ringed seal).

As described in greater depth previously (see ''Acoustic Effects'' in our Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638)), we do not believe that AFSC use of active acoustic sources has the likely potential to cause any effect exceeding Level B harassment of marine mammals. We

have produced what we believe to be precautionary estimates of potential incidents of Level B harassment. There is a general lack of information related to the specific way that these acoustic signals, which are generally highly directional and transient, interact with the physical environment and to a meaningful understanding of marine mammal perception of these signals and occurrence in the areas where AFSC operates. The procedure for producing these estimates, described in detail in our Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638; ''Estimated Take Due to Acoustic Harassment''), represents NMFS's best effort towards balancing the need to quantify the potential for occurrence of Level B harassment with this general lack of information. The sources considered here have moderate to high output frequencies, generally short ping durations, and are typically focused (highly directional) to serve their intended purpose of mapping specific objects, depths, or environmental features. In addition, some of these sources can be operated in different output modes (*e.g.,* energy can be distributed among multiple output beams) that may lessen the likelihood of perception by and potential impacts on marine mammals in comparison with the quantitative estimates that guide our estimated take numbers. We also produced estimates of incidents of potential Level B harassment due to disturbance of hauled-out pinnipeds that may result from the physical presence of researchers; these estimates are combined with the estimates of Level B harassment that may result from use of active acoustic devices.

Here, we consider authorized Level B harassment less than five percent of population abundance to be de minimis, while authorized Level B harassment between 5-15 percent is low. A moderate amount of authorized taking by Level B harassment would be from 15–25 percent, and high above 25 percent. Of the 49 stocks that may be subject to Level B harassment, the level of taking would represent a de minimis impact for 31 stocks and a low impact for an additional ten stocks. We do not consider these impacts further for these 41 stocks. The level of taking by Level B harassment would represent a moderate impact on three additional stocks, the South Kodiak stock of harbor seals, the gray whale, and the offshore stock of killer whales. No taking by M/SI is authorized for the latter two stocks, whereas M/SI is authorized for the harbor seal stock. Therefore, we consider these potential impacts in conjunction with the level of taking by M/SI. The annual taking by M/SI projected for this stock equates to less than one percent of residual PBR; therefore we do not consider this stock further. The total taking by Level B harassment represents a high level of impact for one stock (AT1 stock of killer whale). We discuss this in further detail below. For an additional four stocks (sperm whale and Alaska stocks of three beaked whale species), there is no abundance estimate upon which to base a comparison. However, we note that the anticipated number of incidents of take by Level B harassment are very low (2–22 for these four stocks) and likely represent a de minimis impact on these stocks.

As described previously, there is some minimal potential for temporary effects to hearing for certain marine mammals, but most effects would likely be limited to temporary behavioral disturbance. Effects on individuals that are taken by Level B harassment will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring), reactions that are considered to be of low severity (*e.g.,* Ellison *et al.,* 2012). Individuals may move away from the source if disturbed; but, because the source is itself moving and because of the directional nature of the sources considered here, there is unlikely to be even temporary displacement from areas of significance and any disturbance would be of short duration. Although there is no information on which to base any distinction between incidents of harassment and individuals harassed, the same factors, in conjunction with the fact that AFSC survey effort is widely dispersed in space and time, indicate that repeated exposures of the same individuals would be very unlikely. For these reasons, we do not consider the level of take by acoustic disturbance to represent a significant additional population stressor when considered in context with the level of take by M/SI for any species, including those for which no abundance estimate is available.

There are no additional impacts other than Level B harassment expected for the AT1 stock of killer whales. It should be noted that the AT1 stock of transient killer whales has a critically low population abundance of seven whales. Although the estimate of take by Level B harassment is at 29 percent, this represents only two estimated incidents of temporary and insignificant behavioral disruption, which would not be expected to affect annual rates of recruitment or survival for the stock. We do not discuss this stock further.

Similarly, disturbance of pinnipeds on haul-outs by researchers (expected for harbor seals and Steller sea lions in the GOARA and BSAIRA) are expected to be infrequent and cause only a temporary disturbance on the order of minutes. As noted previously, monitoring results from other activities involving the disturbance of pinnipeds and relevant studies of pinniped populations that experience more regular vessel disturbance indicate that individually significant or population level impacts are unlikely to occur. When considering the individual animals likely affected by this disturbance, only a small fraction of the estimated population abundance of the affected stocks would be expected to experience the disturbance.

For Risso's dolphin, short-finned pilot whale, and the offshore stock of bottlenose dolphin, maximum total potential M/SI due to NMFS' fisheries research activity (SWFSC, NWFSC, and AFSC combined) is approximately 11, 18, and 30 percent of residual PBR, respectively. For example, PBR for Risso's dolphin is currently set at 46 and the annual average of known ongoing anthropogenic M/SI is 3.7, yielding a residual PBR value of 42.3. The maximum combined annual average M/SI incidental to NMFS fisheries research activity is 4.6, or 10.9 percent of residual PBR. The only known source of other anthropogenic mortality for these species is in commercial fisheries. For the Risso's dolphin and offshore stock of bottlenose dolphin, such take is considered to be insignificant and approaching zero mortality and serious injury. This is not the case for the short-finned pilot whale; however, the annual take from fisheries (1.2) and from NMFS's fisheries research (0.6) are both very low. There are no other factors that would lead us to believe that take by M/SI of 18 percent of residual PBR would be problematic for this species. Total potential M/SI due to NMFS' fisheries research activity is approximately 11 percent of residual PBR for the Pribilof Islands stock of harbor seals. However, there are no other known sources of anthropogenic M/SI for this stock or other known significant stressors; therefore, there is no indication that the take by M/SI of 11 percent of residual PBR would be problematic for this stock.

PBR is unknown for harbor seals on the Oregon and Washington coasts and in Washington inland waters (comprised of the Hood Canal, southern Puget Sound, and Washington northern

inland waters stocks). The Hood Canal, southern Puget Sound, and Washington northern inland waters stocks were formerly a single inland waters stock. Both the Oregon/Washington coast and Washington inland waters stocks of harbor seal were considered to be stable following the most recent abundance estimates (in 1999, stock abundances were estimated at 24,732 and 13,692, respectively). However, a Washington Department of Fish and Wildlife expert (S. Jeffries) stated an unofficial abundance of 32,000 harbor seals in Washington (Mapes, 2013). Therefore, it is reasonable to assume that at worst, the stocks have not declined since the last abundance estimates. Ongoing anthropogenic mortality is estimated at 10.6 harbor seals per year for the coastal stock and 13.4 for inland waters seals; therefore, we reasonably assume that the maximum potential annual M/SI incidental to NMFS' fisheries research activities (2.2 and 1.6, respectively) is a small fraction of any sustainable take level that might be calculated for either stock.

As noted above, PBR is also undetermined for the sperm whale, Pacific white-sided dolphin, two stocks of beluga whale, three stocks of harbor porpoise, Alaska stock of Dall's porpoise, and the ringed seal. We follow a similar approach as for harbor seals (see above) in evaluating the significance of the proposed M/SI by describing available information regarding population abundance and other sources of anthropogenic M/SI.

• Rice (1989) estimated that there were 930,000 sperm whales in the North Pacific following the conclusion of commercial whaling. However, this estimate included areas beyond the range of the U.S. North Pacific stock of sperm whales. Kato and Miyashita (1998) produced an estimate of 102,112 (CV = 0.155) sperm whales in the western North Pacific. However, this estimate is considered to be positively biased, and includes whales outside of Alaskan waters. Commercial fishing is the only other source of ongoing anthropogenic M/SI, which is estimated to be 3.7 whales per year. When considered in conjunction with the maximum total annual M/SI anticipated as a result of NMFS fisheries research activities (0.4), we expect that the resulting total annual M/SI (4.1) is a small fraction of any sustainable take level that might be calculated for the stock.

• Historically, the minimum population estimate for the Central North Pacific stock of Pacific white-sided dolphin was 26,880, based on the sum of abundance estimates for four separate survey blocks north of 45°N from surveys conducted during 1987–1990, reported in Buckland *et al.* (1993). This was considered a minimum estimate because the abundance of animals in a fifth block, which straddled the boundary of the two stocks for this species, was not included in the estimate for the North Pacific stock. In addition, much of the potential habitat for this stock was not surveyed between 1987 and 1990 (Muto *et al.,* 2018). Using this minimum abundance estimate in the PBR equation, assuming the default 4 percent productivity rate and a recovery factor of 0.5 (as recommended for stocks of unknown status), produces a PBR value of 268.8. There are no other sources of anthropogenic M/SI for this stock. The maximum total annual M/SI anticipated as a result of NMFS fisheries research activities (1.6) would represent 0.6 percent of residual PBR.

• The historical abundance estimates available in the SARs for the Beaufort Sea and eastern Chukchi stocks of beluga whale allow for calculation of residual PBR values of 510 and 177, respectively. The authorized takes by M/SI for these two stocks are therefore less than 0.1 percent and 0.1 percent, respectively, of the residual PBR values.

• For the Alaska stock of Dall's porpoise, no current estimate of minimum population abundance is available. However, an abundance estimate of 83,400 was estimated on the basis of data collected form 1987–1991 (Hobbs and Lerczak, 1993). Using this population estimate and its associated CV of 0.097, the minimum abundance would be 76,874. Using this estimate with the default productivity rate and the recovery factor for stocks expected to be within the OSP level (Buckland *et al.,* 1993), a PBR value of 1,537.5 may be calculated. Accounting for ongoing M/SI due to commercial fisheries, the maximum total annual M/SI anticipated as a result of NMFS fisheries research activities (3.4) would represent 0.2 percent of residual PBR.

• For the Bering Sea stock of harbor porpoise, a minimum abundance estimate of 40,039 was calculated by Hobbs and Waite (2010) on the basis of a partial abundance estimate, derived from 1999 aerial surveys of Bristol Bay. Although this estimate is formally considered outdated for use in calculating PBR values, we use it here in the same way as the Pacific white-sided dolphin and Dall's porpoise, addressed above. As for the Pacific white-sided dolphin, we use the default productivity rate and recovery factor for stocks of unknown status to calculate a PBR value of 400.4. Accounting for minimal fisheries mortality, the maximum total annual M/SI anticipated as a result of NMFS fisheries research activities (0.4) would represent 0.1 percent of residual PBR.

• For the Gulf of Alaska stock of harbor porpoise, a minimum abundance estimate of 25,987 was calculated by Hobbs and Waite (2010) on the basis of an abundance estimate derived from 1998 aerial surveys of the western Gulf of Alaska. Using the default productivity rate and recovery factor for stocks of unknown status, we calculate a nominal PBR value of 259.9. Accounting for relatively significant ongoing fisheries mortality, the maximum total annual M/SI anticipated as a result of NMFS fisheries research activities (0.8) would represent 0.4 percent of residual PBR.

• A negatively biased minimum abundance estimate of 896 was calculated for the southeast Alaska stock of harbor porpoise on the basis of 2010–2012 aerial surveys (Muto *et al.,* 2018). The estimate is negatively biased because it does not account for observer perception bias and porpoise availability at the surface. However, use of a widely accepted correction factor (2.96) provides a minimum abundance estimate of 2,652 and a corresponding PBR value of 26.5. This PBR value is less than estimated annual ongoing mortality due to commercial fisheries (34). However, the maximum total annual M/SI anticipated as a result of NMFS fisheries research activities (0.2) represents a minimum potential take of one animal over the 5-year period and would represent an insignificant incremental addition to the total annual M/SI (0.6 percent).

• Although NMFS does not provide a formal PBR value for the ringed seal, Muto *et al.* (2018) provide a minimum abundance estimate of 170,000 seals in the U.S. sector of the Bering Sea. This is not considered a reliable estimate for the stock because it does not account for seals in the Chukchi and Beaufort Seas. However, as this is a conservative minimum abundance estimate, we use the corresponding PBR value of 5,100 given by Muto *et al.* (2018). Accounting for minimal ongoing M/SI due to commercial fisheries, as well as ongoing subsistence harvest of ringed seals, the maximum total annual M/SI anticipated as a result of NMFS fisheries research activities (1.6) would represent 0.04 percent of residual PBR.

In summary, our negligible impact analysis is founded on the following factors: (1) The possibility of injury, serious injury, or mortality from the use of active acoustic devices may reasonably be considered discountable; (2) the anticipated incidents of Level B

harassment from the use of active acoustic devices and physical disturbance of pinnipeds consist of, at worst, temporary and relatively minor modifications in behavior; (3) the predicted number of incidents of potential mortality are at insignificant levels for a majority of affected stocks; (4) consideration of additional factors for Risso's dolphin, short-finned pilot whale, the offshore stock of bottlenose dolphin, and the Pribilof Islands stock of harbor seal do not reveal cause for concern; (5) total maximum potential M/SI incidental to NMFS fisheries research activity for southeast Alaska harbor porpoise, considered in conjunction with other sources of ongoing mortality, presents only a minimal incremental additional to total M/SI; (6) available information regarding stocks for which no current PBR estimate is available indicates that total maximum potential M/SI is sustainable; and (7) the presumed efficacy of the planned mitigation measures in reducing the effects of the specified activity to the level of least practicable adverse impact. In combination, we believe that these factors demonstrate that the specified activity will have only short-term effects on individuals (resulting from Level B harassment) and that the total level of taking will not impact rates of recruitment or survival sufficiently to result in population-level impacts.

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 proposed monitoring and mitigation measures, we find that the total marine mammal take from the proposed activities will have a negligible impact on the affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under Section 101(a)(5)(A) of the MMPA for specified 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. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

Please see Table 11 for information relating to this small numbers analysis. The total amount of taking to be authorized is less than five percent for a majority of stocks, and the total amount of taking to be authorized is less than one-third of the stock abundance for all stocks.

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.

Impact on Availability of Affected Species for Taking for Subsistence Uses

In order to issue an LOA, 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 that:

(1) 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) cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

As described in this preamble, the AFSC requested authorization of take incidental to fisheries research activities within Alaskan waters. The planned activities have the potential to result in M/SI of marine mammals as a result of incidental interaction with research gear, and have the potential to result in incidental Level B harassment of marine mammals as a result of the use of active acoustic devices or because of the physical presence of researchers at locations where pinnipeds may be hauled out. These activities also have the potential to result in impacts on the availability of marine mammals for subsistence uses. The AFSC is aware of this potential and is committed to implementing actions to avoid or to minimize any such effects to Alaska Native subsistence communities. The AFSC addresses the potential for their research activities to impact subsistence uses on the following factors:

Actions That May Cause Marine Mammals To Abandon or Avoid Hunting Areas

Some AFSC fisheries research efforts use high-frequency mapping and fish-finding sonars to assess abundance and distribution of target stocks of fish. The high frequency transient sound sources operated by the AFSC are used for a wide variety of environmental and remote-object sensing in the marine environment. These acoustic sources, which are present on most AFSC fishery research vessels, include a variety of single, dual, and multi-beam echosounders, sources used to determine the orientation of trawl nets, and several current profilers. Some of these acoustic sources are likely to be audible to some marine mammal species. Among the marine mammals, most of these sources are unlikely to be audible to whales and most pinnipeds, whereas they may be detected by odontocete cetaceans (and particularly high frequency specialists such as harbor porpoise). There is relatively little direct information about behavioral responses of marine mammals, including the odontocete cetaceans to these devices, but the responses that have been measured in a variety of species to audible sounds suggest that the most likely behavioral responses (if any) would be localized short-term avoidance behavior (see ''Potential Effects of Specified Activities on Marine Mammals and their Habitat'' in our Notice of Proposed Rulemaking (August 1, 2018; 83 FR 37638)). As a general conclusion, while some of the active acoustic sources used during AFSC fisheries research surveys are likely to be detected by some marine species (particularly phocid pinnipeds and odontocete cetaceans), the sound sources with potential for disturbance would be temporary and transient in any particular location as the research vessels move through an area. Any changes in marine mammal behavior in response to the sound sources or physical presence of the research vessel would likely involve temporary avoidance behavior in the vicinity of the research vessel and would return to normal after the vessel passed. Given the small number of research vessels involved and their infrequent and inconsistent presence in any given area from day to day, it is unlikely that the activity would cause animals to avoid any particular area.

Most AFSC fisheries research activities occur well away from land and, in cases where they do approach land, include mitigation measures to minimize the risk of disturbing

pinnipeds hauled out on land. Any incidental disturbance of pinnipeds on haul-outs would likely be infrequent and result in temporary or short term changes in behavior. This sporadic and temporary type of disturbance is not likely to result in a change in use or abandonment of a known haul-out.

AFSC fisheries research activities generally are highly transient and short term (*e.g.,* several hours to a day in any one location) in duration and take place well out to sea, far from coastal or ice pack subsistence hunting activities. It is possible, albeit unlikely, for these fisheries research sound sources to interact with migratory species hunted for subsistence such that there could be short term alterations in migratory pathways. However, as described in the AFSC Communication Plan (Appendix B of AFSC's application), the AFSC will work with subsistence users to identify important areas for marine mammals and subsistence hunters early in the planning process as well as in real time to identify the potential for overlap between migratory pathways, key hunting regions and seasons, and proposed fisheries research. This communication should lead to avoidance of any issues of displacement of marine mammals and their prey.

Activities That May Directly Displace Subsistence Users

AFSC fisheries research primarily utilizes ocean-going ships generally suited for offshore work. These vessels are not designed to work in or near sea ice where much of the subsistence harvest of pinnipeds occurs; thus research activities are most likely to occur outside of periods when this type of hunting occurs. Due to the desire to avoid disturbing pinnipeds hauled out on land, these ships largely avoid nearshore routes that might otherwise put them in the path of seal hunters.

Bowhead whale hunts may occur near sea ice in the spring or in open water in the fall. AFSC fisheries research is only conducted during the open water season in the Arctic so there is no risk of potential interference with subsistence hunts in the spring. However, AFSC fisheries research vessels may be present in whale hunting areas in the fall and could potentially interfere with subsistence activities. The communications plan is designed to minimize the risk of any such interference by advance planning and communication between AFSC scientists and subsistence hunting organizations (*e.g.,* Alaska Eskimo Whaling Commission) and real-time communication between AFSC research vessels as they approach subsistence areas and nearby coastal community contacts. The AFSC is committed to alter its research plans to address any concerns about potential interference and to avoid any such interference in the field.

AFSC fisheries research vessels make port calls in established harbors and ports, thus reducing the chances for interaction with the transit of hunters to and from coastal villages to nearby hunting regions. As described in the Communication Plan provided as Appendix B of AFSC's application, in those rare cases where a research vessel may need to anchor offshore from a subsistence community, AFSC personnel will, within the limits of maritime safety, direct the ship to a predetermined location in coordination with the local subsistence community so as to avoid interfering with those activities.

Activities That May Place Physical Barriers (Vessels and Gear) Between the Marine Mammals and the Subsistence Hunters

The AFSC uses a variety of towed nets and sampling gear to conduct its fisheries and ecosystem research. However, current operational guidelines designed to reduce incidental catch of marine mammals include measures that direct activities away from marine mammals near the research vessel (move-on rule). These measures will reduce the possibility for placing any barriers between subsistence hunters and their marine mammal prey. As outlined in the Communication Plan, AFSC will not deploy such research gear when subsistence hunters have been visually observed in the area.

AFSC fisheries research will also strive to avoid working in any areas when migrating species are present in the immediate vicinity. Per the Communication Plan, the AFSC will coordinate both in advance and in real time with known marine mammal hunting communities within the immediate vicinity of research to avoid any interactions between hunting activity and fisheries research vessels or gear.

We provided AFSC's draft Communication Plan (Appendix B of their application) to the public and invited comment on the document. No comments were received in relation to the Plan; therefore, we find that the plan is appropriate for minimizing the potential for impacts to subsistence uses of marine mammals. The AFSC is committed to conducting its activities in ways that do not affect the availability of marine mammals to subsistence hunters. The AFSC will implement standard operational procedures and mitigation measures to minimize direct impacts on marine mammals and will work with Alaska Native organizations and coastal communities to develop effective communication protocols to minimize the risk of potential interference with subsistence activities. The AFSC will thus work to ensure that its research activities do not negatively impact the availability of marine mammals to Alaska Native subsistence users.

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, we have determined that there will not be an unmitigable adverse impact on subsistence uses from AFSC's activities.

Adaptive Management

The regulations governing the take of marine mammals incidental to AFSC fisheries research survey operations contain an adaptive management component. The inclusion of an adaptive management component will be both valuable and necessary within the context of five-year regulations for activities that have been associated with marine mammal mortality.

The reporting requirements associated with this rule are designed to provide OPR with monitoring data from the previous year to allow consideration of whether any changes are appropriate. OPR and the AFSC will meet annually to discuss the monitoring reports and current science and whether mitigation or monitoring modifications are appropriate. The use of adaptive management allows OPR to consider new information from different sources to determine (with input from the AFSC regarding practicability) on an annual or biennial basis if mitigation or monitoring measures should be modified (including additions or deletions). Mitigation measures could be modified if new data suggests that such modifications would have a reasonable likelihood of reducing adverse effects to marine mammals and if the measures are practicable.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) Results from monitoring reports, as required by MMPA authorizations; (2) results from general marine mammal and sound research; and (3) any information which reveals that marine mammals may have been taken in a manner, extent, or

number not authorized by these regulations or subsequent LOAs.

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 evaluate our proposed action (*i.e.,* the promulgation of regulations and subsequent issuance of incidental take authorization) and alternatives with respect to potential impacts on the human environment. Accordingly, NMFS prepared an Environmental Assessment (EA; *Programmatic Environmental Assessment for Fisheries and Ecosystem Research Conducted and Funded by the Alaska Fisheries Science Center*) to consider the environmental impacts associated with the AFSC's proposed activities as well as the issuance of the regulations and subsequent incidental take authorization. We made the EA available to the public for review and comment, in relation to its suitability for use by OPR as an assessment of the impacts to the human environment of issuance of regulations and subsequent LOAs to AFSC. OPR subsequently signed a Finding of No Significant Impact (FONSI). The final PEA is available on request (see **FOR FURTHER INFORMATION CONTACT**) and the FONSI is posted online at: *www.fisheries.noaa.gov/action/incidental-take-authorization-noaa-fisheries-afsc-fisheries-and-ecosystem-research.*

Endangered Species Act (ESA)

There are multiple marine mammal species listed under the ESA with confirmed or possible occurrence in the specified geographical regions (see Table 1). The authorization of incidental take pursuant to the AFSC's specified activity would not affect any designated critical habitat. OPR requested initiation of consultation with NMFS's Alaska Regional Office (AKRO) under section 7 of the ESA on the promulgation of five-year regulations and the subsequent issuance of LOAs to AFSC under section 101(a)(5)(A) of the MMPA.

On April 5, 2019, the AKRO issued a biological opinion to OPR and to the AFSC (concerning the conduct of the specified activities) which concluded that the issuance of the authorizations is not likely to jeopardize the continued existence of any listed species, including marine mammals.

Classification

Pursuant to the procedures established to implement Executive Order 12866, the Office of Management and Budget has determined that this rule is not significant.

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration at the proposed rule stage that this action will not have a significant economic impact on a substantial number of small entities. AFSC is the sole entity that would be subject to the requirements of these regulations, and the AFSC is not a small governmental jurisdiction, small organization, or small business, as defined by the RFA. No comments were received regarding this certification or on the economic impacts of the rule more generally. As a result, a regulatory flexibility analysis is not required and none has been prepared.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a currently valid OMB control number. However, this rule does not contain a collection-of-information requirement subject to the provisions of the PRA because the applicant is a Federal agency.

List of Subjects in 50 CFR Part 219

Exports, Fish, Imports, Indians, Labeling, Marine mammals, Penalties, Reporting and recordkeeping requirements, Seafood, Transportation.

Dated: August 28, 2019.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For reasons set forth in the preamble, 50 CFR part 219 is amended as follows:

PART 219—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 219 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

■ 2. Add subpart F to read as follows:

Subpart F—Taking Marine Mammals Incidental to Alaska Fisheries Science Center Fisheries Research

Sec.

219.51 Specified activity and specified geographical region.
219.52 Effective dates.
219.53 Permissible methods of taking.
219.54 Prohibitions.
219.55 Mitigation requirements.
219.56 Requirements for monitoring and reporting.
219.57 Letters of Authorization.
219.58 Renewals and modifications of Letters of Authorization.
219.59–219.60 [Reserved]

Subpart F—Taking Marine Mammals Incidental to Alaska Fisheries Science Center Fisheries Research

§ 219.51 Specified activity and specified geographical region.

(a) Regulations in this subpart apply only to the National Marine Fisheries Service's (NMFS) Alaska Fisheries Science Center (AFSC) and those persons it authorizes or funds to conduct activities on its behalf, including the International Pacific Halibut Commission (IPHC), for the taking of marine mammals that occurs in the areas outlined in paragraph (b) of this section and that occurs incidental to research survey program operations.

(b) The taking of marine mammals by AFSC may be authorized in a Letter of Authorization (LOA) only if it occurs within the Gulf of Alaska, Bering Sea and Aleutian Islands, Chukchi Sea and Beaufort Sea, or is conducted by the IPHC in the Bering Sea and Aleutian Islands, Gulf of Alaska, or off the U.S. West Coast.

§ 219.52 Effective dates.

Regulations in this subpart are effective from October 7, 2019, through October 7, 2024.

§ 219.53 Permissible methods of taking.

Under LOAs issued pursuant to §§ 216.106 of this chapter and 219.57, the Holder of the LOA (hereinafter ''AFSC'') may incidentally, but not intentionally, take marine mammals within the area described in § 219.51(b) by Level B harassment associated with use of active acoustic systems and physical or visual disturbance of hauled-out pinnipeds and by Level A harassment, serious injury, or mortality associated with use of hook and line gear, trawl gear, and gillnet gear, provided the activity is in compliance with all terms, conditions, and requirements of the regulations in this subpart and the appropriate LOA.

§ 219.54 Prohibitions.

Notwithstanding takings contemplated in § 219.51 and authorized by a LOA issued under §§ 216.106 of this chapter and 219.57, no person in connection with the activities described in § 219.51 may:

(a) Violate, or fail to comply with, the terms, conditions, and requirements of this subpart or a LOA issued under §§ 216.106 of this chapter and 219.57;

(b) Take any marine mammal not specified in such LOA;

(c) Take any marine mammal specified in such LOA in any manner other than as specified;

(d) Take a marine mammal specified in such LOA if NMFS determines such taking results in more than a negligible impact on the species or stocks of such marine mammal; or

(e) Take a marine mammal specified in such LOA if NMFS determines such taking results in an unmitigable adverse impact on the species or stock of such marine mammal for taking for subsistence uses.

§ 219.55 Mitigation requirements.

When conducting the activities identified in § 219.51(a), the mitigation measures contained in any LOA issued under §§ 216.106 of this chapter and 219.57 must be implemented. These mitigation measures shall include but are not limited to:

(a) *General conditions.* (1) AFSC shall convey relevant mitigation, monitoring, and reporting requirements to the IPHC, as indicated in the following subparts;

(2) AFSC shall take all necessary measures to coordinate and communicate in advance of each specific survey with the National Oceanic and Atmospheric Administration's (NOAA) Office of Marine and Aviation Operations (OMAO) or other relevant parties on non-NOAA platforms to ensure that all mitigation measures and monitoring requirements described herein, as well as the specific manner of implementation and relevant event-contingent decision-making processes, are clearly understood and agreed upon. AFSC shall convey this requirement to IPHC;

(3) AFSC shall coordinate and conduct briefings at the outset of each survey and as necessary between ship's crew (Commanding Officer/master or designee(s), as appropriate) and scientific party in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures. AFSC shall convey this requirement to IPHC;

(4) AFSC shall coordinate as necessary on a daily basis during survey cruises with OMAO personnel or other relevant personnel on non-NOAA platforms to ensure that requirements, procedures, and decision-making processes are understood and properly implemented. AFSC shall convey this requirement to IPHC;

(5) When deploying any type of sampling gear at sea, AFSC shall at all times monitor for any unusual circumstances that may arise at a sampling site and use best professional judgment to avoid any potential risks to marine mammals during use of all research equipment. AFSC shall convey this requirement to IPHC;

(6) AFSC shall implement handling and/or disentanglement protocols as specified in the guidance that shall be provided to AFSC survey personnel. AFSC shall convey this requirement to IPHC;

(7) AFSC shall not approach within 1 km of locations where marine mammals are aggregated, including pinniped rookeries and haul-outs; and

(8) AFSC shall adhere to a final Communication Plan. In summary and in accordance with the Plan, AFSC shall:

(i) Notify and provide potentially affected Alaska Native subsistence communities with the Communication Plan through a series of mailings, direct contacts, and planned meetings throughout the regions where AFSC fisheries research is expected to occur;

(ii) Meet with potentially affected subsistence communities to discuss planned activities and to resolve potential conflicts regarding any aspects of either the fisheries research operations or the Communication Plan;

(iii) Develop field operations plans as necessary, which shall address how researchers will consult and maintain communication with contacts in the potentially affected subsistence communities when in the field, including a list of local contacts and contact mechanisms, and which shall describe operational procedures and actions planned to avoid or minimize the risk of interactions between AFSC fisheries research and local subsistence activities;

(iv) Schedule post-season informational sessions with subsistence contacts from the study areas to brief them on the outcome of the AFSC fisheries research and to assess performance of the Communication Plan and individual field operations or cruise plans in working to minimize effects to subsistence activities; and

(v) Evaluate overall effectiveness of the Communications Plan in year four of any LOA issued pursuant to §§ 216.106 of this chapter and 219.57.

(b) *Trawl survey protocols.* (1) AFSC shall conduct trawl operations as soon as is practicable upon arrival at the sampling station;

(2) AFSC shall initiate marine mammal watches (visual observation) at least 15 minutes prior to beginning of net deployment, but shall also conduct monitoring during any pre-set activities including trackline reconnaissance, CTD casts, and plankton or bongo net hauls. Marine mammal watches shall be conducted by scanning the surrounding waters with the naked eye and rangefinding binoculars (or monocular). During nighttime operations, visual observation shall be conducted using the naked eye and available vessel lighting;

(3) AFSC shall implement the move-on rule mitigation protocol, as described in this paragraph. If one or more marine mammals are observed and are considered at risk of interacting with the vessel or research gear, or appear to be approaching the vessel and are considered at risk of interaction, AFSC shall either remain onsite or move on to another sampling location. If remaining onsite, the set shall be delayed. If the animals depart or appear to no longer be at risk of interacting with the vessel or gear, a further observation period shall be conducted. If no further observations are made or the animals still do not appear to be at risk of interaction, then the set may be made. If the vessel is moved to a different section of the sampling area, the move-on rule mitigation protocol would begin anew. If, after moving on, marine mammals remain at risk of interaction, the AFSC shall move again or skip the station. Marine mammals that are sighted shall be monitored to determine their position and movement in relation to the vessel to determine whether the move-on rule mitigation protocol should be implemented. AFSC may use best professional judgment in making these decisions;

(4) AFSC shall maintain visual monitoring effort during the entire period of time that trawl gear is in the water (*i.e.,* throughout gear deployment, fishing, and retrieval). If marine mammals are sighted before the gear is fully removed from the water, AFSC shall take the most appropriate action to avoid marine mammal interaction. AFSC may use best professional judgment in making this decision;

(5) If trawling operations have been suspended because of the presence of marine mammals, AFSC may resume trawl operations when practicable only when the animals are believed to have departed the area. AFSC may use best professional judgment in making this determination;

(6) AFSC shall implement standard survey protocols to minimize potential for marine mammal interactions, including maximum tow durations at target depth and maximum tow distance, and shall carefully empty the trawl as quickly as possible upon retrieval; and

(7) Whenever surface trawl nets are used in southeast Alaska, AFSC must install and use acoustic deterrent devices, with two pairs of the devices installed near the net opening. AFSC must ensure that the devices are operating properly before deploying the net.

(c) *Longline survey protocols.* (1) AFSC shall deploy longline gear as soon as is practicable upon arrival at the sampling station. AFSC shall convey this requirement to IPHC;

(2) AFSC shall initiate marine mammal watches (visual observation) no less than 30 minutes (or for the duration of transit between set locations, if shorter than 30 minutes) prior to both deployment and retrieval of longline gear. Marine mammal watches shall be conducted by scanning the surrounding waters with the naked eye and rangefinding binoculars (or monocular). During nighttime operations, visual observation shall be conducted using the naked eye and available vessel lighting. AFSC shall convey this requirement to IPHC;

(3) AFSC shall implement the move-on rule mitigation protocol, as described in this paragraph. If one or more marine mammals are observed in the vicinity of the planned location before gear deployment, and are considered at risk of interacting with the vessel or research gear, or appear to be approaching the vessel and are considered at risk of interaction, AFSC shall either remain onsite or move on to another sampling location. If remaining onsite, the set shall be delayed. If the animals depart or appear to no longer be at risk of interacting with the vessel or gear, a further observation period shall be conducted. If no further observations are made or the animals still do not appear to be at risk of interaction, then the set may be made. If the vessel is moved to a different section of the sampling area, the move-on rule mitigation protocol would begin anew. If, after moving on, marine mammals remain at risk of interaction, the AFSC shall move again or skip the station. Marine mammals that are sighted shall be monitored to determine their position and movement in relation to the vessel to determine whether the move-on rule mitigation protocol should be implemented. AFSC may use best professional judgment in making these decisions. AFSC shall convey this requirement to IPHC;

(4) AFSC shall maintain visual monitoring effort during the entire period of gear deployment and retrieval. If marine mammals are sighted before the gear is fully deployed or retrieved, AFSC shall take the most appropriate action to avoid marine mammal interaction. AFSC may use best professional judgment in making this decision. AFSC shall convey this requirement to IPHC; and

(5) If deployment or retrieval operations have been suspended because of the presence of marine mammals, AFSC may resume such operations when practicable only when the animals are believed to have departed the area. AFSC may use best professional judgment in making this decision. AFSC shall convey this requirement to IPHC.

(d) *Gillnet survey protocols.* (1) AFSC shall conduct gillnet operations as soon as is practicable upon arrival at the sampling station;

(2) AFSC shall conduct marine mammal watches (visual observation) prior to beginning of net deployment. Marine mammal watches shall be conducted by scanning the surrounding waters with the naked eye and rangefinding binoculars (or monocular);

(3) AFSC shall implement the move-on rule mitigation protocol. If one or more marine mammals are observed in the vicinity of the planned location before gear deployment, and are considered at risk of interacting with research gear, AFSC shall either remain onsite or move on to another sampling location. If remaining onsite, the set shall be delayed. If the animals depart or appear to no longer be at risk of interacting with the gear, a further observation period shall be conducted. If no further observations are made or the animals still do not appear to be at risk of interaction, then the set may be made. If the vessel is moved to a different area, the move-on rule mitigation protocol would begin anew. If, after moving on, marine mammals remain at risk of interaction, the AFSC shall move again or skip the station. Marine mammals that are sighted shall be monitored to determine their position and movement in relation to the vessel to determine whether the move-on rule mitigation protocol should be implemented. AFSC may use best professional judgment in making these decisions;

(4) AFSC shall maintain visual monitoring effort during the entire period of time that gillnet gear is in the water (*i.e.,* throughout gear deployment, fishing, and retrieval). If marine mammals are sighted before the gear is fully removed from the water, and appear to be at risk of interaction with the gear, AFSC shall pull the gear immediately. AFSC may use best professional judgment in making this decision;

(5) If gillnet operations have been suspended because of the presence of marine mammals, AFSC may resume gillnet operations when practicable only when the animals are believed to have departed the area. AFSC may use best professional judgment in making this determination; and

(6) AFSC must install and use acoustic deterrent devices whenever gillnets are used. AFSC must ensure that the devices are operating properly before deploying the net.

§ 219.56 Requirements for monitoring and reporting.

(a) *Compliance coordinator.* AFSC shall designate a compliance coordinator who shall be responsible for ensuring compliance with all requirements of any LOA issued pursuant to §§ 216.106 of this chapter and 219.57 and for preparing for any subsequent request(s) for incidental take authorization. AFSC shall convey this requirement to IPHC.

(b) *Visual monitoring program.* (1) Marine mammal visual monitoring shall occur prior to deployment of trawl, longline, and gillnet gear, respectively; throughout deployment of gear and active fishing of research gears (not including longline soak time); prior to retrieval of longline gear; and throughout retrieval of all research gear. AFSC shall convey this requirement to IPHC; and

(2) Marine mammal watches shall be conducted by watch-standers (those navigating the vessel and/or other crew) at all times when the vessel is being operated. AFSC shall convey this requirement to IPHC.

(c) *Training.* (1) AFSC must conduct annual training for all chief scientists and other personnel who may be responsible for conducting dedicated marine mammal visual observations to explain mitigation measures and monitoring and reporting requirements, mitigation and monitoring protocols, marine mammal identification, completion of datasheets, and use of equipment. AFSC may determine the agenda for these trainings;

(2) AFSC shall also dedicate a portion of training to discussion of best professional judgment, including use in any incidents of marine mammal interaction and instructive examples where use of best professional judgment was determined to be successful or unsuccessful; and

(3) AFSC shall convey these training requirements to IPHC.

(d) *Handling procedures and data collection.* (1) AFSC must develop and implement standardized marine mammal handling, disentanglement, and data collection procedures. These standard procedures will be subject to

approval by NMFS's Office of Protected Resources (OPR). AFSC shall convey these procedures to IPHC;

(2) When practicable, for any marine mammal interaction involving the release of a live animal, AFSC shall collect necessary data to facilitate a serious injury determination. AFSC shall convey this requirement to IPHC;

(3) AFSC shall provide its relevant personnel with standard guidance and training regarding handling of marine mammals, including how to identify different species, bring an individual aboard a vessel, assess the level of consciousness, remove fishing gear, return an individual to water, and log activities pertaining to the interaction. AFSC shall convey this requirement to IPHC; and

(4) AFSC shall record such data on standardized forms, which will be subject to approval by OPR. AFSC shall also answer a standard series of supplemental questions regarding the details of any marine mammal interaction. AFSC shall convey this requirement to IPHC.

(e) *Reporting.* (1) AFSC shall report all incidents of marine mammal interaction to NMFS's Protected Species Incidental Take database, including those resulting from IPHC activities, within 48 hours of occurrence and shall provide supplemental information to OPR upon request. Information related to marine mammal interaction (animal captured or entangled in research gear) must include details of survey effort, full descriptions of any observations of the animals, the context (vessel and conditions), decisions made, and rationale for decisions made in vessel and gear handling;

(2) AFSC must submit annual reports.

(i) AFSC shall submit an annual summary report to OPR not later than ninety days following the end of a given year. AFSC shall provide a final report within thirty days following resolution of comments on the draft report; and

(ii) These reports shall contain, at minimum, the following:

(A) Annual line-kilometers surveyed during which the EK60, ME70, ES60, 7111 (or equivalent sources) were predominant and associated pro-rated estimates of actual take;

(B) Summary information regarding use of all longline, gillnet, and trawl gear, including number of sets, tows, etc., specific to each gear;

(C) Accounts of all incidents of significant marine mammal interactions, including circumstances of the event and descriptions of any mitigation procedures implemented or not implemented and why;

(D) A written evaluation of the effectiveness of AFSC mitigation strategies in reducing the number of marine mammal interactions with survey gear, including best professional judgment and suggestions for changes to the mitigation strategies, if any;

(E) Final outcome of serious injury determinations for all incidents of marine mammal interactions where the animal(s) were released alive; and

(F) A summary of all relevant training provided by AFSC and any coordination with NMFS' Alaska Regional Office.

(3) AFSC shall convey these reporting requirements to IPHC and shall provide IPHC reports to OPR subject to the same schedule.

(f) *Reporting of injured or dead marine mammals.* (1) In the unanticipated event that the activity defined in § 219.51(a) clearly causes the take of a marine mammal in a prohibited manner, AFSC personnel engaged in the research activity shall immediately cease such activity until such time as an appropriate decision regarding activity continuation can be made by the AFSC Director (or designee). The incident must be reported immediately to OPR and the Alaska Regional Stranding Coordinator, NMFS. OPR will review the circumstances of the prohibited take and work with AFSC to determine what measures are necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. The immediate decision made by AFSC regarding continuation of the specified activity is subject to OPR concurrence. The report must include the following information:

(i) Time, date, and location (latitude/longitude) of the incident;

(ii) Description of the incident;

(iii) Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility);

(iv) Description of all marine mammal observations in the 24 hours preceding the incident;

(v) Species identification or description of the animal(s) involved;

(vi) Status of all sound source use in the 24 hours preceding the incident;

(vii) Water depth;

(viii) Fate of the animal(s); and

(ix) Photographs or video footage of the animal(s).

(2) In the event that AFSC discovers an injured or dead marine mammal and determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition), AFSC shall immediately report the incident to OPR and the Alaska Regional Stranding Coordinator, NMFS. The report must include the information identified in paragraph (f)(1) of this section. Activities may continue while OPR reviews the circumstances of the incident. OPR will work with AFSC to determine whether additional mitigation measures or modifications to the activities are appropriate.

(3) In the event that AFSC discovers an injured or dead marine mammal and determines that the injury or death is not associated with or related to the activities defined in § 219.51(a) (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, scavenger damage), AFSC shall report the incident to OPR and the Alaska Regional Stranding Coordinator, NMFS, within 24 hours of the discovery. AFSC shall provide photographs or video footage or other documentation of the stranded animal sighting to OPR.

(4) AFSC shall convey these requirements to IPHC.

§ 219.57 Letters of Authorization.

(a) To incidentally take marine mammals pursuant to these regulations, AFSC must apply for and obtain a Letter of Authorization (LOA).

(b) An LOA, unless suspended or revoked, may be effective for a period of time not to exceed the expiration date of these regulations.

(c) If an LOA expires prior to the expiration date of these regulations, AFSC may apply for and obtain a renewal of the LOA.

(d) In the event of projected changes to the activity or to mitigation and monitoring measures required by an LOA, AFSC must apply for and obtain a modification of the LOA as described in § 219.58.

(e) The LOA shall set forth:

(1) Permissible methods of incidental taking;

(2) Means of effecting the least practicable adverse impact (*i.e.,* mitigation) on the species, its habitat, and on the availability of the species for subsistence uses; and

(3) Requirements for monitoring and reporting.

(f) Issuance of the LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations.

(g) Notice of issuance or denial of an LOA shall be published in the **Federal Register** within thirty days of a determination.

§ 219.58 Renewals and modifications of Letters of Authorization.

(a) An LOA issued under §§ 216.106 of this chapter and 219.57 for the

activity identified in § 219.51(a) shall be renewed or modified upon request by the applicant, provided that:

(1) The proposed specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for these regulations (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section), and

(2) OPR determines that the mitigation, monitoring, and reporting measures required by the previous LOA under these regulations were implemented.

(b) For an LOA modification or renewal requests by the applicant that include changes to the activity or the mitigation, monitoring, or reporting (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section) that do not change the findings made for the regulations or result in no more than a minor change in the total estimated number of takes (or distribution by species or years), OPR may publish a notice of proposed LOA in the **Federal Register**, including the associated analysis of the change, and solicit public comment before issuing the LOA.

(c) An LOA issued under §§ 216.106 of this chapter and 219.57 for the activity identified in § 219.51(a) may be modified by OPR under the following circumstances:

(1) *Adaptive management.* OPR may modify (including augment) the existing mitigation, monitoring, or reporting measures (after consulting with AFSC regarding the practicability of the modifications) if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring set forth in the preamble for these regulations.

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in an LOA:

(A) Results from AFSC's monitoring from the previous year(s);

(B) Results from other marine mammal and/or sound research or studies; and

(C) Any information that reveals marine mammals may have been taken in a manner, extent or number not authorized by these regulations or subsequent LOAs.

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, OPR will publish a notice of proposed LOA in the **Federal Register** and solicit public comment.

(2) *Emergencies.* If OPR determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in LOAs issued pursuant to §§ 216.106 of this chapter and 219.57, an LOA may be modified without prior notice or opportunity for public comment. Notice would be published in the **Federal Register** within thirty days of the action.

§§ 219.59–219.60 [Reserved]

[FR Doc. 2019–18930 Filed 9–4–19; 8:45 am]

BILLING CODE 3510–22–P

FEDERAL REGISTER

Vol. 84 Thursday,

No. 172 September 5, 2019

Part III

Department of Energy

10 CFR Part 430

Energy Conservation Program: Energy Conservation Standards for General Service Incandescent Lamps; Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Part 430

EERE–2019–BT–STD–0022]

RIN 1904–AE76

Energy Conservation Program: Energy Conservation Standards for General Service Incandescent Lamps

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

ACTION: Notice of proposed determination and request for comment.

SUMMARY: The Energy Policy and Conservation Act of 1975, as amended (EPCA), directs DOE to initiate a rulemaking for general service lamps (GSLs) that, among other requirements, determines whether standards in effect for general service incandescent lamps (GSILs, a subset of GSLs) should be amended. In this notice of proposed determination (NOPD), DOE has initially determined that energy conservation standards for GSILs do not need to be amended and asks for comment on this proposed determination and associated analyses and results.

DATES:

Comments: Written comments and information are requested and will be accepted on or before November 4, 2019.

Meeting: DOE will hold a public meeting on Tuesday, October 15, 2019, from 10:00 a.m. to 3:00 p.m., in Washington, DC. The meeting will also be broadcast as a webinar. See section VII, ''Public Participation,'' for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

ADDRESSES: The public meeting will be held at the U.S. Department of Energy, Forrestal Building, Room 8E–089, 1000 Independence Avenue SW, Washington, DC 20585.

Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *http://www.regulations.gov*. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–BT–STD–0022, by any of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

(2) *Email: GSIL2019STD0022@ee.doe.gov*. Include the docket number EERE–BT–STD–0022 in the subject line of the message.

(3) *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

(4) *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 telefacsimiles (faxes) will be accepted. For detailed instructions on submitting comments and additional information on this process, see section VII 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, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at *http://www.regulations.gov/docket?D=EERE-2019-BT-STD-0022*. The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section VII, ''Public Participation,'' for further 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, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Email: *ApplianceStandardsQuestions@ee.doe.gov*.

Ms. Celia Sher, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–6122. Email: *Celia.Sher@hq.doe.gov*.

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Synopsis of the Proposed Determination
II. Introduction
A. Authority and Background
1. Current Standards
2. History of Standards Rulemakings for GSILs
III. General Discussion
A. Product Classes and Scope of Coverage
B. Test Procedure
C. Technological Feasibility
1. General
2. Maximum Technologically Feasible Levels
D. Energy Savings
1. Determination of Savings
2. Significance of Savings
E. Economic Justification
1. Specific Criteria
a. Economic Impact on Manufacturers and Consumers
b. Savings in Operating Costs Compared to Increase in Price
c. Energy Savings
d. Lessening of Utility or Performance of Products
e. Impact of Any Lessening of Competition
f. Need for National Energy Conservation
g. Other Factors
2. Rebuttable Presumption
IV. Methodology and Discussion of Related Comments
A. Market and Technology Assessment
1. Scope of Coverage
2. Metric
3. Technology Options
4. Screening Analysis
5. Product Classes
B. Engineering Analysis
1. Representative Product Classes
2. Baseline Lamps
3. More-Efficacious Substitutes
4. Efficacy Levels
5. Scaling to Other Product Classes
6. Product *Substitutes*
C. Product Price Determination
D. Energy Use Analysis
1. Operating Hours
a. Residential Sector
b. Commercial Sector
2. Input Power
3. Lighting Controls
E. Life-Cycle Cost and Payback Period Analysis
1. Product Cost
2. Installation Cost
3. Annual Energy Consumption
4. Energy Prices
5. Energy Price Trends
6. Product Lifetime
7. Discount Rates
8. Efficacy Distribution
9. LCC Savings Calculation
10. Payback Period Analysis
F. Shipments Analysis
1. Shipments Model
a. Lamp Demand Module
b. Price-Learning Module
c. Market-Share Module
G. National Impact Analysis
1. National Energy Savings
2. Net Present Value Analysis
H. Manufacturer Impact Analysis
1. Manufacturer Production Costs

2. Shipments Projections
3. Product and Capital Conversion Costs
4. Markup Scenarios
V. Analytical Results and Conclusions
A. Trial Standard Levels
B. Economic Impacts on Individual Consumers
1. Life-Cycle Cost and Payback Period
2. Rebuttable Presumption Payback
C. National Impact Analysis
1. Energy Savings
2. Net Present Value of Consumer Costs and Benefits
D. Economic Impacts on Manufacturers
1. Industry Cash Flow Analysis Results
2. Direct Impacts on Employment
3. Impacts on Manufacturing Capacity
4. Impacts on Subgroups of Manufacturers
5. Cumulative Regulatory Burden
E. Proposed Determination
1. Technological Feasibility
2. Significant Conservation of Energy
3. Economic Justification
4. Summary
VI. Procedural Issues and Regulatory Review
A. Review Under Executive Order 12866
B. Review Under Executive Orders 13771 and 13777
C. Review Under the Regulatory Flexibility Act
D. Review Under the National Environmental Policy Act of 1969
E. Review Under Executive Order 13132
F. Review Under Executive Order 12988
G. Review Under the Unfunded Mandates Reform Act of 1995
H. Review Under the Treasury and General Government Appropriations Act, 1999
I. Review Under Executive Order 12630
J. Review Under the Treasury and General Government Appropriations Act, 2001
K. Review Under Executive Order 13211
L. Information Quality
VII. Public Participation
A. Attendance at Public Meeting
B. Procedure for Submitting Prepared General Statements for Distribution
C. Conduct of Public Meeting
D. The Time and Date of the Public Meeting and Submission of Comments
E. Issues on Which DOE Seeks Comment
VIII. Approval of the Office of the Secretary

I. Synopsis of the Proposed Determination

Title III, Part B [1] of the Energy Policy and Conservation Act of 1975, as amended (EPCA),[2] established the Energy Conservation Program for Consumer Products Other Than Automobiles. (42 U.S.C. 6291–6309) These products include GSILs, the subject of this NOPD.

DOE is issuing this NOPD pursuant to the EPCA requirement that DOE must initiate a rulemaking for GSLs that, among other requirements, determines whether standards in effect for GSILs (a subset of GSLs) should be amended. (42 U.S.C. 6295(i)(6)(A))

For this proposed determination, DOE analyzed GSILs defined at title 10 of the Code of Federal Regulations (CFR) part 430, subpart A, section 430.2 and subject to standards specified in 10 CFR 430.32(x). DOE first analyzed the technological feasibility of more efficient GSILs. For those GSILs for which DOE determined higher standards to be technologically feasible, DOE estimated energy savings that would result from potential energy conservation standards by conducting a national impacts analysis (NIA). DOE evaluated whether higher standards would be economically justified by conducting life-cycle cost (LCC) and payback period (PBP) analyses, and estimated the net present value (NPV) of the total costs and benefits experienced by consumers. In addition to the consideration of these criteria, DOE conducted a manufacturer impact analyses (MIA).

Based on the results of these analyses, summarized in section V of this document, DOE has tentatively determined that current standards for GSILs do not need to be amended because more stringent standards are not economically justified.

II. Introduction

The following section briefly discusses the statutory authority underlying this proposed determination, as well as some of the relevant historical background related to standards for GSLs.

A. Authority and Background

Title III, Part B of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles, which includes GSILs (a subset of GSLs) as covered products. (42 U.S.C. 6292(a)(14)) Amendments to EPCA in the Energy Independence and Security Act of 2007 (EISA 2007) directed DOE to conduct two rulemaking cycles to evaluate energy conservation standards for GSLs. (42 U.S.C. 6295(i)(6)(A)–(B)) GSLs are currently defined in EPCA to include GSILs, compact fluorescent lamps (CFLs), general service light-emitting diode (LED) lamps and organic light-emitting diode (OLED) lamps, and any other lamps that the Secretary of Energy (Secretary) determines are used to satisfy lighting applications traditionally served by GSILs. (42 U.S.C. 6291(30)(BB))

For the first rulemaking cycle, Congress instructed DOE to initiate a rulemaking process prior to January 1, 2014, to consider two questions: (1) Whether to amend energy conservation standards for general service lamps and (2) whether ''the exemptions for certain incandescent lamps should be maintained or discontinued.'' (42 U.S.C. 6295(i)(6)(A)(i)) Further, if the Secretary determines that the standards in effect for GSILs should be amended, EPCA provides that a final rule must be published by January 1, 2017, with a compliance date at least 3 years after the date on which the final rule is published. (42 U.S.C. 6295(i)(6)(A)(iii)) In developing such a rule, DOE must consider a minimum efficacy standard of 45 lumens per watt (lm/W). (42 U.S.C. 6295(i)(6)(A)(ii)) If DOE fails to complete a rulemaking in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv) or a final rule from the first rulemaking cycle does not produce savings greater than or equal to the savings from a minimum efficacy standard of 45 lm/W, the statute provides a ''backstop'' under which DOE must prohibit sales of GSLs that do not meet a minimum 45 lm/W standard beginning on January 1, 2020. (42 U.S.C. 6295(i)(6)(A)(v))

The EISA-prescribed amendments further directed DOE to initiate a second rulemaking cycle by January 1, 2020, to determine whether standards in effect for GSILs should be amended with more-stringent requirements and if the exemptions for certain incandescent lamps should be maintained or discontinued. (42 U.S.C. 6295(i)(6)(B)(i)) For the second review of energy conservation standards, the scope is not limited to incandescent lamp technologies. (42 U.S.C. 6295(i)(6)(B)(ii))

The energy conservation program for covered products under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) the establishment of Federal energy conservation standards, and (4) certification and enforcement procedures. The Federal Trade Commission (FTC) is primarily responsible for labeling, and DOE implements the remainder of the program.

Subject to certain criteria and conditions, DOE is required to develop test procedures to measure the energy efficiency, energy use, or estimated annual operating cost of each covered product. (42 U.S.C. 6295(o)(3)(A) and (r)) Manufacturers of covered products must use the prescribed DOE test procedure as the basis for certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA and when making representations to the public regarding the energy use or efficiency of those products. (42 U.S.C. 6293(c) and 6295(s)) Similarly, DOE must use these test procedures to

[1] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

[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 (October 23, 2018).

determine whether the products comply with standards adopted pursuant to EPCA. (42 U.S.C. 6295(s)) The DOE test procedures for GSILs appear at 10 CFR part 430, subpart B, appendix R.

Federal energy conservation requirements generally supersede State laws or regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) Absent limited exceptions, states generally are precluded from adopting energy conservation standards for covered products both before an energy conservation standard becomes effective, and after an energy conservation standard becomes effective. (42 U.S.C. 6297(b) and (c)) However, the statute contains three narrow exceptions to this general preemption provision specific to GSLs in 42 U.S.C. 6295(i)(6)(A)(vi). Under the limited exceptions from preemption specific to GSLs that Congress included in EPCA, only California and Nevada have authority to adopt, with an effective date beginning January 1, 2018 or after, either: (1) A final rule adopted by the Secretary in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv); (2) if a final rule has not been adopted in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv), the backstop requirement under 42 U.S.C. 6295(i)(6)(A)(v); or (3) in the case of California only, if a final rule has not been adopted in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv), any California regulations related to ''these covered products'' adopted pursuant to state statute in effect as of the date of enactment of EISA 2007. (42 U.S.C. 6295(i)(6)(A)(vi)) Because none of these narrow exceptions from preemption are available to California and Nevada, all states, including California and Nevada, are prohibited from adopting energy conservation standards for GSLs.[3]

Pursuant to the amendments contained in EISA 2007, any final rule for new or amended energy conservation standards promulgated after July 1, 2010, is required to address standby mode and off mode energy use. (42 U.S.C. 6295(gg)(3)) Specifically, when DOE adopts a standard for a covered product after that date, it must, if justified by the criteria for adoption of standards under EPCA (42 U.S.C. 6295(o)), incorporate standby mode and off mode energy use into a single standard, or, if that is not feasible, adopt a separate standard for such energy use for that product. (42 U.S.C. 6295(gg)(3)(A)–(B)) DOE's current test procedure for GSILs does not address standby mode and off mode energy use because DOE concluded in a 2009 final rule that these modes of energy consumption were not applicable to the lamps. 74 FR 31829, 31833 (July 6, 2009). In this analysis DOE only considers active mode energy use in its determination of whether energy conservation standards for GSILs need to be amended.

DOE is prohibited from prescribing an amended standard that DOE determines will not result in significant conservation of energy, is not technologically feasible, or is not economically justified. (42 U.S.C. 6295(o)(3)) An evaluation of economic justification requires that DOE determine whether the benefits of a standard exceed its burdens through consideration, to the greatest extent practicable, the following seven statutory factors:

(1) The economic impact of the standard on manufacturers and consumers of the products subject to the standard;

(2) The savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that are likely to result from the standard;

(3) The total projected amount of energy (or as applicable, water) savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the covered products likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy and water conservation; and

(7) Other factors the Secretary of Energy (''Secretary'') considers relevant.

(42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

DOE is publishing this NOPD in satisfaction of EPCA's requirement to determine whether the standards in effect for GSILs should be amended. (42 U.S.C. 6295(i)(6)(A)(i) and (iii))

1. Current Standards

In a final rule published on March 23, 2009, DOE codified the current energy conservation standards, prescribed by EISA, for GSILs manufactured after January 1, 2012; January 1, 2013; or January 1, 2014. 74 FR 12058. These standards require a color rendering index (CRI) greater than or equal to 80 for standard spectrum lamps (or greater than or equal to 75 for modified spectrum lamps) and, for four specified lumen ranges, a rated wattage no greater than and a rated lifetime no less than the values set forth in DOE's regulations at 10 CFR 430.32(x)(1) and repeated in the tables below.

TABLE II.1—FEDERAL ENERGY CONSERVATION STANDARDS FOR STANDARD SPECTRUM GSILS

Rated lumen ranges	Maximum rate wattage	Minimum rate life-time	Effective date
1490–2600	72	1,000 hrs	1/1/2012
1050–1489	53	1,000 hrs	1/1/2013
750–1049	43	1,000 hrs	1/1/2014
310–749	29	1,000 hrs	1/1/2014

TABLE II.2—FEDERAL ENERGY CONSERVATION STANDARDS FOR MODIFIED SPECTRUM GSILS

Rated lumen ranges	Maximum rate wattage	Minimum rate life-time	Effective date
1118–1950	72	1,000 hrs	1/1/2012
788–1117	53	1,000 hrs	1/1/2013
563–787	43	1,000 hrs	1/1/2014
232–562	29	1,000 hrs	1/1/2014

[3] DOE provides a more detailed explanation as to why the preemption exceptions are not available to California and Nevada in its General Service Lamps Definition Rule published elsewhere in today's **Federal Register**.

2. History of Standards Rulemakings for GSILs

GSILs are a subset of GSLs. As described in section II.A, EPCA directed DOE to conduct two rulemaking cycles to evaluate energy conservation standards for GSLs and outlined several specific criteria for each rulemaking cycle. DOE initiated the first GSL standards rulemaking process by publishing in the **Federal Register** a notice of a public meeting and availability of a framework document. 78 FR 73737 (December 9, 2013); see also 79 FR 73503 (December 11, 2014) (notice of public meeting and availability of preliminary analysis). DOE later issued a notice of proposed rulemaking (NOPR) to propose amended energy conservation standards for GSLs. 81 FR 14528, 14629–14630 (March 17, 2016) (the March 2016 GSL NOPR). The March 2016 GSL NOPR focused on the first question that Congress directed DOE to consider—whether to amend energy conservation standards for general service lamps. (42 U.S.C. 6295(i)(6)(A)(i)(I)) In the March 2016 GSL NOPR proposing energy conservation standards for GSLs, DOE stated that it would be unable to undertake any analysis regarding GSILs and other incandescent lamps because of a then applicable congressional restriction (the Appropriations Rider [4]) on the use of appropriated funds to implement or enforce 10 CFR 430.32(x). 81 FR 14528, 14540–14541 (March 17, 2016). Notably, the applicability of this Appropriations Rider, which had been extended in multiple appropriations through 2017, is no longer in effect.[5]

In response to comments on the March 2016 GSL NOPR, DOE conducted additional research and published a notice of proposed definition and data availability (NOPDDA), which proposed to amend the definitions of GSIL, GSL, and other supporting terms. 81 FR 71794, 71815 (Oct. 18, 2016). DOE explained that the October 2016 NOPDDA related to the second question that Congress directed DOE to consider—whether ''the exemptions for certain incandescent lamps should be maintained or discontinued,'' and stated explicitly that the NOPDDA was not a rulemaking to establish an energy conservation standard for GSLs. (42 U.S.C. 6295(i)(6)(A)(i)(II)); see also 81 FR 71798. The relevant ''exemptions,'' DOE explained, referred to the 22 categories of incandescent lamps that are statutorily excluded from the definitions of GSIL and GSL. 81 FR 71798. In the NOPDDA, DOE clarified that it was defining what lamps constitute GSLs so that manufacturers could understand how any potential energy conservation standards might apply to the market. *Id.*

On January 19, 2017, DOE published two final rules concerning the definition of GSL and related terms. 82 FR 7276; 82 FR 7322. The January 2017 definition final rules amended the definitions of GSIL and GSL by bringing certain categories of lamps that had been excluded by statute from the definition of GSIL within the definitions of GSIL and GSL. Like the October 2016 NOPDDA, DOE stated that the January 2017 definition final rules related only to the second question that Congress directed DOE to consider, regarding whether to maintain or discontinue certain ''exemptions.'' (42 U.S.C. 6295(i)(6)(A)(i)(II)). That is, neither of the two final rules issued on January 19, 2017, purported to establish energy conservation standards applicable to GSLs.

With the removal of the Appropriations Rider in the Consolidated Appropriations Act, 2017, DOE is no longer restricted from undertaking analysis and decision making required by the first question presented by Congress, *i.e.,* whether to amend energy conservation standards for general service lamps, including GSILs. Thus, on August 15, 2017, DOE published a notice of data availability (NODA) and request for information seeking data for GSILs and other incandescent lamps. 82 FR 38613 (August 2017 NODA). The purpose of this NODA was to assist DOE in making a decision on the first question posed to DOE by Congress; *i.e.,* a determination regarding whether standards for GSILs should be amended. Comments submitted in response to the NODA also led DOE to re-consider the decisions it had already made with respect to the second question presented to DOE; *i.e.,* whether the exemptions for certain incandescent lamps should be maintained or discontinued. As a result of the comments received in response to the August 2017 NODA, DOE re-assessed the legal interpretations underlying certain decisions made in the January 2017 definition final rules and issued a NOPR on February 11, 2019 to withdraw the revised definitions of GSL, GSIL, and the supporting definitions established in the January 2017 definition rules (the February 2019 NOPR). 84 FR 3120. DOE held a public meeting on February 28, 2019 to hear oral comments and solicit information and data relevant to the February 2019 NOPR. Representatives for manufacturers, trade associations, environmental and energy efficiency advocates, and other interested parties attended the meeting.[6]

The determination on whether to amend standards for GSILs remains a decision DOE is obligated to make and is addressed in this NOPD. DOE has used the data and comments received in response to the August 2017 NODA and any relevant data and comments received in response to the February 2019 NOPR to conduct its analysis of whether energy conservation standards for GSILs need to be amended.

III. General Discussion

DOE developed this proposed determination after considering oral and written comments, data, and information from interested parties that represent a variety of interests. This NOPD addresses issues raised by these commenters.

A. Product Classes and Scope of Coverage

When evaluating and establishing energy conservation standards, DOE divides covered products into product classes by the type of energy used or by capacity or other performance-related features that justify differing standards. In making a determination whether a performance-related feature justifies a different standard, DOE must consider such factors as the utility of the feature to the consumer and other factors DOE determines are appropriate. (42 U.S.C. 6295(q)) The product classes for this proposed determination are discussed in further detail in section IV.A.5 of this document. This proposed determination covers GSILs as currently defined in 10 CFR 430.2, which is the same as the statutory definition for GSIL. The scope of coverage is discussed in further detail in section IV.A.1 of this document.

B. Test Procedure

EPCA sets forth generally applicable criteria and procedures for DOE's adoption and amendment of test procedures. (42 U.S.C. 6293) Manufacturers of covered products must

[4] Section 312 of the Consolidated and Further Continuing Appropriations Act, 2016 (Pub. L. 114–113, 129 Stat. 2419) prohibits expenditure of funds appropriated by that law to implement or enforce: (1) 10 CFR 430.32(x), which includes maximum wattage and minimum rated lifetime requirements for GSILs; and (2) standards set forth in section 325(i)(1)(B) of EPCA (42 U.S.C. 6295(i)(1)(B)), which sets minimum lamp efficiency ratings for incandescent reflector lamps.

[5] See, the Consolidated Appropriations Act of 2017 (Pub. L. 115–31, div. D, tit. III); See also, Consolidated Appropriations Act, 2018 (Pub. L. 115–141); Continuing Appropriations Act, 2019 (Pub. L. 115–245).

[6] A transcript of the public meeting and supporting documents are available in the docket at: *https://www.regulations.gov/docket?D=EERE-2018-BT-STD-0010.*

use these test procedures to certify to DOE that their product complies with energy conservation standards and to quantify the efficiency of their product. DOE's current energy conservation standards for GSILs are expressed in terms of a maximum rated wattage and a minimum rated lifetime. (See 10 CFR 430.32(x))

A final rule published on July 6, 2009 revised the test procedure for GSILs to reflect the energy conservation standards prescribed by EISA. The July 2009 final rule concluded that GSILs do not operate in standby or off mode. 74 FR 31829. DOE published a test procedure final rule on January 27, 2012, establishing revised active mode test procedures for GSILs. 77 FR 4203. The test procedure for GSILs is codified in appendix R to subpart B of 10 CFR part 430.

DOE has since published a request for information (RFI) to initiate a data collection process to consider whether to amend DOE's test procedures for general service fluorescent lamps, GSILs, and incandescent reflector lamps. 82 FR 37031 (August 8, 2017).

C. Technological Feasibility

1. General

In evaluating potential amendments to energy conservation standards, DOE conducts a screening analysis based on information gathered on all current technology options and prototype designs that could improve the efficiency of the products or equipment that are the subject of the rulemaking. As the first step in such an analysis, DOE develops a list of technology options for consideration in consultation with manufacturers, design engineers, and other interested parties. DOE then determines which of those means for improving efficiency are technologically feasible. DOE considers technologies incorporated in commercially available products or in working prototypes to be technologically feasible. 10 CFR part 430, subpart C, appendix A, section 4(a)(4)(i)

After DOE has determined that particular technology options are technologically feasible, it further evaluates each technology option in light of the following additional screening criteria: (1) Practicability to manufacture, install, and service; (2) adverse impacts on product utility or availability; and (3) adverse impacts on health or safety. 10 CFR part 430, subpart C, appendix A, section 4(a)(4)(ii)–(iv) Additionally, it is DOE policy not to include in its analysis any proprietary technology that is a unique pathway to achieving a certain efficacy level. Section IV.A.4 of this document discusses the results of the screening analysis for GSILs, particularly the designs DOE considered, those it screened out, and those that are the basis for the standards considered in this proposed determination.

2. Maximum Technologically Feasible Levels

As when DOE proposes to adopt an amended standard for a type or class of covered product, in this analysis it must determine the maximum improvement in energy efficiency or maximum reduction in energy use that is technologically feasible for such a product. (42 U.S.C. 6295(p)(1)) Accordingly, in the engineering analysis, DOE determined the maximum technologically feasible (''max-tech'') improvements in energy efficiency for GSILs, using the design parameters for the most efficient products available on the market or in working prototypes. The max-tech levels that DOE determined for this analysis are described in section IV.B of this proposed determination.

D. Energy Savings

1. Determination of Savings

For the trial standard level (TSL) evaluated, DOE projected energy savings from application of the TSL to the GSIL purchased in the 30-year period that begins in the assumed year of compliance with the potential standards (2023–2052). The savings are measured over the entire lifetime of the GSILs and substitute lamps purchased in the 30-year period. DOE quantified the energy savings attributable to TSL 1 as the difference in energy consumption between the standards case with substitution effects and the no-new-standards case. The no-new-standards case represents a projection of energy consumption that reflects how the market for a product would likely evolve in the absence of amended energy conservation standards. In this case, the standards case represents energy savings not from the technology outlined in TSL 1, but from product substitution as consumers are priced out of the market for GSILs. DOE used its NIA spreadsheet model to estimate national energy savings (NES) from potential amended standards for GSILs. The NIA spreadsheet model (described in section IV.G of this document) calculates energy savings in terms of site energy, which is the energy directly consumed by products at the locations where they are used. For electricity, DOE reports NES in terms of site energy savings and source energy savings, the latter of which is the savings in the energy that is used to generate and transmit the site electricity. DOE also calculates NES in terms of full-fuel-cycle (FFC) energy savings. The FFC metric includes the energy consumed in extracting, processing, and transporting primary fuels (*i.e.,* coal, natural gas, petroleum fuels), and thus presents a more complete picture of the impacts of energy conservation standards.[7] DOE's approach is based on the calculation of an FFC multiplier for each of the energy types used by covered products or equipment. For more information on FFC energy savings, see section IV.G of this document.

2. Significance of Savings

In determining whether amended standards are needed, DOE must consider whether such standards will result in significant conservation of energy. (42 U.S.C. 6295(m)(1)(A)) Although the term ''significant'' is not defined in EPCA, DOE recently proposed to define a significant energy savings threshold (''Process Rule''). 84 FR 3910 (February 13, 2019). Specifically, DOE stated that it is considering using a two-step approach that would consider both a quad threshold value (over a 30-year period) and a percentage threshold value to ascertain whether a potential standard satisfies 42 U.S.C. 6295(o)(3)(B) to ensure that DOE avoids setting a standard that ''will not result in significant conservation of energy.'' 84 FR 3901, 3924. DOE's updates to the Process Rule have not yet been finalized.

E. Economic Justification

1. Specific Criteria

EPCA provides seven factors to be evaluated in determining whether a potential energy conservation standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)) The following sections discuss how DOE has addressed each of those seven factors in this rulemaking.

a. Economic Impact on Manufacturers and Consumers

In determining the impacts of a potential amended standard on manufacturers, DOE conducts an MIA, as discussed in section IV.H. DOE first uses an annual cash-flow approach to determine the quantitative impacts. This step includes both a short-term assessment—based on the cost and

[7] The FFC metric is discussed in DOE's statement of policy and notice of policy amendment. 76 FR 51282 (Aug. 18, 2011), as amended at 77 FR 49701 (Aug. 17, 2012).

capital requirements during the period between when a regulation is issued and when entities must comply with the regulation—and a long-term assessment over a 30-year period. The industry-wide impacts analyzed include industry net present value (INPV), which values the industry based on expected future cash flows; cash flows by year; changes in revenue and income; and other measures of impact, as appropriate. Second, DOE analyzes and reports the impacts on different types of manufacturers, including impacts on small manufacturers. Third, DOE considers the impact of standards on domestic manufacturer employment and manufacturing capacity, as well as the potential for standards to result in plant closures and loss of capital investment. Finally, DOE takes into account cumulative impacts of various DOE regulations and other regulatory requirements on manufacturers.

For individual consumers, measures of economic impact include the changes in LCC and PBP associated with new or amended standards. These measures are discussed further in the following section. For consumers in the aggregate, DOE also calculates the national net present value of the economic impacts applicable to a particular rulemaking. DOE also evaluates the LCC impacts of potential standards on identifiable subgroups of consumers that may be affected disproportionately by a national standard. However, because DOE has tentatively concluded amended standards for GSILs would not result in significant energy savings and, as discussed further in section V.E.3, would not be economically justified for one of the potential standard levels evaluated based on the PBP analysis, DOE did not conduct an LCC subgroup analysis for this notice.

b. Savings in Operating Costs Compared to Increase in Price

EPCA requires DOE to consider the savings in operating costs throughout the estimated average life of the covered product compared to any increase in the price of the covered product that is likely to result from the imposition of the standard. (42 U.S.C. 6295(o)(2)(B)(i)(II)) DOE conducts this comparison in its LCC and PBP analysis.

The LCC is the sum of the purchase price of a product (including its installation) and the operating expense (including energy, maintenance, and repair expenditures) discounted over the lifetime of the product. To account for uncertainty and variability in specific inputs, such as product lifetime and discount rate, DOE uses a distribution of values, with probabilities attached to each value. For its analysis, DOE assumes that consumers will purchase the covered products in the first year of compliance with amended standards. In this analysis, DOE estimates the consumer LCC of the covered product under a standards scenario and, as an input to the NPV, the consumer LCC of switching to substitute products as a replacement for the covered product. However, as described above the statutory factor addressed in this analysis is the savings in operating costs throughout the estimated average life of the *covered product* in the type (or class) compared to any increase in the price of, or in the initial charges for, or maintenance expenses of, the *covered products* which are likely to result from the imposition of the standard (emphasis added). Moreover, EPCA prohibits DOE from prescribing an amended or new standard if doing so is likely to result in the unavailability in the United States in any *covered product* type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States at the time of the Secretary's finding (emphasis added). As such, while DOE presents the LCC of switching to substitute products as a replacement for the covered product, DOE cannot, in this determination, consider those LCC savings in making a determination as to whether amended standards for the covered product are economically justified because those LCC savings result from the unavailability of the covered product. Rather, DOE's determination regarding economic justification must be based on LCC savings resulting from establishing an amended standard for the covered product, *i.e.,* GSILs.

The LCC savings for the considered standard levels are calculated relative to the no-new-standards case and the PBP for the considered efficacy levels are calculated relative to the baseline. DOE's LCC and PBP analysis is discussed in further detail in section IV.E of this document.

c. Energy Savings

Although significant conservation of energy is a separate statutory requirement for adopting an energy conservation standard, EPCA requires DOE, in determining the economic justification of a standard, to consider the total projected energy savings that are expected to result directly from the standard. (42 U.S.C. 6295(o)(2)(B)(i)(III)) As discussed in section IV.G, DOE uses the NIA spreadsheet to project national site energy savings.

d. Lessening of Utility or Performance of Products

In establishing classes of products, and in evaluating design options and the impact of potential standard levels, DOE evaluates standards that would not lessen the utility or performance of the considered products. (42 U.S.C. 6295(o)(2)(B)(i)(IV)) Based on data available to DOE, the standards considered in this proposed determination would not reduce the utility or performance of the products under consideration in this proposed determination.

e. Impact of Any Lessening of Competition

EPCA directs DOE to consider the impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from a proposed standard. (42 U.S.C. 6295(o)(2)(B)(i)(V)) It also directs the Attorney General to determine the impact, if any, of any lessening of competition likely to result from a standard and to transmit such determination to the Secretary within 60 days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. (42 U.S.C. 6295(o)(2)(B)(ii)) Because DOE is not proposing standards for GSILs, DOE did not transmit a copy of its proposed determination to the Attorney General.

f. Need for National Energy Conservation

In evaluating the need for national energy conservation, DOE expects that energy savings from amended standards would likely provide improvements to the security and reliability of the nation's energy system. Reductions in the demand for electricity also may result in reduced costs for maintaining the reliability of the nation's electricity system. Energy savings from amended standards also would likely result in environmental benefits in the form of reduced emissions of air pollutants and greenhouse gases primarily associated with fossil-fuel based energy production. Because DOE has tentatively concluded amended standards for GSILs would not be economically justified for the potential standard level evaluated based on the PBP analysis, DOE did not conduct a utility impact analysis or emissions analysis for this NOPD.

g. Other Factors

EPCA allows the Secretary of Energy, in determining whether a standard is economically justified, to consider any other factors that the Secretary deems to

be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII))

2. Rebuttable Presumption

As set forth in 42 U.S.C. 6295(o)(2)(B)(iii), EPCA creates a rebuttable presumption that an energy conservation standard is economically justified if the additional cost to the consumer of a product that meets the standard is less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable DOE test procedure. DOE's LCC and PBP analyses generate values used to calculate the effect potential amended energy conservation standards would have on the payback period for consumers. These analyses include, but are not limited to, the 3-year payback period contemplated under the rebuttable-presumption test. In addition, DOE routinely conducts an economic analysis that considers the full range of impacts to consumers, manufacturers, the nation, and the environment, as required under 42 U.S.C. 6295(o)(2)(B)(i). The results of this analysis serve as the basis for DOE's evaluation of the economic justification for a potential standard level (thereby supporting or rebutting the results of any preliminary determination of economic justification). The rebuttable-presumption payback calculation is discussed in section V.B.2 of this document.

IV. Methodology and Discussion of Related Comments

This section addresses the analyses DOE has performed for this proposed determination with regard to GSILs. Separate subsections address each component of DOE's analyses. DOE used several analytical tools to estimate the impact of potential energy conservation standards. The first tool is a spreadsheet that calculates the LCC savings and PBP of potential energy conservation standards. The NIA uses a second spreadsheet set that provides shipments projections and calculates NES and net present value of total consumer costs and savings expected to result from potential energy conservation standards. DOE uses the third spreadsheet tool, the Government Regulatory Impact Model (GRIM), to assess manufacturer impacts of potential standards. These three spreadsheet tools are available in the docket (see *Docket* section at the beginning of this NOPD).

A. Market and Technology Assessment

DOE develops information in the market and technology assessment that provides an overall picture of the market for the products concerned, including the purpose of the products, the industry structure, manufacturers, market characteristics, and technologies used in the products. This activity includes both quantitative and qualitative assessments, based primarily on publicly available information. The subjects addressed in the market and technology assessment for this proposed determination include (1) a determination of the scope and product classes, (2) manufacturers and industry structure, (3) existing efficiency programs, (4) shipments information, (5) market and industry trends, and (6) technologies or design options that could improve the energy efficiency of GSILs. The key findings of DOE's market assessment are summarized in the following sections.

1. Scope of Coverage

GSIL means a standard incandescent or halogen type lamp that is intended for general service applications; has a medium screw base; has a lumen range of not less than 310 lumens and not more than 2,600 lumens or, in the case of a modified spectrum lamp, not less than 232 lumens and not more than 1,950 lumens; and is capable of being operated at a voltage range at least partially within 110 and 130 volts; however this definition does not apply to the following incandescent lamps: (1) An appliance lamp; (2) A black light lamp; (3) A bug lamp; (4) A colored lamp; (5) An infrared lamp; (6) A left-hand thread lamp; (7) A marine lamp; (8) A marine signal service lamp; (9) A mine service lamp; (10) A plant light lamp; (11) A reflector lamp; (12) A rough service lamp; (13) A shatter-resistant lamp (including a shatter-proof lamp and a shatter-protected lamp); (14) A sign service lamp; (15) A silver bowl lamp; (16) A showcase lamp; (17) A 3-way incandescent lamp; (18) A traffic signal lamp; (19) A vibration service lamp; (20) A G shape lamp with a diameter of 5 inches or more; (21) A T shape lamp that uses not more than 40 watts or has a length of more than 10 inches; and (22) A B, BA, CA, F, G16–1/2, G–25, G30, S, or M–14 lamp of 40 watts or less. 10 CFR 430.2 In this analysis, DOE relied on the definition of ''general service incandescent lamp'' currently in 10 CFR 430.2.

2. Metric

Current energy conservation standards for GSILs are applicable to active mode energy use and are based on a maximum wattage for a given lumen range. In this proposed determination, DOE used efficacy (lumens divided by watts, or lm/W) to assess active mode energy use. The measurement of lumens and watts and the calculation of lamp efficacy for GSILs is included in the current test procedure at appendix R to subpart B of 10 CFR part 430.

3. Technology Options

To develop a list of technology options, DOE reviewed manufacturer catalogs, recent trade publications, technical journals, and the 2015 IRL final rule [8] for incandescent reflector lamps (IRLs), and consulted with technical experts. Based on DOE's review of product offerings and their efficacies in manufacturer catalogs and DOE's Compliance Certification Management System (CCMS) database, GSILs are not commercially available at efficacy levels above that which is currently required. However, DOE identified an infrared coatings technology previously used in commercially available IRLs that could be used to improve the efficiency of currently commercially available GSILs.

Infrared (IR) coatings on incandescent lamps are used to reflect some of the radiant energy emitted back onto the filament. This infrared radiation then supplies heat to the filament and the operating temperature increases. An increase in operating temperature results in a higher light output and therefore an increase in efficacy. These infrared coatings are most commonly applied directly to the burner, or capsule, of a halogen lamp, which achieves the greatest directed reflection back onto the filament for the lowest infrared coating usage. For more detail, see chapter 3 of the technical support document (TSD) for the 2015 IRL final rule.[9]

In response to the August 2017 NODA and the February 2019 NOPR, several stakeholders commented on potential pathways to improve the efficacy of GSILs. The National Electrical Manufacturers Association (NEMA) and General Electric (GE) stated that there are no GSILs available that are more efficacious than the current GSILs on the market. (NEMA, No. 4 at p. 31; [10]

[8] Documents from DOE's rulemaking for IRLs are available here: *https://www.regulations.gov/docket?D=EERE-2011-BT-STD-0006*.

[9] The TSD for the 2015 IRL final rule is available at *https://www.regulations.gov/document?D=EERE-2011-BT-STD-0006-0066*.

[10] A notation in this form provides a reference for information that is in the docket of either the August 2017 NODA (Docket No. EERE–2017–BT–NOA–0052) or the February 2019 NOPR (Docket No. EERE–2018–BT–STD–0010). This notation indicates that the statement preceding the reference is document number 4 in the applicable docket, and appears at page 31 of that document.

GE, No. 3 at p. 7) [11] However, NEMA and GE both noted that more efficacious GSILs were previously manufactured and distributed in commerce. (NEMA, No. 4 at p. 32; GE, No. 3 at p. 14) [11] GE, several years ago, offered two GSILs that used a halogen capsule with an infrared coating, referred to as halogen infrared (HIR) technology. Both HIR lamps had rated lifetimes of 3,000 hours and the 60-watt equivalent had a rated wattage of 45 watts whereas the 100-watt equivalent had a rated wattage of 65 watts. GE stated that neither of the products were commercially successful and both were discontinued after several years. (GE, No. 3 at p. 14) [11] GE also noted that the lifetime of the HIR lamp could be shortened to reduce its wattage and therefore make it more efficacious but the purchase price would not change and there would be fewer hours over which to recover the high initial purchase price. (GE, No. 3 at p. 16) [11] NEMA added in response to the February 2019 NOPR that Venture Lighting had also sold but then discontinued a more efficacious halogen GSIL and that TCP had never introduced a more efficacious halogen GSIL because it determined the cost of the product was too high. (NEMA, No. 329 at pp. 37–38) [12]

Because HIR technology was used in GSILs in the past and is still used in commercially available IRLs, it is a technology that could be used to improve the efficiency of currently commercially available GSILs. Although IRLs include a reflector to direct light, the presence of a reflector is not necessary to employ HIR technology. An IR coating is applied directly to a halogen capsule, which is present in lamps both with and without reflectors. Indeed, currently commercially available GSILs and IRLs include halogen capsules. GE stated that the lamps were not commercially successful because they could not be ''economically justified'' (GE, No. 3 at pp. 14–16),[11] and DOE is directed by EPCA to consider enumerated factors in evaluating whether standards are economically justified. (42 U.S.C. 6295(o)(2)(B)(i)) The analysis corresponding to the EPCA requirements and the results are presented in section V. DOE does not consider cost when identifying technology options.

In summary, for this analysis, DOE considers the technology options shown in Table IV.1.

TABLE IV.1—GSIL TECHNOLOGY OPTIONS

Name of technology option	Description
Higher Temperature Operation	Operating the filament at higher temperatures, the spectral output shifts to lower wavelengths, increasing its overlap with the eye sensitivity curve.
Microcavity Filaments	Texturing, surface perforations, microcavity holes with material fillings, increasing surface area and thereby light output.
Novel Filament Materials	More efficient filament alloys that have a high melting point, low vapor pressure, high strength, high ductility, or good radiating characteristics.
Thinner Filaments	Thinner filaments to increase operating temperature. This measure may shorten the operating life of the lamp.
Crystallite Filament Coatings	Layers of micron or submicron crystallites deposited on the filament surface that increases emissivity of the filament.
Higher Efficiency Inert Fill Gas	Filling lamps with alternative gases, such as Krypton, to reduce heat conduction.
Higher Pressure Tungsten-Halogen Lamps	Increased halogen bulb burner pressurization, allowing higher temperature operation.
Non-Tungsten-Halogen Regenerative Cycles	Novel filament materials that regenerate.
Infrared Glass Coatings	When used with a halogen burner, this is referred to as an HIR lamp. Infrared coatings on the inside of the bulb to reflect some of the radiant energy back onto the filament.
Infrared Phosphor Glass Coatings	Phosphor coatings that can absorb infrared radiation and re-emit it at shorter wavelengths (visible region of light), increasing the lumen output.
Ultraviolet Phosphor Glass Coatings	Phosphor coatings that convert ultraviolet radiation into longer wavelengths (visible region of light), increasing the lumen output.
High Reflectance Filament Supports	Filament supports that include a reflective face that reflects light to another filament, the reflective face of another filament support, or radially outward.
Permanent Infrared Reflector Coating Shroud	Permanent shroud with an IR reflector coating and a removable and replaceable lamp can increase efficiency while reducing manufacturing costs by allowing IR reflector coatings to be reused.
Higher Efficiency Burners	A double-ended burner that features a lead wire outside of the burner, where it does not interfere with the reflectance of energy from the burner wall back to the burner filament in HIR lamps.

4. Screening Analysis

DOE uses the following four screening criteria to determine which technology options are suitable for further consideration in an energy conservation standards rulemaking:

(1) *Technological feasibility.* Technologies that are not incorporated in commercial products or in working prototypes will not be considered further.

(2) *Practicability to manufacture, install, and service.* If it is determined that mass production and reliable installation and servicing of a technology in commercial products could not be achieved on the scale necessary to serve the relevant market at the time of the projected compliance date of the standard, then that technology will not be considered further.

(3) *Impacts on product utility or product availability.* If it is determined that a technology would have significant adverse impact on the utility of the product to significant subgroups of consumers or would result in the unavailability of any covered product type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as products

[11] These documents were submitted to the docket of DOE's request for data regarding incandescent lamps (Docket No. EERE–2017–BT–NOA–0052).

[12] This document was submitted to the docket of DOE's proposal to withdraw the revised definitions of GSL and GSIL that take effect on January 1, 2020. (Docket No. EERE–2018–BT–STD–0010)

generally available in the United States at the time, it will not be considered further.

(4) *Adverse impacts on health or safety.* If it is determined that a technology would have significant adverse impacts on health or safety, it will not be considered further.

10 CFR part 430, subpart C, appendix A, 4(a)(4) and 5(b)

In summary, if DOE determines that a technology, or a combination of technologies, fails to meet one or more of the listed four criteria, it will be excluded from further consideration in the engineering analysis. Additionally, it is DOE policy not to include in its analysis any proprietary technology that is a unique pathway to achieving a certain efficacy level.

DOE reviewed the technology options identified in Table IV.1 and screened out several because DOE could not find evidence of their existence in working prototypes or commercially available products. For several of them, DOE also screened them out based on the practicability to manufacture and/or impacts on product utility. Table IV.2 summarizes the technology options screened out.

TABLE IV.2—GSIL TECHNOLOGY OPTIONS SCREENED OUT OF THE ANALYSIS

Design option excluded	Screening criteria
Novel Filament Materials	Technological feasibility, Practicability to manufacture, install, and service, Adverse impact on product utility.
Microcavity Filaments	Technological feasibility, Practicability to manufacture, install, and service, Adverse impact on product utility.
Crystallite Filament Coatings	Technological feasibility, Practicability to manufacture, install, and service.
High Reflectance Filament Supports	Technological feasibility, Practicability to manufacture, install, and service.
Non-Tungsten-Halogen Regenerative Cycles	Technological feasibility, Practicability to manufacture, install, and service, Adverse impact on product utility.
Permanent Infrared Reflector Coating Shroud	Technological feasibility, Practicability to manufacture, install, and service.
Infrared Phosphor Glass Coating	Technological feasibility, Practicability to manufacture, install, and service.
Ultraviolet Phosphor Glass Coating	Technological feasibility, Practicability to manufacture, install, and service.

DOE did not screen out infrared glass coatings. As noted in section IV.A.3, infrared glass coatings were previously used to improve the efficiency of GSILs; however those products were not commercially viable and are no longer available. The existence of a commercially available GSIL that employed the technology in the recent past, in addition to the existence of a commercially available IRL that currently employs the technology on halogen capsules that could be used in GSILs, indicates that infrared glass coatings are technologically feasible and practicable to manufacture, install, and service. DOE is not aware of any adverse impacts on product utility or adverse impacts on health or safety; IRLs that use the technology have been available for at least 10 years with no significant issues. As described by GE, it was a business decision to discontinue the GSILs that utilized infrared glass coatings because of their high costs. DOE considers economic impacts on consumers, manufacturers, and the nation as described in sections IV.E, IV.H, and IV.G.

DOE tentatively concludes that the remaining technologies pass all four screening criteria to be examined further as design options in this analysis. In summary, DOE did not screen out the following technology options and considers them as design options in the engineering analysis:

- Higher Temperature Operation
- Thinner Filaments
- Higher Efficiency Inert Fill Gas
- Higher Pressure Tungsten-Halogen Lamps
- Infrared Glass Coatings
- Higher Efficiency Burners

5. Product Classes

In general, when evaluating and establishing energy conservation standards, DOE divides the covered product into classes by (1) the type of energy used, (2) the capacity of the product, or (3) any other performance-related feature that affects energy efficiency and justifies different standard levels, considering factors such as consumer utility. (42 U.S.C. 6295(q)) Product classes for GSILs are currently divided based on lamp spectrum and lumen output.

DOE proposes to maintain separate product classes based on lamp spectrum. Modified spectrum [13] lamps provide unique utility to consumers by providing a different type of light than standard spectrum lamps, much like fluorescent and light-emitting diode (LED) lamps with different correlated color temperature (CCT) values. However, the same technologies that modify the spectral emission of a lamp also decrease lamp efficacy. To modify the spectrum, the coating absorbs a portion of the light emission from the filament. Neodymium coatings or other coatings on modified spectrum lamps absorb some of the visible emission from the incandescent filament (usually red), creating a modified, reduced spectral emission. Since the neodymium or other coatings absorb some of the lumen output from the filament, these coatings decrease the efficacy of the lamp. Because of the impact on both efficacy and utility, DOE is proposing to maintain separate product classes based on spectrum. DOE is proposing separate product classes for standard spectrum GSILs (those without modification to the spectral emission) and modified spectrum GSILs (some portion of the spectral emission is absorbed).

DOE did not separate product classes based on lumen output for the evaluation under this proposed determination. As described in section IV.B.4, DOE evaluated efficacy levels (ELs) that use an equation to determine the minimum required efficacy based on the lamp's lumen output. Current product classes for GSILs are separated based on lumen output, with a constant maximum wattage specified for a given lumen range. This results in the minimum efficacy requirement increasing as lumen output increases across a given lumen range. DOE evaluated efficacy levels that follow the same trend; that is, minimum required efficacy increases as lumen output increases. Because DOE is evaluating efficacy levels based on an equation in which the minimum efficacy requirement changes based on the lumen output of the lamp, DOE did not evaluate separate product classes based on lumen output.

In summary, DOE evaluated two product classes for GSILs—one for GSILs that meet the definition of

[13] See CFR 430.2 for the definition of ''modified spectrum'' with respect to an incandescent lamp.

modified spectrum in 10 CFR 430.2 and one for standard spectrum GSILs (*i.e.,* do not meet the definition of modified spectrum). See chapter 3 of the NOPD TSD for further discussion.

B. Engineering Analysis

In the engineering analysis, DOE selects representative product classes to analyze. It then selects baseline lamps within those representative product classes and identifies more-efficacious substitutes for the baseline lamps. DOE uses these more-efficacious lamps to develop efficacy levels.

For this proposed determination, DOE selected more efficacious substitutes in the engineering analysis and determined the consumer prices of those substitutes in the product price determination. DOE estimated the consumer price of lamps directly because reverse-engineering is impractical since the lamps are not easily disassembled. By combining the results of the engineering analysis and the product price determination, DOE derived typical inputs for use in the LCC analysis and NIA. Section IV.C discusses the product price determination.

The methodology for the engineering analysis consists of the following steps: (1) Select representative product classes, (2) select baseline lamps, (3) identify more efficacious substitutes, (4) develop efficacy levels by directly analyzing representative product classes, and (5) scale efficacy levels to non-representative product classes. The details of the engineering analysis are discussed in chapter 5 of the NOPD TSD.

1. Representative Product Classes

In the case where a covered product has multiple product classes, DOE identifies and selects certain product classes as ''representative'' and concentrates its analytical effort on those classes. DOE chooses product classes as representative primarily because of their high market volumes. Based on its assessment of product offerings, DOE analyzed as representative standard spectrum GSILs (only 3 percent of commercially available halogen GSILs were marketed as having a modified spectrum). This is consistent with the 2015 IRL rulemaking in which DOE analyzed, with support from NEMA, standard spectrum IRLs as representative. 79 FR 24068, 24107 (April 29, 2014).

2. Baseline Lamps

For each representative product class, DOE selects a baseline lamp as a reference point against which to measure changes resulting from energy conservation standards. Typically the baseline lamp is the most common, least efficacious lamp that meets existing energy conservation standards. In this analysis, DOE selected as a baseline the least efficacious lamp meeting standards with the most common lumen output and, where possible, with the most common wattage, lifetime, input voltage, and shape for the product class.

DOE reviewed certified GSILs in DOE's compliance certification database and also used a database of commercially available products to identify the baseline lamp. DOE identified 60 watt equivalent lamps, or lamps with a lumen output between 750 and 1,049 lumens, to be the most common lamps based on the number of products certified within this lumen range in the compliance certification database. This is consistent with DOE's conclusion in the March 2016 GSL NOPR that 60-watt equivalent lamps were the most popular lamps within the 310 to 2,000 lumen product class. 81 FR 14528, 14568–14569 (March 17, 2016). DOE also analyzed certified GSILs to identify a common wattage and lifetime. For lamps with a lumen output between 750 and 1,049 lumens, DOE found certified rated wattage values to range from 41.9 to 43 watts and certified rated lifetime values to range from 1,000 to 2,056 hours. The wattage values were distributed among the range and about equally distributed between values that would round to 42 watts and values that would round to 43 watts. Products available in catalogs and on websites reported rated wattage to the nearest whole number rather than the nearest tenth of a watt. A database of commercially available products showed the most popular wattage to be 43 watts (92 percent of all halogen GSILs within the lumen range, 100 percent of all GSILs marketed as a 60 watt equivalent). Among GSILs with a lumen output between 750 and 1,049 lumens, the most common rated lifetime was 1,000 hours (76 percent of all certified GSILs within the lumen range). This was consistent with the database for commercially available products—over 80 percent of halogen lamps with a lumen output between 750 and 1,049 lumens had a lifetime of 1,000 hours and all halogen lamps in the designated lumen range that were marketed as 60 watt equivalents also had a lifetime of 1,000 hours. In addition to rated wattage and rated lifetime, 95 percent of commercially available halogen lamps (100 percent of commercially available halogen lamps marketed as 60 watt equivalents) within the designated lumen range had an input voltage of 120 volts and 70 percent of commercially available halogen lamps within the designated lumen range had an A19 bulb shape.

DOE selected the baseline lamp shown in Table IV.3 because it just meets existing standards within the most common lumen range and also has other common characteristics described in the preceding paragraph. See chapter 5 of the NOPD TSD for more detail.

TABLE IV.3—BASELINE GSIL

EL	Technology	Wattage	Bulb shape	Initial lumens	Rated lifetime (hrs)	Efficacy (lm/W)
EL 0/Baseline	Halogen	43	A19	750	1,000	17.4

3. More-Efficacious Substitutes

Because few, if any, consumers are anticipated to buy HIR lamps under TSL 1, DOE expects that consumers who presently buy GSILs would substitute less expensive lamps, such as CFLs and LEDs. DOE evaluated more-efficacious lamps as replacements for the baseline lamp by considering commercially available products and technologies not eliminated in the screening analysis. DOE could not use data in the compliance certification database to evaluate more efficacious lamps because the information required to calculate efficacy was not included; rated wattage was reported for a given lumen range rather than for an exact lumen output. Instead, DOE reviewed its database of commercially available GSILs for lamps that met the definition of a GSIL, had a lumen output between 750 and 1,049 lumens, had an A-shape, and had a higher efficacy than the baseline lamp while still exceeding the minimum standard established by EISA. DOE did not identify any commercially available GSILs that could serve as more efficacious substitutes for the baseline lamp.

Because no commercially available products could serve as a more efficacious substitute for the baseline lamp, DOE modeled a more efficacious substitute based on design options identified in the screening analysis. As noted in section IV.A.4, the technology options identified as design options must be technologically feasible; practicable to manufacture, install, and service; have no adverse impacts on product utility or product availability; and have no adverse impacts on health or safety.

DOE modeled a more efficacious substitute for the baseline lamp assuming that the modeled lamp utilized IR coatings on the halogen capsule within the baseline lamp. In this instance, the model is based on an actual lamp that previously had been commercially available but was taken off the market for economic reasons, including high upfront cost. The inclusion of an IR coating also increases the lamp's operating temperature and pressure (two other identified design options). DOE's modeled lamp did not incorporate thinner filaments, higher efficiency inert fill gas, or higher efficiency burners because it did not believe including those design options would increase the efficacy beyond that achieved by the combination of an IR coating and higher temperature and pressure operation.

DOE reviewed information submitted by GE regarding GSILs that it previously offered for sale. GE's 60 watt equivalent GSIL that employed IR coatings had a rated wattage of 45 watts and a lifetime of 3,000 hours. DOE reviewed information on discontinued products and found a label that indicated this product had a lumen output of 870 lumens. DOE used a similar methodology as in the 2009 IRL rulemaking [14] and the 2015 IRL rulemaking [15] to adjust the lumen output and lifetime of the lamp to be equal to that of the baseline lamp (see chapter 5 of the TSD for the 2009 IRL final rule). Making these adjustments lowered the rated wattage of the modeled lamp to 34.3 watts. This decrease in wattage in consistent with GE's comment that lowering the lifetime of the HIR lamp would reduce its wattage and therefore make it more efficacious. (GE, No. 3 at p. 16) [11] DOE identifies only energy-saving substitutes in the engineering analysis. The performance characteristics of the modeled HIR lamp are shown in Table IV.4.

TABLE IV.4—MORE EFFICACIOUS GSIL SUBSTITUTES

EL	Technology	Wattage	Bulb shape	Initial lumens	Rated lifetime (hrs)	Efficacy (lm/W)
EL 1	HIR	34.3	A19	750	1,000	21.9

4. Efficacy Levels

After identifying more-efficacious substitutes for the baseline lamp, DOE developed ELs based on the consideration of several factors, including: (1) The design options associated with the specific lamps being studied, (2) the ability of lamps across lumen outputs to comply with the standard level of a given product class, and (3) the max-tech level.

DOE is employing an equation-based approach in this NOPD. DOE is relying on a continuous equation based on its assessment that a step function, where efficacy rises significantly at certain increments in lumen output, is not representative of the technology used by the products covered by this proposed determination. DOE recognizes that a step function increases the potential for products to be introduced at the lowest possible efficacy point in each step. While this could potentially encourage the development of similar-wattage products across the industry, a wide variety of replacement wattages would offer the consumer a greater number of choices. For example, LED lamps exist in many different wattages and consumer choice has been positively impacted. For these reasons, the limitations of a step function outweigh its benefits and DOE is therefore evaluating a standard based on a smooth, continuous equation.

DOE is evaluating a lumens-based approach in this notice. The primary utility provided by a lamp is lumen output, which can be achieved through a wide range of wattages depending on the lamp technology. For this reason, lamps providing equivalent lumen output and therefore intended for the same applications should be subject to the same minimum efficacy requirements. Thus, DOE is considering a continuous equation for ELs that develops a relationship between lumen output and efficacy.

DOE reviewed the equation form used in the March 2016 GSL NOPR to evaluate its applicability to GSILs. Specifically, DOE considered the following equation that relates the lumen output of a lamp to lamp efficacy:

$$Efficacy = A - 29.42 * 0.9983^{\text{initial lumen output}}$$

Where A is a constant that varies by EL.

In the preliminary analysis [16] for the GSL energy conservation standards rulemaking, DOE utilized a database of commercially available lamps to evaluate efficacy trends of GSLs across a range of lumen outputs in order to fit the curve. DOE confirmed the curve fit matched product performance, particularly in the low and high ends of the GSL lumen range. Although GSILs were not included in that analysis because it was legally prohibited by an Appropriations Rider from doing so, the relationship characterized by the equation is consistent with the current standards for GSILs. The structure of the current standards, with a maximum wattage for a given lumen range, results in the least stringent requirement being at the lowest lumen output within each lumen range. Since the current standards have required compliance, products on the market have generally been offered at the lowest lumen output within given lumen range, likely because it is easiest to comply with these requirements. When plotting these commercially available lamps, the efficacy increases as lumen output increases, with the largest jump in efficacy occurring between the lowest and next-lowest lumen output range and each successive jump in efficacy being smaller than the one prior to it. The equation under consideration characterizes the same trend; that is, efficacy sharply increases as lumen

[14] DOE published a final rule on July 14, 2009 amending energy conservation standards for IRLs. The docket for the 2009 rulemaking is available at *https://www.regulations.gov/docket?D=EERE-2006-STD-0131*.

[15] Chapter 5 of the TSD for the 2015 IRL final rule is available at *https://www.regulations.gov/document?D=EERE-2011-BT-STD-0006-0066*.

[16] Prior to publishing the March 2016 GSL NOPR, DOE published a notice in the **Federal Register** announcing the availability of the preliminary analysis. 79 FR 73503 (Dec. 11, 2014).

output increases at the lowest part of the lumen range and then the increases slow down such that a curve is formed with a steep slope at the low end of the lumen range and a flatter slope at the high end of the lumen range. Because the equation from the March 2016 GSL NOPR characterizes the same lumen output-efficacy relationship shown by the current GSIL standards, DOE has used this equation form to establish ELs for GSILs.

As described in section IV.B.3, DOE identified, through modeling, one GSIL technology that could perform at an efficacy higher than existing standards. DOE developed one EL based on the efficacy of the more modeled lamp. Based on a lumen output of 750 lumens and an efficacy of 21.9 lm/W (see Table IV.4), DOE determined EL 1 to have an A value of 30.0. Table IV.5 summarizes the EL developed by the engineering analysis.

TABLE IV.5—EL FOR GSIL REPRESENTATIVE PRODUCT CLASS BASED ON ENGINEERING ANALYSIS

Representative product class	Efficacy level	Efficacy
		lm/W
Standard Spectrum GSILs	EL 1	30.0 − 29.42 * 0.9983 ^ Initial Lumen Output.

5. Scaling to Other Product Classes

DOE identifies and selects certain product classes as representative and analyzes these product classes directly. DOE chooses representative product classes primarily due to their high market volumes. The ELs for product classes that are not directly analyzed (''non-representative product classes'') are then determined by scaling the ELs of the representative product classes. For this analysis DOE directly analyzed standard spectrum GSILs but did not directly analyze modified spectrum GSILs.

DOE developed an EL for the modified spectrum product class by scaling the EL of the standard spectrum product class. The primary difference between these product classes is the lamp spectrum; a coating applied to the lamp modifies its spectral emission but also decreases its efficacy. DOE developed a scaling factor by comparing existing standards for standard spectrum GSILs to similar modified spectrum GSILs. From this analysis DOE determined that the modified spectrum lamps are 25 percent less efficacious than standard spectrum lamps. DOE applied this reduction to the A-value for the EL developed in section IV.B.4.

Table IV.6 summarizes the efficacy requirements for the non-representative product class.

TABLE IV.6—EL FOR GSIL NON-REPRESENTATIVE PRODUCT CLASS BASED ON ENGINEERING ANALYSIS

Non-representative product class	Efficacy level	Efficacy
		lm/W
Modified Spectrum GSILs	EL 1	22.5 − 29.42 * 0.9983 ^ Initial Lumen Output.

6. Product Substitutes

If energy conservation standards for GSILs are amended, consumers may substitute alternative lamps that are not GSILs due to the high upfront cost and long PBP associated with HIR technology. DOE notes that EPCA prohibits DOE from prescribing an amended or new standard if that standard is likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States at the time of the Secretary's finding. 42 U.S.C. 6295(o)(4) As such, DOE could not set a standard applicable to GSILs that results in consumers being left with no choice but an alternative lamp that is a different product type or has different performance characteristics or features than GSILs.

In this analysis, DOE considered several alternatives available to consumers that have the same base type (medium screw base) and input voltage (120 volts) as the baseline lamp. DOE considered two more efficacious lamps that consumers may choose if standards for GSILs are amended: A CFL and an LED lamp. As noted by GE and NEMA, CFLs and LED lamps can be used to satisfy lighting applications traditionally served by incandescent general service lamps. (GE, No. 3 at p. 7; NEMA, No. 4 at p. 31) [11] For consumers who are resistant to changing technology, and for those who are trying to replace a 60 watt incandescent lamp with a 60 watt replacement, DOE also considered a shatter-resistant incandescent lamp that is exempt from the definition of GSIL. Because this lamp is not a GSIL, it would not be subject to amended standards for GSILs and would remain available on the market. However, all of the lamps considered in this consumer choice analysis represent a change in product type, technology and performance characteristics compared to a halogen or HIR lamp, and, thus are provided for informational purposes only. Table IV.7 summarizes the performance characteristics of the GSIL alternatives that consumers can choose if GSIL standards are amended.

TABLE IV.7—ALTERNATIVE LAMPS CONSUMERS MAY SUBSTITUTE FOR GSILS

Option	Technology	Wattage	Bulb shape	Initial lumens	Rated lifetime (hrs)	Efficacy (lm/W)
A	Incandescent	60	A19	587	4,000	9.8
B	CFL	13	Spiral	900	10,000	69.2
C	LED	9	A19	800	15,000	88.9

C. Product Price Determination

Typically, DOE develops manufacturer selling prices (MSPs) for covered products and applies markups to create end-user prices to use as inputs to the LCC analysis and NIA. Because GSILs are difficult to reverse-engineer (*i.e.,* not easily disassembled), DOE directly derives end-user prices for GSILs. End-user price refers to the product price a consumer pays before tax and installation.

In the March 2016 GSL NOPR, DOE observed a range of consumer prices paid for a lamp, depending on the distribution channel through which the lamp was purchased. Specifically, DOE identified the following four main distribution channels: Small Consumer-Based Distributors (*i.e.,* internet retailers, grocery stores, drug stores); Large Consumer-Based Distributors: (*i.e.,* home centers, mass merchants, hardware stores); Electrical Distributors; and State Procurement. For each distribution channel, DOE calculated an average price for the representative lamp unit at each EL using prices for the representative lamp unit and similar lamp models. Because the similar lamp models included in the average price were equivalent to the representative lamp unit in terms of performance and utility (*i.e.,* had similar wattage, CCT, bulb shape, base type, CRI), DOE considered the pricing of these lamps to be representative of the technology of the EL. DOE developed average end-user prices for the representative lamp units sold in each of the four main distribution channels identified. DOE then calculated an average weighted end-user price using estimated shipments through each distribution channel. DOE applied a 10 percent weighting to the Small Consumer-Based Distributors channel, 80 percent to the Large Consumer-Based Distributors channel, 5 percent to the Electrical Distributors channel, and 5 percent to the State Procurement channel.

DOE used the methodology from the March 2016 GSL NOPR to calculate the prices for the GSIL baseline lamp and the three consumer choice alternatives. GSILs and the three consumer choice alternatives are purchased through the same distribution channels as the CFL and LED lamps analyzed in the March 2016 GSL NOPR.

Because DOE modeled an HIR lamp at EL 1, which is not currently commercially available, DOE could not gather prices for commercially available lamps and use the same methodology as the March 2016 GSL NOPR. Instead, DOE reviewed the incremental pricing from the 2015 IRL final rule for the baseline halogen lamp and the more efficacious HIR substitute. HIR technology can be utilized in both omnidirectional lamps and reflector lamps because it is applied directly to halogen capsules contained within both lamp types. DOE therefore added the incremental change in end-user price from the 2015 IRL final rule to the baseline GSIL analyzed in this evaluation.

GE stated that HIR lamps are expensive because the coating of the halogen capsules occurs during a slow and expensive batch manufacturing process. A heavy glass outer jacket is also used because the capsule operates at a higher pressure than standard halogen capsules. GE stated that the price for the HIR lamp it used to offer for sale ranged from $6.00 to $9.00 per lamp depending on the retailer and packaging quantity and that the average price was $7.00 per lamp. GE asserted that reducing the price much below $6.00 was not a long-term economic option because the high cost of the product left little profit margin for the manufacturer or retailer at lower prices. (GE, No. 325 at p. 5) [12] As described in the preceding paragraph, DOE determined the price of the HIR lamp at EL 1 by reviewing the prices for the halogen baseline and HIR lamp in the 2015 IRL final rule. That analysis concluded the price of the HIR lamp to be $7, which aligns with the price estimate submitted by GE. DOE notes that $7 is significantly more than consumers currently pay for 43W Halogen lamps ($1.81), IRLs ($2.15), CFLs ($2.94), and LEDs ($3.00), further illustrating that HIR lamp technology is not commercially viable.

Table IV.8 summarizes the prices of the GSILs analyzed in this rulemaking and Table IV.9 summarizes the prices of the alternative lamps consumers may choose if standards for GSILs are amended.

TABLE IV.8—END-USER PRICES FOR GSILS

EL	Technology	Wattage	Initial lumens	Rated lifetime (hrs)	Efficacy (lm/W)	End-user price
EL 0	Halogen	43	750	1,000	17.4	$1.81
EL 1	HIR	34.3	750	1,000	21.9	7.00

TABLE IV.9—END-USER PRICES FOR CONSUMER CHOICE ALTERNATIVES

Option	Technology	Wattage	Initial lumens	Rated lifetime (hrs)	Efficacy (lm/W)	End-user price
A	Inc	60	587	4,000	9.8	$2.15
B	CFL	13	900	10,000	69.2	2.94
C	LED	9	800	15,000	88.9	3.00

D. Energy Use Analysis

The purpose of the energy use analysis is to determine the annual energy consumption of GSILs in representative U.S. single-family homes, multi-family residences, and commercial buildings, and to assess the energy savings potential of an amended energy conservation standard applied to GSILs. To develop annual energy use estimates, DOE multiplied GSIL input power by the number of hours of use (HOU) per year and a factor representing the impact of controls. The energy use analysis estimates the range of energy use of GSILs in the field (*i.e.,* as they are actually used by consumers). The energy use analysis provides the basis for other analyses DOE performed, particularly assessments of the energy savings and the savings in consumer operating costs that could result from adoption of amended or new standards.

DOE analyzed energy use in the residential and commercial sectors separately but did not explicitly analyze GSILs installed in the industrial sector. This is because far fewer GSILs are installed in that sector compared to the commercial sector, and the average

operating hours for GSILs in the two sectors were assumed to be approximately equal. In the energy use and subsequent analyses, DOE analyzed these sectors together (using data specific to the commercial sector), and refers to the combined sector as the commercial sector.

1. Operating Hours

a. Residential Sector

GE commented in response to the August 2017 NODA on GSILs and other incandescent lamps that the 2010 DOE Lighting Market Characterization (LMC) report [17] estimated operating hours of GSLs at 1.8 hours per day. (GE, No. 3 at p. 5) [11] DOE notes that a newer version of the LMC report has subsequently come out and that both the 2010 and 2015 LMC reports relied primarily on data from field studies in California.[18] To take into account the regional variability in the average HOU of GSILs in the residential sector—which were assumed to have similar HOU to MSB A-type lamps—DOE used the same methodology as for the March 2016 GSL NOPR. DOE used data from various regional field-metering studies of GSL operating hours conducted across the U.S. to determine the regional variation in average HOU. Chapter 7 of the NOPD TSD lists the regional metering studies used. Specifically, DOE determined the average HOU for each EIA 2015 Residential Energy Consumption Survey (RECS) reportable domain (*i.e.,* state, or group of states).[19] [20] For regions without HOU metered data, DOE used data from adjacent regions. DOE estimated the national weighted-average HOU of GSILs in the residential sector to be 2.3 hours per day.

The operating hours of lamps in actual use are known to vary significantly based on the room type the lamp is located in; therefore, DOE estimated this variability by developing HOU distributions for each room type using data from Northwest Energy Efficiency Alliance's (NEEA's) Residential Building Stock Assessment Metering Study (RBSAM),[21] a metering study of 101 single-family houses in the Northwest. DOE assumed that the shape of the HOU distribution for a particular room type would be the same across the United States, even if the average HOU for that room type varied by geographic location. To determine the distribution of GSILs by room type, DOE used data from NEEA's 2011 RBSAM for single-family homes,[22] which included GSL room-distribution data for more than 1,400 single-family homes throughout the Northwest.

b. Commercial Sector

DOE determined the HOU for commercial GSILs in the same way as for the March 2016 GSL NOPR. For each commercial building type presented in the 2015 LMC, DOE determined average HOU based on the fraction of installed lamps utilizing each of the light source technologies typically used in GSLs and the HOU for each of these light source technologies. DOE estimated the national-average HOU for the commercial sector by weighting the building-specific HOU for GSLs by the relative floor space of each building type as reported in in the 2012 EIA Commercial Buildings Energy Consumption Survey (CBECS).[23] The national weighted-average HOU for GSLs, and therefore GSILs, in the commercial sector were estimated at 11.8 hours per day. To capture the variability in HOU for individual consumers in the commercial sector, DOE used data from NEEA's 2014 Commercial Building Stock Assessment (CBSA).[24] As for the residential sector, DOE assumed that the shape of the HOU distribution from the CBSA was similar for the U.S. as a whole.

2. Input Power

The input power used in the energy use analysis is the input power presented in the engineering analysis (section IV.B) for the representative lamps considered in this rulemaking.

3. Lighting Controls

For GSILs that operate with controls, DOE assumed an average energy reduction of 30 percent (in keeping with the March 2016 GSL NOPR). This estimate was based on a meta-analysis of field measurements of energy savings from commercial lighting controls by Williams, et al.[25] Because field measurements of energy savings from controls in the residential sector are very limited, DOE assumed that controls would have the same impact as in the commercial sector.

For this NOPD, DOE assumed that 9 percent of residential GSILs are on controls, which aligns with the fraction of lamps reported to be on dimmers or occupancy sensors in the 2015 LMC.

As in the March 2016 GSL NOPR, for the NOPD DOE assumed that building codes would drive an increase in floor space utilizing controls in the commercial sector. DOE notes that the estimate of the impact of controls on energy consumption increases over time in the commercial sector, but does not require an update to the HOU estimate.

DOE welcomes any relevant data and comment on the energy use analysis methodology.

E. Life-Cycle Cost and Payback Period Analysis

DOE conducted LCC and PBP analyses to evaluate the economic effects on individual consumers of potential energy conservation standards for GSILs. In particular, DOE performed LCC and PBP analyses to evaluate, in part, the savings in operating costs throughout the estimated average life of GSILs compared to any associated increase in costs likely to result from the standards TSL. The effect of new or amended energy conservation standards on individual consumers usually involves a reduction in operating cost and an increase in purchase cost. DOE used the following two metrics to measure effects on the consumer:

- The LCC (life-cycle cost) is the total consumer expense of an appliance or product, consisting of total installed cost (manufacturer selling price, distribution chain markups, sales tax, and installation costs) plus operating costs (expenses for energy use,

[17] Navigant Consulting, Inc. *Final Report: 2010 U.S. Lighting Market Characterization.* 2012. U.S. Department of Energy: Washington, DC (Last accessed July 22, 2019.) *http://apps1.eere.energy.gov/buildings/publications/pdfs/ssl/2010-lmc-final-jan-2012.pdf.*

[18] Navigant Consulting, Inc. *2015 U.S. Lighting Market Characterization.* 2017. U.S. Department of Energy: Washington, DC Report No. DOE/EE–1719. (Last accessed July 5, 2019.) *https://energy.gov/eere/ssl/downloads/2015-us-lighting-market-characterization.*

[19] The 2015 RECS provided detail only to the division, not reportable domain, level; therefore, in creating its residential consumer sample DOE randomly assigned a RECS reportable domain to each consumer based on the reportable domain breakdown from RECS 2009.

[20] U.S. Department of Energy–Energy Information Administration. *2015 RECS Survey Data.* (Last accessed July 2, 2019.) *https://www.eia.gov/consumption/residential/data/2015/.*

[21] Ecotope Inc. *Residential Building Stock Assessment: Metering Study.* 2014. Northwest Energy Efficiency Alliance: Seattle, WA. Report No. E14–283. (Last accessed July 5, 2019.) *https://neea.org/resources/2011-rbsa-metering-study.*

[22] Northwest Energy Efficiency Alliance. *2011 Residential Building Stock Assessment Single-Family Database.* (Last accessed July 5, 2019.) *https://neea.org/resources/2011-rbsa-single-family-database.*

[23] U.S. Department of Energy—Energy Information Administration. *2012 CBECS Survey Data.* (Last accessed July 5, 2019.) *http://www.eia.gov/consumption/commercial/data/2012/index.cfm?view=microdata.*

[24] Navigant Consulting, Inc. *2014 Commercial Building Stock Assessment: Final Report.* 2014. Northwest Energy Efficiency Alliance: Seattle, WA. (Last accessed July 5, 2019.) *https://neea.org/resources/2014-cbsa-final-report.*

[25] Williams, A., B. Atkinson, K. Garbesi, E. Page, and F. Rubinstein. Lighting Controls in Commercial Buildings. *LEUKOS.* 2012. 8(3): pp. 161–180.

maintenance, and repair) and any applicable disposal costs. To compute the operating costs, DOE discounts future operating costs to the time of purchase and sums them over the lifetime of the product. For this NOPD, DOE presents annualized LCC because average GSIL lifetimes are less than a year in the commercial sector.

• The PBP (payback period) is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of a more-efficient product through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost at higher efficacy levels by the change in annual operating cost for the year that amended or new standards are assumed to take effect.

For each considered efficiency standard level, DOE measures the change in annualized LCC relative to the annualized LCC in the no-new-standards case, which reflects the estimated efficacy distribution of GSILs in the absence of new or amended energy conservation standards. DOE presents LCC savings results for two scenarios with different efficacy distributions: DOE presents the LCC savings of GSILs, the covered product in this NOPD, for a GSIL-only scenario in which consumers select only between GSIL options and also includes LCC savings for a scenario with substitution in which consumers may purchase out-of-scope lamps as an input to the NPV calculation. For details on the two scenarios, see section IV.F. The PBP for each efficacy level is measured relative to the baseline efficacy level. The LCC savings with substitution effects is additionally not comparable to the PBP analysis because it extends beyond the covered product in this NOPD.

For each considered efficacy level, DOE calculated the annualized LCC and PBP for a nationally-representative set of potential customers. Separate calculations were conducted for the residential and commercial sectors. DOE developed consumer samples based on the 2015 RECS and the 2012 CBECS for the residential and commercial sectors, respectively. For each consumer in the sample, DOE determined the energy consumption of the lamp purchased and the appropriate electricity price. By developing consumer samples, the analysis captured the variability in energy consumption and energy prices associated with the use of GSILs.

DOE added sales tax, which varied by state, and installation cost (for the commercial sector) to the cost of the product developed in the product price determination to determine the total installed cost. Inputs to the calculation of operating expenses include annual energy consumption, energy prices and price projections, lamp lifetimes, and discount rates. DOE created distributions of values for lamp lifetimes, discount rates, and sales taxes, with probabilities attached to each value, to account for their uncertainty and variability.

For the GSIL standard case (*i.e.,* case where a standard would be in place at a particular TSL), DOE measured the annualized LCC savings resulting from the technological requirements for GSILs at the considered standard relative to the efficacy distribution in the no-new-standards case for the covered product scenario. DOE also presents annualized LCC savings that include substitution effects and their effects on efficacy distribution in the standards case relative to the estimated efficacy distribution in the no-new-standards case for a scenario in which consumers can substitute out-of-scope products. The efficacy distributions in the substitution scenario include market trends that can result in some lamps with efficacies that exceed the minimum efficacy associated with the standard under consideration. In contrast, the PBP only considers the average time required to recover any increased first cost associated with a purchase at a particular EL relative to the baseline product.

The computer model DOE used to calculate the annualized LCC and PBP results relies on a Monte Carlo simulation to incorporate uncertainty and variability into the analysis. The Monte Carlo simulations randomly sample input values from the probability distributions and consumer user samples. The model calculated the annualized LCC and PBP for a sample of 10,000 consumers per simulation run.

DOE calculated the annualized LCC and PBP as if each consumer were to purchase a new product in the expected year of required compliance with amended standards. Any amended standards would apply to GSILs manufactured 3 years after the date on which any amended standard is published. (42 U.S.C. 6295(i)(6)(A)(iii)) As this proposed rule is being published in 2019, DOE used 2023 as the first full year in which compliance with any amended standards for GSILs could occur.

Table IV.10 summarizes the approach and data DOE used to derive inputs to the LCC and PBP calculations. The subsections that follow provide further discussion. Details of the spreadsheet model, and of all the inputs to the LCC and PBP analyses, are contained in chapter 8 of the NOPD TSD and its appendices.

TABLE IV.10—SUMMARY OF INPUTS AND METHODS FOR THE LCC AND PBP ANALYSIS * [26]

Inputs	Source/method
Product Cost	Weighted-average end-user price determined in the product price determination. For the LCC with substitution, DOE used a price-learning analysis to project the price of the CFL and LED lamp alternatives in the compliance year.
Sales Tax	Derived 2023 population-weighted-average tax values for each state based on Census population projections and sales tax data from Sales Tax Clearinghouse.
Installation Costs	Used RSMeans and U.S. Bureau of Labor Statistics data to estimate an installation cost of $1.54 per installed GSIL for the commercial sector.
Annual Energy Use	Derived in the energy use analysis. Varies by geographic location and room type in the residential sector and by building type in the commercial sector.
Energy Prices	Based on 2018 average and marginal electricity price data from the Edison Electric Institute. Electricity prices vary by season and U.S. region.
Energy Price Trends	Based on *AEO 2019* price forecasts.
Product Lifetime	A Weibull survival function is used to provide the survival probability as a function of GSIL age, based on the GSIL's rated lifetime, sector-specific HOU, and impact of dimming.

[26] Although DOE addresses the validity of California law relating to GSILs in the General Service Lamps Definition Rule published elsewhere in today's **Federal Register**, in generating its consumer samples, DOE did not sample consumers from California.

TABLE IV.10—SUMMARY OF INPUTS AND METHODS FOR THE LCC AND PBP ANALYSIS * [26]—Continued

Inputs	Source/method
Discount Rates	Approach involves identifying all possible debt or asset classes that might be used to purchase the considered appliances, or might be affected indirectly. Primary data source was the Federal Reserve Board's Survey of Consumer Finances.
Efficacy Distribution	Estimated by the market-share module of shipments model. See chapter 9 of the NOPD TSD for details.
Compliance Date	2023.

* References for the data sources mentioned in this table are provided in the sections following the table or in chapter 8 of the NOPD TSD.

1. Product Cost

As noted in section IV.C, DOE rulemaking analyses typically calculate consumer product costs by multiplying MSPs developed in the engineering analysis by the markups along with sales taxes. For GSILs, the engineering analysis determined end-user prices directly; therefore, for the LCC analysis, the only adjustment was to add sales taxes, which were assigned to each household or building in the LCC sample based on its location.

In the LCC with substitution scenario, DOE used a price-learning analysis to determine the impact of GSIL standards on consumers who select a CFL or LED lamp alternative under a standard. The price-learning analysis accounts for changes in LED lamp prices that are expected to occur between the time for which DOE has data for lamp prices (2018) and the assumed compliance date of the rulemaking (2023). For details on the price-learning analysis, see section IV.F.1.b.

2. Installation Cost

Installation cost includes labor, overhead, and any miscellaneous materials and parts needed to install the product. For this NOPD, DOE assumed an installation cost of $1.54 per installed commercial GSIL (based on RSMeans [27] and U.S. Bureau of Labor Statistics data [28]), but zero installation cost for residential GSILs.

3. Annual Energy Consumption

For each sampled household or commercial building, DOE determined the energy consumption for a lamp using the approach described previously in section IV.D of this document.

4. Energy Prices

DOE used both marginal and average electricity prices to calculate operating costs. Specifically, DOE used average electricity prices for the baseline EL and marginal electricity prices to characterize incremental electricity cost savings associated with other TSLs. DOE estimated these prices using data published with the Edison Electric Institute (EEI) Typical Bills and Average Rates reports for summer and winter 2018.[29] DOE assigned seasonal marginal and average prices to each household in the LCC sample based on its location. DOE assigned seasonal marginal and average prices to each commercial building in the LCC sample based on its location and annual energy consumption.

5. Energy Price Trends

To arrive at electricity prices in future years, DOE multiplied the electricity prices described above by the forecast of annual residential or commercial electricity price changes for each Census division from EIA's AEO 2019, which has an end year of 2050.[30] To estimate the trends after 2050, DOE used the compound annual growth rate of change between 2035 and 2050. For each purchase sampled, DOE applied the projection for the Census division in which the purchase was located. The AEO electricity price trends do not distinguish between marginal and average prices, so DOE used the same (AEO 2019) trends for both marginal and average prices.

DOE used the electricity price trends associated with the AEO Reference case, which is a business-as-usual estimate, given known market, demographic, and technological trends.

6. Product Lifetime

DOE considered the lamp lifetime to be the service lifetime (*i.e.,* the age at which the lamp is retired from service). For GSILs, the lifetime model incorporates the rated lifetime, the presence of controls, and the installation sector. For CFL and LED lamp alternatives, DOE used the methodology from the reference (''Renovation-Driven'') lifetime scenario from the March 2016 GSL NOPR.

For a detailed discussion of the development of lamp lifetimes, see appendix 8C of the NOPD TSD.

7. Discount Rates

In the calculation of LCC, DOE applies discount rates appropriate to commercial and residential consumers to estimate the present value of future operating costs. DOE estimated a distribution of discount rates for GSILs based on cost of capital of publicly traded firms in the sectors that purchase GSILs.

DOE applies weighted average discount rates calculated from consumer debt and asset data, rather than marginal or implicit discount rates. DOE notes that the LCC does not analyze the equipment purchase decision, so the implicit discount rate is not relevant in this model. The LCC estimates net present value over the lifetime of the equipment, so the appropriate discount rate will reflect the general opportunity cost of household funds, taking this time scale into account. Given the long time horizon modeled in the LCC, the application of a marginal interest rate associated with an initial source of funds is inaccurate. Regardless of the method of purchase, consumers are expected to continue to rebalance their debt and asset holdings over the LCC analysis period, based on the restrictions consumers face in their debt payment requirements and the relative size of the interest rates available on debts and assets. DOE estimates the aggregate impact of this rebalancing using the historical distribution of debts and assets.

To establish residential discount rates for the LCC analysis, DOE identified all relevant household debt or asset classes in order to approximate a consumer's opportunity cost of funds related to appliance energy cost savings. It estimated the average percentage shares of the various types of debt and equity by household income group using data

[27] RSMeans. *Facilities Maintenance & Repair Cost Data 2013.* 2012. RSMeans: Kingston, MA.

[28] U.S. Department of Labor–Bureau of Labor Statistics. *May 2014 Occupational Employment Statistics Survey. National Occupational and Wage Estimates.* (Last accessed July 30, 2019.) *http://www.bls.gov/oes/tables.htm.*

[29] Edison Electric Institute. *Typical Bills and Average Rates Report.* 2018. Winter 2018, Summer 2018: Washington, DC.

[30] U.S. Energy Information Administration. *Annual Energy Outlook 2019 with projections to 2050.* 2019. Washington, DC. Report No. AEO2019. (Last accessed July 5, 2019.) *https://www.eia.gov/outlooks/AEO/pdf/AEO2019.pdf.*

from the Federal Reserve Board's Survey of Consumer Finances (SCF) for 1995, 1998, 2001, 2004, 2007, 2010, 2013, and 2016.[31] Using the SCF and other sources, DOE developed a distribution of rates for each type of debt and asset by income group to represent the rates that may apply in the year in which amended standards would take effect.

For commercial consumers, DOE used the cost of capital to estimate the present value of cash flows to be derived from a typical company project or investment. Most companies use both debt and equity capital to fund investments, so the cost of capital is the weighted-average cost to the firm of equity and debt financing. This corporate finance approach is referred to as the weighted-average cost of capital. DOE used currently available economic data in developing discount rates.

8. Efficacy Distribution

To accurately estimate the share of consumers that would be affected by a potential energy conservation standard at a particular TSL, DOE's LCC analysis considered the projected distribution (*i.e.,* market shares) of product efficacies that consumers purchase under the no-new-standards case and the standards case (*i.e.,* the case where a standard would be set at TSL 1) in the assumed compliance year. The estimated market shares for the no-new-standards case and each standards case are determined by the shipments analysis and are shown in Table IV.11 and Table IV.12 for the LCC with substitution scenario and the LCC GSIL-only scenario, respectively. In the LCC with substitution scenario, DOE estimates that the GSILs that are covered by this NOPD would account for 11.3% of the residential market share in 2023 in the absence of federal standards, and 3.8% of the residential market under TSL 1. That is, most consumers would switch from GSILs to out-of-scope substitutes under TSL 1 due to high product price.

TABLE IV.11—GSIL MARKET SHARE DISTRIBUTION BY TRIAL STANDARD LEVEL IN 2023—LCC WITH SUBSTITUTION

Trial standard level	EL 0 43 W halogen (%)	EL 1 34.3 W HIR (%)	60 W incandescent * (%)	13 W CFL * (%)	9 W LED * (%)	Total ** (%)
Residential						
No-New-Standards	11.3	0	4.0	5.2	79.5	100
TSL 1	0	3.8	4.1	6.2	86.0	100
Commercial						
No-New-Standards	2.7	0	0	3.1	94.2	100
TSL 1	0	0.3	0	3.2	96.5	100

* Incandescent lamps, CFLs, and LED lamps are out-of-scope consumer choice alternatives for GSILs (see section IV.B.6).
** The total may not sum to 100% due to rounding.

The market share for GSIL lamps in the LCC GSIL-only (*i.e.* covered product) scenario are shown in Table IV.12. DOE estimates HIR lamps will represent 2.3% of the GSIL residential market in the no-new-standards case.

TABLE IV.12—GSIL MARKET SHARE DISTRIBUTION BY TRIAL STANDARD LEVEL IN 2023—LCC STANDARDS SCENARIO

Trial standard level	EL 0 43 W halogen (%)	EL 1 34.3 W HIR (%)	Total * (%)
Residential			
No-New-Standards	97.7	2.3	100
TSL 1	0	100	100
Commercial			
No-New-Standards	99.0	1.0	100
TSL 1	0	100	100

* The total may not sum to 100% due to rounding.

See section IV.F of this NOPD and chapter 9 of the NOPD TSD for further information on the derivation of the market efficacy distributions.

9. LCC Savings Calculation

DOE calculated the annualized LCC savings at TSL 1 based on the change in annualized LCC for the standards case compared to the no-new-standards case. In the covered product scenario, this approach models the actual lifecycle cost of HIR lamps under TSL 1 compared to the lifecycle cost of GSILs in the no-new standards case. In contrast, the LCC savings results in the substitution scenario also includes out-of-scope lamps in the efficacy distribution for both the standards case and the no-new-standards case. That is, the LCC with substitution analysis considers the upfront price and operating costs of out-of-scope lamps that consumers would substitute for covered GSILs. This approach models how consumers would substitute other lamps (which are more efficient and sometimes less-expensive) and is intended to more accurately reflect the impact of a potential standard on consumers. In a standards scenario, consumers are unable to recover the

[31] U.S. Board of Governors of the Federal Reserve System. *Survey of Consumer Finances.* 1995, 1998, 2001, 2004, 2007, 2010, 2013 and 2016. (Last accessed July 16, 2019.) *http://www.federalreserve.gov/econresdata/scf/scfindex.htm.*

upfront price of HIR lamps and as a result experience negative LCC savings.

DOE used the consumer-choice model in the shipments analysis to determine the fraction of consumers that purchase each lamp option under a standard, but the model is unable to track the purchasing decision for individual consumers in the LCC sample. However, DOE must track any difference in purchasing decision for each consumer in the sample in order to determine the fraction of consumers who experience a net cost. Therefore, DOE assumed that the rank order of consumers, in terms of the efficacy of the product they purchase, is the same in the no-new-standards case as in the standards cases. In other words, DOE assumed that the consumers who purchased the most-efficacious products in the efficacy distribution in the no-new-standards case would continue to do so in standards cases, and similarly, those consumers who purchased the least efficacious products in the efficacy distribution in the no-new-standards case would continue to do so in standards cases. This assumption is only relevant in determining the fraction of consumers who experience a net cost in the annualized LCC savings calculation, and has no effect on the estimated national impact of a potential standard.

10. Payback Period Analysis

The PBP is the amount of time it takes the consumer to recover the additional installed cost of more-efficient products, compared to baseline products, through energy cost savings. PBPs are expressed in years. PBPs that exceed the life of the product mean that the increased total installed cost is not recovered in reduced operating expenses.

The inputs to the PBP calculation for each efficacy level are the change in total installed cost of the product and the change in the first-year annual operating expenditures relative to the baseline. The PBP calculation typically uses the same inputs as the LCC analysis, except that discount rates are not needed. In this notice, DOE presents the LCC savings in the standards case for a covered product scenario along with an LCC with substitution scenario, the latter of which differs from the PBP because it includes out-of-scope lamps rather than only the product that would be directly regulated by a GSIL standard.

EPCA, as amended, establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii)) For each considered efficacy level, DOE determined the value of the first year's energy savings by calculating the energy savings in accordance with the applicable DOE test procedure, and multiplying those savings by the average energy price projection for the year in which compliance with the amended standards would be required.

DOE welcomes any relevant data and comment on the LCC and PBP analysis methodology.

F. Shipments Analysis

DOE uses projections of annual product shipments to calculate the national impacts of potential amended energy conservation standards on energy use, NPV, and future manufacturer cash flows.[32] The shipments model takes a stock-accounting approach, tracking market shares of each product class and the vintage of units in the stock. Stock accounting uses product shipments as inputs to estimate the age distribution of in-service product stocks for all years. The age distribution of in-service product stocks is a key input to calculations of both the NES and NPV, because lamp energy consumption and operating costs for any year depend on the age distribution of the stock. The shipments analysis also provides the efficacy distribution in the year of compliance which is an input to calculating LCC savings.

1. Shipments Model

The shipments model projects shipments of GSILs over a thirty-year analysis period for the no-new-standards case and for the standards case. Separate shipments projections are calculated for the residential sector and for the commercial sector. The shipments model used to estimate GSIL lamp shipments for this rulemaking has three main interacting elements: (1) A lamp demand module that estimates the demand for GSIL lighting and GSIL alternatives for each year of the analysis period; (2) a price-learning module that projects future prices based on historic price trends; and (3) a market-share module that assigns shipments to the available lamp options.

DOE modeled shipments for two scenarios: For the purposes of the covered product scenario LCC scenario, DOE ran a version of the shipments analysis where consumers selected between product options for the covered product at issue in this NOPD (*i.e.* GSILs). As an input to the NIA, DOE modeled a scenario where consumers select between GSIL options and out of scope alternatives, including CFL, LED, and traditional incandescent *(e.g.,* shatter resistant) lamps, because amended standards on GSILs could affect substitution rates. DOE welcomes any relevant data and comment on the shipments analysis methodology.

a. Lamp Demand Module

The lamp demand module first estimates the national demand for GSILs and potential alternative products in each year for the covered product scenario and the substitution scenario, respectively. The demand calculation assumes that sector-specific lighting capacity (maximum lumen output of installed lamps) remains fixed per square foot of floor space over the analysis period, and total floor space changes over the analysis period according to the EIA's *AEO 2019* projections of US residential and commercial floor space.[33] A lamp turnover calculation estimates demand for new lamps in each year based on the growth of floor space in each year, the expected demand for replacement lamps, and sector-specific assumptions about the distribution of per-lamp lumen output desired by consumers. The demand for replacements is computed based on the historical shipments of lamps, the expected lifetimes of the lamps (in terms of total hours of operation), and sector-specific assumptions about lamp operating hours. For the substitution scenario, the lamp demand module also accounts for the adoption of integral LED luminaires into lighting applications traditionally served by GSILs and for consumers' transitioning between GSILs and CFLs or LED lamps both prior to and during the analysis period, either spontaneously or due to amended standards.

NEMA commented in response to the February 2019 NOPR that shipments of GSILs are declining as shipments of LED lamps continue to exhibit strong growth and that GSILs represent a reduced fraction of the overall stock of GSLs compared to a few years ago (NEMA, No. 329 at pp. 44–48).[12] Along similar lines, LEDVANCE commented in response to the August 2017 NODA on

[32] DOE uses data on manufacturer shipments as a proxy for national sales, as aggregate data on sales are lacking. In general one would expect a close correspondence between shipments and sales.

[33] U.S. Energy Information Administration. *Annual Energy Outlook 2019 with projections to 2050.* 2019. Washington, DC. Report No. AEO2019. (Last accessed July 5, 2019.) *https://www.eia.gov/outlooks/AEO/pdf/AEO2019.pdf.*

GSILs and other incandescent lamps that there has been brisk substitution of GSILs with LED lamps and declines in lamp shipments as consumers switch to LED lamps with longer lifetimes. (LEDVANCE, No. 9 at p. 3) [11] In the shipments analysis for this NOPD, DOE incorporated data on relative lamp shipments and market share by technology through 2018, as provided by NEMA in its comments on the February 2019 NOPR and in its published lamp indices.[34] (NEMA, No. 329 at pp. 52–53) [12] DOE notes that these data show a much faster adoption of LED GSLs than has previously been projected by DOE's solid-state lighting program; further, the data show that LED GSL adoption is growing at the expense of both CFLs and GSILs. In the scenario for substitution, fitting the NEMA data to the widely used Bass model for the market adoption of new technology [35] suggests that, even in the absence of Federal regulation, LED lamps will have captured a significant majority of the GSL market by 2023 (79.5 percent of the residential market and 92.0 percent of the commercial market). After incorporating this growth in LED lamp market share prior to 2023 the shipments analysis for this NOPD shows a substantial growth in LED lamp shipments prior to 2023, owing to the ongoing market transition in the absence of standards.

b. Price-Learning Module

The price-learning module estimates lamp prices in each year of the analysis period using a standard price-learning model,[36] which relates the price of a given technology to its cumulative production, as represented by total cumulative shipments. GSILs represent a mature technology that have reached a stable price point due to the high volume of total cumulative shipments, so price learning was not considered in the LCC GSIL-only scenario. However, in the scenario with substitution, CFL and LED alternative lamps may continue to drop in price due to price learning. Current cumulative shipments are determined for each lighting technology (CFL and LED) at the start of the analysis period and are augmented in each subsequent year of the analysis based on the shipments determined for the prior year. New prices for each technology are calculated from the updated cumulative shipments according to the learning (or experience) curve for each technology. The current year's shipments, in turn, affect the subsequent year's prices. Because LED lamps are a relatively young technology, their cumulative shipments increase rapidly and hence they undergo a substantial price decline during the shipments analysis period. CFL prices, by contrast, undergo a negligible price decline, owing to the low shipments volume and relative maturity of this technology.

c. Market-Share Module

The market-share module apportions the lamp shipments in each year among the different lamp options developed in the engineering analysis, based on consumer sensitivity various lamp features. For the covered product scenario, to lamp price energy savings were the only features considered. For the substitution scenario, lifetime and mercury content were also considered, as measured in a market study,[37] as well as on consumer preferences for lighting technology as revealed in historical shipments data. The market-share module assumes that, when replacing a lamp, consumers will choose among all of the available lamp options. Substitution matrices were developed to specify the product choices available to consumers. The substitution scenario considered CFLs, LEDs, and traditional incandescent alternatives to the covered product. The available options additionally depend on the case under consideration; in each standards case corresponding to a TSL, only those lamp options at or above the particular standard level, and relevant alternative lamps, are considered to be available. In the substitution scenario, the market-share module also incorporates a limit on the diffusion of LED technology into the market using the widely accepted Bass adoption model,[38] the parameters of which are based on data on the market penetration of LED lamps published by NEMA,[39] as discussed previously. In the LCC covered product scenario, DOE used a Bass diffusion curve in the no-new-standards case to model the adoption of HIR lamps assuming these lamps would be a new entry to market in 2020. The Bass diffusion curves puts a limit on the maximum market share allowed for HIR lamps in each year of the analysis.

In this way, the module assigns market shares to the different ELs, and consumer choice alternatives, based on observations of consumer preferences.

G. National Impact Analysis

The NIA assesses the NES and the national NPV from a national perspective of total consumer costs and savings that would be expected to result from new or amended standards at specific TSLs.[40] (''Consumer'' in this context refers to consumers of the product being regulated and includes both residential and commercial consumers.) DOE calculated the NES and NPV based on projections of annual product shipments and prices from the shipments scenario with substitution, along with the HOU and energy prices from the energy use and LCC with substitution analyses.[41] For the present analysis, DOE projected the energy savings, operating-cost savings, product costs, and NPV of consumer benefits over the lifetime of GSILs sold from 2023 through 2052. However, unlike for other DOE rulemakings, the energy savings and NPV of consumer benefits are not those associated with the technology in question for TSL 1. The price of HIR lamps under TSL 1 would be preventatively high for most consumers, and HIR efficacy is too low for consumers to recover these costs in energy savings. Because manufacturers are unlikely to product HIR lamps and consumers are unlikely to purchase them, there are no energy savings or benefits from transitioning to HIR technology.

DOE evaluates the impacts of new and amended standards by comparing a case without such standards against standards-case projections. The no-new-standards case characterizes energy use and consumer costs in the absence of new or amended energy conservation standards. DOE compares the no-new-standards case with projections characterizing the market if DOE adopted new or amended standards at specific TSLs. For the standards cases,

[34] National Electrical Manufacturers Association. *Lamp Indices.* (Last accessed July 23, 2019.) *http://www.nema.org/Intelligence/Pages/Lamp-Indices.aspx.*

[35] Bass, F.M. A New Product Growth Model for Consumer Durables. *Management Science.* 1969. 15(5): pp. 215–227.

[36] Taylor, M. and S.K. Fujita. *Accounting for Technological Change in Regulatory Impact Analyses: The Learning Curve Technique.* 2013. Lawrence Berkeley National Laboratory: Berkeley, CA. Report No. LBNL–6195E. (Last accessed June 23, 2015.) *https://eta.lbl.gov/publications/accounting-technological-change.*

[37] Krull, S. and D. Freeman. *Next Generation Light Bulb Optimization.* 2012. Pacific Gas and Electric Company. (Last accessed July 23, 2019.) *http://www.etcc-ca.com/sites/default/files/OLD/images/stories/Lighting_Conjoint_Study_v020712f.pdf.*

[38] Bass, F.M. A New Product Growth Model for Consumer Durables. *Management Science.* 1969. 15(5): pp. 215–227.

[39] National Electrical Manufacturers Association. *Lamp Indices.* (Last accessed July 23, 2019.) *http://www.nema.org/Intelligence/Pages/Lamp-Indices.aspx.*

[40] The NIA accounts for impacts in the 50 States and the U.S. territories.

[41] For the NIA, DOE adjusts the installed cost data from the LCC analysis to exclude sales tax, which is a transfer.

DOE considers how a given standard would likely affect the market shares of products with efficacies greater than the standard, as well as consumer choice alternatives. Any energy savings or benefits estimated in the standards case are the result of product shifting as, given GE's experience and the economics at issue, manufacturers are unlikely to produce and consumers are unlikely to purchase GSIL–HIR products. Instead, consumers are more likely to substitute different product types such as CFLs and LEDs, which have different performance characteristics and features. As noted above, EPCA prohibits DOE from prescribing an amended or new standard if that the standard is likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States at the time of the Secretary's finding.

DOE uses a spreadsheet model to calculate the energy savings and the national consumer costs and savings from each TSL. Interested parties can review DOE's analyses by changing various input quantities within the spreadsheet. The NIA spreadsheet model uses typical values (as opposed to probability distributions) as inputs.

Table IV.12 summarizes the inputs and methods DOE used for the NIA analysis for the NOPD. Discussion of these inputs and methods follows the table.

TABLE IV.12—SUMMARY OF INPUTS AND METHODS FOR THE NATIONAL IMPACT ANALYSIS

Inputs	Method
Shipments	Annual shipments for each lamp option from shipments model for the no-new standards case and each TSL analyzed.
Assumed compliance date of standard	January 1, 2023.
No-new-standards efficacy distribution	Estimated by the market-share module of the shipments analysis.
Standards-case efficacy distribution	Estimated by the market-share module of the shipments analysis.
Annual energy use per unit	Calculated for each lamp option based on inputs from the Energy Use Analysis.
Total installed cost per unit	Uses lamp prices, and for the commercial sector only, installation costs from the LCC analysis.
Electricity prices	Estimated marginal electricity prices from the LCC analysis.
Energy price trends	*AEO 2019* forecasts (to 2050) and extrapolation thereafter.
Annual operating cost per unit	Calculated for each lamp option using the energy use per unit, and electricity prices and trends.
Energy Site-to-Source Conversion	A time-series conversion factor based on *AEO 2019*.
Discount rate	Three and seven percent real.
Present year	2019.

1. National Energy Savings

The NES analysis involves a comparison of national energy consumption of the considered products in each standards case with consumption in the case with no new or amended energy conservation standards. DOE calculated the annual national energy consumption by multiplying the number of units (stock) of each lamp option (by vintage or age) by the unit energy consumption (also by vintage) for each year in the analysis. The NES is based on the difference in annual national energy consumption for the no-new-standards case and each of the standards cases. DOE estimated the energy consumption and savings based on site electricity and converted that quantity to the energy consumption and savings at the power plant using annual conversion factors derived from *AEO 2019*. Cumulative energy savings are the sum of NES for each year over the analysis period, taking into account the full lifetime of GSILs shipped in 2052.

DOE tracks both the energy consumption of GSILs and substitute out-of-scope lamps (*e.g.,* CFL, LED, and traditional incandescent lamps). Under the standards case, the increase in cost or lack of availability of GSIL options can lead to consumers choosing out-of-scope alternative lamps. This leads to a decrease in GSIL shipments that appears as a decrease in GSIL energy consumption, while the increase in out-of-scope shipments appears as an increase in energy consumption for those lamp types. DOE also calculated the overall energy impact of a standard including the increased energy consumption of out-of-scope lamps.

DOE generally accounts for the direct rebound effect in its NES analyses. Direct rebound reflects the idea that as appliances become more efficient, consumers use more of their service because their operating cost is reduced. In the case of lighting, the rebound effect could be manifested in increased HOU or in increased lighting density (lamps per square foot). DOE assumed no rebound effect for GSILs in this analysis, consistent with the assumption of no rebound in the reference scenario in the March 2016 GSL NOPR. DOE is not aware of any data supporting rebound when consumers switch from halogen GSILs to HIR GSILs. DOE seeks any relevant data and comment on the potential rebound effect for GSILs.

In response to the recommendations of a committee on ''Point-of-Use and Full-Fuel-Cycle Measurement Approaches to Energy Efficiency Standards'' appointed by the National Academy of Sciences, DOE announced its intention to use FFC measures of energy use and greenhouse gas and other emissions in the national impact analyses and emissions analyses included in future energy conservation standards rulemakings. 76 FR 51281 (August 18, 2011). After evaluating the approaches discussed in the August 18, 2011 notice, DOE published a statement of amended policy in which DOE explained its determination that EIA's National Energy Modeling System (NEMS) is the most appropriate tool for its FFC analysis and its intention to use NEMS for that purpose. 77 FR 49701 (August 17, 2012). NEMS is a public domain, multi-sector, partial equilibrium model of the U.S. energy sector that EIA uses to prepare its *AEO*.[42] The approach used for deriving FFC measures of energy use and emissions is described in appendix 10B of the NOPD TSD.

2. Net Present Value Analysis

The inputs for determining the NPV of the total costs and benefits experienced by consumers are: (1) Total annual increases in installed cost; (2)

[42] For more information on NEMS, refer to *The National Energy Modeling System: An Overview,* DOE/EIA–0581 (98) (Feb.1998) (Available at: *http://www.eia.gov/oiaf/aeo/overview/).*

total annual savings in operating costs; and (3) a discount factor to calculate the present value of costs and savings. DOE calculates net savings each year as the difference between the no-new-standards case and each standards case in terms of total savings in operating costs versus total increases in installed costs. DOE calculates operating-cost savings over the lifetime of each product shipped during the analysis period.

The direct efficacy improvements from TSL 1 do not result in any benefits. First, manufacturers are unlikely to produce HIR lamps. Manufacturers that have produced and attempted to sell such lamps in the recent past have found it uneconomic to do so. However, if a manufacturer were hypothetically willing to produce such a lamp, consumers would either (1) purchase the HIR lamp and be unable to recoup the expense in energy savings or (2) choose not to purchase the HIR lamp due to high purchase price. As a result DOE does not anticipate that adoption of HIR technology to result directly in any consumer benefits. Instead, any benefit from TSL 1 would result from product shifting as consumers substitute more efficient alternative product types with different performance characteristics and features. As discussed in section IV.F.1.b of this NOPD, DOE developed prices for alternative LED and CFL lamps using a price-learning module incorporated in the shipments analysis.

The operating cost savings in this document are primarily the result of product shifting. The operating-cost savings are primarily energy cost savings, which are calculated using the estimated energy savings in each year and the projected price of electricity. To estimate energy prices in future years, DOE multiplied the average national marginal electricity prices by the forecast of annual national-average residential or commercial electricity price changes in the Reference case from *AEO 2019,* which has an end year of 2050. To estimate price trends after 2050, DOE used the average annual rate of change in prices from 2035 to 2050.

In calculating the NPV, DOE multiplies the net savings in future years by a discount factor to determine their present value. For this NOPD, DOE estimated the NPV of consumer benefits using both a 3-percent and a 7-percent real discount rate. DOE uses these discount rates in accordance with guidance provided by the Office of Management and Budget (OMB) to federal agencies on the development of regulatory analysis.[43] The discount rates for the determination of NPV are in contrast to the discount rates used in the LCC analysis, which are designed to reflect a consumer's perspective. The 7-percent real value is an estimate of the average before-tax rate of return to private capital in the U.S. economy. The 3-percent real value represents the ''social rate of time preference,'' which is the rate at which society discounts future consumption flows to their present value.

H. Manufacturer Impact Analysis

DOE performed an MIA to estimate the financial impacts of potential amended energy conservation standards on manufacturers of GSILs. DOE relied on the GRIM, an industry cash flow model with inputs specific to this rulemaking. The key GRIM inputs include data on the industry cost structure, unit production costs, product shipments, manufacturer markups, and investments in research and development (R&D) and manufacturing capital required to produce compliant products. The key GRIM outputs are the INPV, which is the sum of industry annual cash flows over the analysis period, discounted using the industry-weighted average cost of capital, and the impact to domestic manufacturing employment. The GRIM calculates cash flows using standard accounting principles and compares changes in INPV between the no-new-standards case and each standards case. The difference in INPV between the no-new-standards case and a standards case represents the financial impact of amended energy conservation standards on manufacturers. To capture the uncertainty relating to manufacturer pricing strategies following potential amended standards, the GRIM estimates a range of possible impacts under different manufacturer markup scenarios.

DOE created initial estimates for the industry financial inputs used in the GRIM (*e.g.,* tax rate; working capital rate; net property plant and equipment expenses; selling, general, and administrative (SG&A) expenses; R&D expenses; depreciation expenses; capital expenditures; and industry discount rate) based on publicly available sources, such as company filings of form 10–K from the SEC or corporate annual reports.[44]

The GRIM uses several factors to determine a series of annual cash flows starting with the announcement of potential standards and extending over a 30-year period following the compliance date of potential standards. These factors include annual expected revenues, costs of sales, SG&A and R&D expenses, taxes, and capital expenditures. In general, energy conservation standards can affect manufacturer cash flow in three distinct ways: (1) Creating a need for increased investment, (2) raising production costs per unit, and (3) altering revenue due to higher per-unit prices and changes in sales volumes.

The GRIM spreadsheet uses inputs to arrive at a series of annual cash flows, beginning in 2019 (the reference year of the analysis) and continuing to 2052. DOE calculated INPVs by summing the stream of annual discounted cash flows during this period. DOE used a real discount rate of 6.1 percent for GSIL manufacturers. This initial discount rate estimate was derived using the capital asset pricing model in conjunction with publicly available information (*e.g.,* 10-year treasury rates of return and company specific betas).

1. Manufacturer Production Costs

Manufacturing more efficacious GSILs is more expensive because of the machinery required to coat halogen capsules and the process by which the capsules are coated. The changes in the MPCs of covered products can affect the revenues, gross margins, and cash flow of the industry. Typically, DOE develops MSPs for the covered products using reverse-engineering. These costs are used as an input to the LCC analysis and NIA. However, because GSILs are difficult to reverse-engineer, DOE derived end-user prices directly in the product price determination and then used the end-user prices in conjunction with distribution chain markups to calculate the MSPs of GSILs. See section IV.C for a further explanation of the product price determination.

To determine MPCs of GSILs from the end-user prices calculated in the engineering analysis, DOE divided the end-user prices by the home center markup to calculate the MSP. DOE then divided the MSP by the manufacturer markup to get the MPCs. DOE determined the home center markup to be 1.52 and the manufacturer markup to be 1.40 for all GSILs. Markups are further described in section IV.H.4 of this document.

[43] United States Office of Management and Budget. Circular A–4: Regulatory Analysis,'' (Sept. 17, 2003), section E (Available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*).

[44] 10–Ks are collected from the SEC's EDGAR database: *https://www.sec.gov/edgar.shtml* or from annual financial reports collected from individual company websites.

2. Shipments Projections

The GRIM estimates manufacturer revenues based on total unit shipment projections and the distribution of those shipments by TSL. Changes in sales volumes and efficiency mix over time can significantly affect manufacturer finances. For this analysis, the GRIM uses the NIA's annual shipment projections starting in 2019 (the reference year) and ending in 2052 (the end year of the analysis period).

3. Product and Capital Conversion Costs

Potential amended energy conservation standards could cause manufacturers to incur conversion costs to bring their production facilities and product designs into compliance. DOE evaluated the level of conversion-related expenditures that would be needed to comply with each considered TSL. For the MIA, DOE classified these conversion costs into two major groups: (1) Product conversion costs; and (2) capital conversion costs. Product conversion costs are investments in research, development, testing, marketing, and other non-capitalized costs necessary to make product designs comply with amended energy conservation standards. Capital conversion costs are investments in property, plant, and equipment necessary to adapt or change existing production facilities such that new compliant product designs can be fabricated and assembled.

To evaluate the level of capital conversion costs manufacturers would likely incur to comply with the analyzed energy conservation standards DOE used data submitted during the 2015 IRL rulemaking to estimate costs to update manufacturer production lines. DOE then estimated the number of production lines currently in existence and the number of production lines that would be required to be updated at the analyzed TSL using DOE's public compliance certification database. DOE then multiplied these numbers together (*i.e.,* capital conversion costs per production line and number of production lines that would need to be updated) to get the final estimated capital conversion costs at the analyzed TSL.

To evaluate the level of product conversion costs manufacturers would likely incur to comply with the analyzed energy conservation standards, DOE used data submitted during the 2015 IRL rulemaking to estimate per model R&D and testing and certification costs for the TSL. DOE then estimated the number of models that would need to be redesigned at each analyzed TSL. DOE then multiplied these numbers together to get the final estimated product conversion costs for the analyzed TSL.

In general, DOE assumes all conversion-related investments occur between the estimated year of publication of the final rule and the year by which manufacturers must comply with the potential amended standards. The conversion cost figures used in the GRIM can be found in Table V.9 and section V.D of this document.

4. Markup Scenarios

To calculate the MPCs used in the GRIM, DOE divided the end-user prices calculated in the engineering analysis by the home center markup and the manufacturer markup. The home center markup was calculated in the March 2016 GSL NOPR by reviewing SEC 10–K reports of publicly traded home centers. DOE continued to use a home center markup of 1.52 in this analysis.

The manufacturer markup accounts for the non-production costs (*i.e.,* SG&A, R&D, and interest) along with profit. Modifying the manufacturer markup in the standards case yields different sets of impacts on manufacturers. For the MIA, DOE modeled two standards-case manufacturer markup scenarios to represent uncertainty regarding the potential impacts on prices and profitability for manufacturers following the implementation of analyzed energy conservation standards: (1) A preservation of gross margin markup scenario; and (2) a technology specific markup scenario. These scenarios lead to different manufacturer markup values that, when applied to the MPCs, result in varying revenue and cash flow impacts.

Under the preservation of gross margin scenario, DOE applied a single uniform ''gross margin percentage'' manufacturer markup of 1.40 across all analyzed lamps, which assumes that manufacturers would be able to maintain the same amount of profit as a percentage of revenues for all lamps analyzed.

Under the technology specific markup scenario, DOE assumed that incandescent lamps, CFLs, and LED lamps have different manufacturer markups. As sales of lamp technologies that are no longer able to meet the analyzed energy conservation standards are no longer sold, the average manufacturer markup is reduced. DOE estimated an incandescent lamp manufacturer markup of approximately 1.525, a CFL manufacturer markup of approximately 1.453, and an LED lamp manufacturer markup of approximately 1.380. In the no-new-standards case these technology specific manufacturer markups produce an identical INPV as in the preservation of gross margin markup scenario.

A comparison of industry financial impacts under the two manufacturer markup scenarios is presented in section V.D.1 of this document.

V. Analytical Results and Conclusions

A. Trial Standard Levels

DOE analyzed the benefits and burdens of one trial standard level for GSILs. TSL 1 is composed of EL 1 and is the max-tech EL for GSILs.

DOE analyzed the benefits and burdens by conducting the analyses described in section IV for each TSL. Table V.1 presents the TSLs and the corresponding ELs for GSLs.

TABLE V.1—COMPOSITION OF TSLS FOR GSILS

TSL	EL	Technology required to comply with standard	Description
TSL 0	EL 0	Halogen	No new GSIL standard.
TSL 1	EL 1	Halogen Infrared (HIR)	HIR standard in 2023.

B. Economic Impacts on Individual Consumers

DOE analyzed the cost effectiveness (*i.e.,* the savings in operating costs compared to any increase in purchase price likely to result from the imposition of a standard) by considering the LCC and PBP. DOE presents the LCC of the covered product (*i.e.,* HIR lamps) and also presents a second LCC, which is used as an input for the NPV, which goes beyond GSILs and accounts for the purchase price and operating costs of out-of-scope substitute lamps (''LCC with substitution''). These analyses are discussed in the following sections.

1. Life-Cycle Cost and Payback Period

In general, higher-efficiency products can affect consumers in two ways: (1) Purchase price increases and (2) annual operating costs decrease. Inputs used for calculating the annualized LCC and PBP include total installed costs (*i.e.,* product price plus installation costs), and operating costs (*i.e.,* annual energy use, energy prices, energy price trends, repair costs, and maintenance costs). The annualized LCC calculation also uses product lifetime and a discount rate.

Table V.2 shows the average annualized LCC and PBP results for the ELs considered for GSILs in this analysis. For both the residential and commercial sector, the payback period for HIR lamps is approximately three times longer than the product life. As a result, consumers who buy HIR technologies have increased life cycle costs and do not see a benefit at TSL 1. Table V.3 shows the average annualized LCC savings for HIR lamps under TSL 1. Over 97% of residential and commercial consumers who purchase HIR lamps experience a net cost in the standards case.

Table V.4 shows the average annualized LCC savings under a product shifting scenario for TSL 1. Very few consumers are anticipated to buy HIR technology in the standards case, assuming manufacturers produce the product. Instead these numbers reflect the result of a substitution effect as consumers are priced out of the market for GSILs. That is, TSL 1 is anticipated to increase the cost of GSILs by 286 percent relative to a no-standards case, therefore driving some consumers to shift toward out-of-scope alternative lamps, yielding a reduction in operating costs relative to the base case.

DOE recognizes that the current quantifiable framework does not represent the full welfare effects of this shift in consumer purchase decisions due to an energy conservation standard. In the 2015 IRL final rule, DOE ''committed to developing a framework that can support empirical quantitative tools for improved assessment of the consumer welfare impacts of appliance standards.'' (80 FR 4141) DOE remains committed to this goal and to enhancing the methodology the Department uses to represent and quantify the consumer welfare impacts of its standards.

TABLE V.2—AVERAGE ANNUALIZED LCC AND PBP RESULTS BY EFFICACY LEVEL

EL	Average costs 2018$					Simple payback years	Average lifetime years
	Installed cost	Annualized installed cost	First year's operating cost	Annualized lifetime operating cost	Annualized LCC		
Residential Sector							
0	1.94	1.99	4.50	4.70	6.69	.....	2.0
1	7.49	7.69	3.59	3.75	11.44	6.09	2.0
Commercial Sector							
0	3.48	12.39	13.56	14.68	27.08	.....	0.7
1	9.04	32.19	10.82	11.71	43.91	2.03	0.7

Note: The results for each EL are calculated assuming that all consumers use products at that EL. The PBP is measured relative to the baseline product.

TABLE V.3—AVERAGE ANNUALIZED LCC SAVINGS RESULTS BY TRIAL STANDARD LEVEL—COVERED PRODUCT

[GSILs]

TSL	EL	GSIL life-cycle cost savings	
		Average annualized LCC savings* 2018$	Percent of consumers that experience net cost
Residential Sector			
1	1	−4.77	97.7
Commercial Sector			
1	1	−16.85	99.0

TABLE V.4—AVERAGE ANNUALIZED LCC SAVINGS RESULTS BY TRIAL STANDARD LEVEL—LCC WITH SUBSTITUTION

TSL	EL	Life-cycle cost savings	
		Average annualized LCC savings* 2018$	Percent of consumers that experience net cost
Residential Sector			
1	1	1.23	4.0

TABLE V.4—AVERAGE ANNUALIZED LCC SAVINGS RESULTS BY TRIAL STANDARD LEVEL—LCC WITH SUBSTITUTION—Continued

TSL	EL	Life-cycle cost savings	
		Average annualized LCC savings* 2018$	Percent of consumers that experience net cost
Commercial Sector			
1	1	10.36	0.43

* The savings represent the average annualized LCC savings for affected consumers.

The cost of HIR lamps cannot be recovered, and the LCC savings are negative for the covered product at issue in this NOPD. When accounting for out-of-scope product substitutes, average LCC savings are positive at TSL 1 because the majority of consumers shift to an out-of-scope LED lamp.

2. Rebuttable Presumption Payback

As discussed in section IV.E.9, EPCA establishes a rebuttable presumption that an energy conservation standard is economically justified if the increased purchase cost for a product that meets the standard is less than three times the value of the first-year energy savings resulting from the standard. In calculating a rebuttable presumption PBP for each of the considered ELs, DOE used discrete values, and, as required by EPCA, based the energy use calculation on the DOE test procedure for GSILs. In contrast, the PBPs presented in section V.B.1 were calculated using distributions that reflect the range of energy use in the field. See chapter 8 of the NOPD TSD for more information on the rebuttable presumption payback analysis.

C. National Impact Analysis

This section presents DOE's estimates of the NES and the NPV of consumer benefits that would result from each of the considered TSLs as potential amended standards. For these estimates, DOE included the impact of consumers substituting GSILs for out-of-scope CFL, LED, and incandescent alternatives.

1. Energy Savings

To estimate the energy savings attributable to potential amended standards for GSILs, DOE compared their energy consumption under the no-new-standards case to their anticipated energy consumption under each TSL. The savings are measured over the entire lifetime of products purchased in the 30-year period that begins in the year of anticipated compliance with amended standards (2023–2052). Table V.4 presents DOE's projections of the NES for each TSL considered for GSILs, as well as considered GSIL alternatives. The savings were calculated using the approach described in section IV.G of this document. In addition to GSIL energy savings, Table V.4 illustrates the increased energy consumption of consumers who transition to out-of-scope lamps, including CFL, LED, and incandescent alternatives, because more consumers purchase these lamps at TSL 1 relative to the no-standards case.

TABLE V.4—CUMULATIVE NATIONAL ENERGY SAVINGS FOR GSILS AND GSIL ALTERNATIVES; 30 YEARS OF SHIPMENTS

[2023–2052]

	TSL 1
Site Energy Savings (quads):	
GSILs	0.240
CFL alternatives	(0.003)
LED alternatives	(0.043)
Incandescent alternatives	(0.002)
Total	0.192
Source Energy Savings (quads):	
GSILs	0.646
CFL alternatives	(0.009)
LED alternatives	(0.115)
Incandescent alternatives	(0.007)
Total	0.516
FFC Energy Savings (quads):	
GSILs	0.677
CFL alternatives	(0.010)
LED alternatives	(0.120)
Incandescent alternatives	(0.007)
Total	0.540

OMB Circular A–4 [45] requires agencies to present analytical results, including separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs. Circular A–4 also directs agencies to consider the variability of key elements underlying the estimates of benefits and costs. For this proposed

[45] U.S. Office of Management and Budget. *Circular A–4: Regulatory Analysis.* September 17, 2003. Available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.*

determination, DOE undertook a sensitivity analysis using 9 years, rather than 30 years, of product shipments. The choice of a 9-year period is a proxy for the timeline in EPCA for the review of certain energy conservation standards and potential revision of and compliance with such revised standards.[46] The review timeframe established in EPCA is generally not synchronized with the product lifetime, product manufacturing cycles, or other factors specific to GSILs. Thus, such results are presented for informational purposes only and are not indicative of any change in DOE's analytical methodology. The NES sensitivity analysis results based on a 9-year analytical period are presented in Table V.5. The impacts are counted over the lifetime of GSILs purchased in 2023–2031.

TABLE V.6—CUMULATIVE NATIONAL ENERGY SAVINGS FOR GSILS AND GSIL ALTERNATIVES; 9 YEARS OF SHIPMENTS

[2023–2031]

	TSL 1
Site Energy Savings (quads):	
GSILs	0.075
CFL alternatives	(0.003)
LED alternatives	(0.012)
Incandescent alternatives	(0.001)
Total	0.059
Source Energy Savings (quads):	
GSILs	0.204
CFL alternatives	(0.007)
LED alternatives	(0.033)
Incandescent alternatives	(0.003)
Total	0.161
FFC Energy Savings (quads):	
GSILs	0.214
CFL alternatives	(0.007)
LED alternatives	(0.035)
Incandescent alternatives	(0.003)
Total	0.169

2. Net Present Value of Consumer Costs and Benefits

DOE estimated the cumulative NPV of the total costs and savings for consumers that would result from TSL 1 for GSILs. However, as described above, the benefits of TSL 1 do not come from improved efficiency for the product for which DOE is making a determination whether existing standards should be amended. Rather, due to the likelihood that manufacturers will not produce the product, and fact that consumers would be unlikely to buy it, DOE does not anticipate that adoption of HIR technology will result in any consumer benefits. Instead, any benefit from TSL 1 is the result of product shifting as consumers respond to the high upfront price of HIR lamps and substitute lower-cost, out-of-scope alternatives. In accordance with OMB's guidelines on regulatory analysis,[47] DOE calculated NPV using both a 7-percent and a 3-percent real discount rate. Table V.7 shows the consumer NPV results with impacts counted over the lifetime of GSILs purchased in 2023–2052.

TABLE V.7—CUMULATIVE NET PRESENT VALUE OF QUANTIFIABLE CONSUMER BENEFITS FOR GSILS AND GSIL ALTERNATIVES; 30 YEARS OF SHIPMENTS

[2023–2052]

	TSL 1
3 percent (billions 2018$):	
GSILs	5.436
CFL alternatives	(0.110)
LED alternatives	(1.082)
Incandescent alternatives	(0.071)
Total	4.173
7 percent (billions 2018$):	

[46] Section 325(m) of EPCA requires DOE to review its standards at least once every 6 years, and requires, for certain products, a 3-year period after any new standard is promulgated before compliance is required, except that in no case may any new standards be required within 6 years of the compliance date of the previous standards. If DOE makes a determination that amended standards are not needed, it must conduct a subsequent review within three years following such a determination. As DOE is evaluating the need to amend the standards, the sensitivity analysis is based on the review timeframe associated with amended standards. While adding a 6-year review to the 3-year compliance period adds up to 9 years, DOE notes that it may undertake reviews at any time within the 6-year period and that the 3-year compliance date may yield to the 6-year backstop. A 9-year analysis period may not be appropriate given the variability that occurs in the timing of standards reviews and the fact that for some products, the compliance period is 5 years rather than 3 years.

[47] U.S. Office of Management and Budget. *Circular A–4: Regulatory Analysis.* September 17, 2003. Available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.*

TABLE V.7—CUMULATIVE NET PRESENT VALUE OF QUANTIFIABLE CONSUMER BENEFITS FOR GSILS AND GSIL ALTERNATIVES; 30 YEARS OF SHIPMENTS—Continued

[2023–2052]

	TSL 1
GSILs	2.960
CFL alternatives	(0.072)
LED alternatives	(0.602)
Incandescent alternatives	(0.044)
Total	2.241

The NPV results based on the aforementioned 9-year analytical period are presented in Table V.8. The impacts are counted over the lifetime of products purchased in 2023–2031. As mentioned previously, such results are presented for informational purposes only and are not indicative of any change in DOE's analytical methodology or decision criteria.

TABLE V.8—CUMULATIVE NET PRESENT VALUE OF QUANTIFIABLE CONSUMER BENEFITS FOR GSIL AND GSIL ALTERNATIVES; 9 YEARS OF SHIPMENTS

[2023–2031]

	TSL 1
3 percent (billions 2018$):	
GSILs	2.154
CFL alternatives	(0.088)
LED alternatives	(0.441)
Incandescent alternatives	(0.040)
Total	1.585
7 percent (billions 2018$):	
GSILs	1.548
CFL alternatives	(0.062)
LED alternatives	(0.328)
Incandescent alternatives	(0.030)
Total	1.128

D. Economic Impacts on Manufacturers

DOE performed an MIA to estimate the impact of analyzed energy conservation standards on manufacturers of GSILs. In this instance, DOE also can look to the actual experience of manufacturers that have produced HIR lamps in the recent past. The following section describes the expected impacts on GSIL manufacturers at the analyzed TSL.

1. Industry Cash Flow Analysis Results

In this section, DOE provides the results from the MIA, which examines changes in the industry that would result from the analyzed standards. The following tables illustrate the estimated financial impacts (represented by changes in INPV) of potential amended energy conservation standards on manufacturers of GSILs, as well as the conversion costs that DOE estimates manufacturers of GSILs would incur at the analyzed TSL.

To evaluate the range of cash-flow impacts on the GSIL industry, DOE modeled two manufacturer markup scenarios that correspond to the range of anticipated market responses to potential standards. Each markup scenario results in a unique set of cash flows and corresponding industry values at the analyzed TSL. In the following discussion, the INPV results refer to the difference in industry value between the no-new-standards case and the standards case that result from the sum of discounted cash flows from the reference year (2019) through the end of the analysis period (2052).

DOE modeled a preservation of gross margin markup scenario. This scenario assumes that in the standards case, manufacturers would be able to pass along all the higher production costs required for more efficacious products to their consumers. DOE also modeled a technology specific markup scenario. In the technology specific markup scenario, different lamp technologies (incandescent, CFL, LED) have different manufacturer markups.

Table V.8 and Table V.9 present the results of the industry cash flow analysis for GSIL manufacturers under the preservation of gross margin and the technology specific markup scenarios.

TABLE V.9—MANUFACTURER IMPACT ANALYSIS FOR GSILS—PRESERVATION OF GROSS MARGIN MARKUP SCENARIO

	Units	No-new-standards case	TSL 1
INPV	*2018$ millions*	317.5	312.2
Change in INPV	*2018$ millions*		(5.0)
	%		(1.6)

TABLE V.9—MANUFACTURER IMPACT ANALYSIS FOR GSILS—PRESERVATION OF GROSS MARGIN MARKUP SCENARIO—Continued

	Units	No-new-standards case	TSL 1
Product Conversion Costs	*2018$ millions*		2.8
Capital Conversion Costs	*2018$ millions*		6.0
Total Conversion Costs	*2018$ millions*		8.8

TABLE V.10—MANUFACTURER IMPACT ANALYSIS FOR GSILS—TECHNOLOGY SPECIFIC MARKUP SCENARIO

	Units	No-new-standards case	TSL 1
INPV	*2018$ millions*	317.5	313.6
Change in INPV	*2018$ millions*		(3.7)
	%		(1.2)
Product Conversion Costs	*2018$ millions*		2.8
Capital Conversion Costs	*2018$ millions*		6.0
Total Conversion Costs	*2018$ millions*		8.8

At TSL 1, DOE estimates that impacts on INPV will range from −$5 million to −$3.7 million, or a change in INPV of −1.6 to −1.2 percent. At TSL 1, free cash-flow is $30.0 million, which is a decrease of approximately $3.7 million compared to the no-new-standards case value of $33.7 million in 2022, the year leading up to the potential standard.

At TSL 1, GSIL manufacturers spend approximately $6 million to purchase equipment necessary to manufacture HIR capsules and spend approximately $2.8 million in R&D and testing costs to introduce the newly created HIR products. Lighting manufacturers sell approximately 15 million fewer units annually after 2023 at TSL 1 because most consumers purchase longer lifetime products. Should manufacturers make the unlikely decision to produce HIR lamps, they might experience some increase in revenue due to some consumers purchasing significantly more expensive HIR lamps. However, any increase in revenue is outweighed by the $8.8 million in conversion costs that is spent prior to the compliance year in both the preservation of gross margin and technology specific margin markup scenarios. This results in a slight decrease in INPV in both markup scenarios. Manufacturers, anticipating the cost of transitioning product lines and the lack of consumer interest in HIR lamps, are highly unlikely to undertake these expenses.

2. Direct Impacts on Employment

DOE typically presents quantitative estimates of the potential changes in production employment that could result from the analyzed energy conservation standard levels. However, all production facilities that once produced GSILs in the U.S. have either closed or are scheduled to close prior to 2023, the estimated compliance year of analyzed standards. Therefore, DOE assumed there will not be any domestic employment for GSIL production after 2023, and that none of the analyzed standards would impact domestic GSIL production employment. While there is limited CFL and LED lamp production in the U.S., DOE does not assume that any CFL or LED lamp domestic production employment would be impacted by the analyzed standards. Therefore, the proposed determination would not have a significant impact on domestic employment in the GSIL industry.

3. Impacts on Manufacturing Capacity

DOE does not anticipate any significant capacity constraints at the analyzed energy conservation standards. At TSL 1, manufacturers would most likely need to purchase machines used to coat halogen capsules. These machines are known equipment and are currently used for incandescent reflector lamp production. Equipment costs for these machines are included in the MIA as part of the capital conversion costs at TSL 1. Supply would most likely be able to meet the increase in demand for the machines given the 3-year compliance period for any potential energy conservation standards.

4. Impacts on Subgroups of Manufacturers

Using average cost assumptions to develop an industry cash-flow estimate may not be adequate for assessing differential impacts among manufacturer subgroups. Small manufacturers, niche equipment manufacturers, and manufacturers exhibiting cost structures substantially different from the industry average could be affected disproportionately. DOE identified one manufacturer subgroup for GSILs, small manufacturers.

For the small business subgroup analysis, DOE applied the small business size standards published by the Small Business Administration (SBA) to determine whether a company is considered a small business. The size standards are codified at 13 CFR part 121. To be categorized as a small business under NAICS code 335110, ''electric lamp bulb and part manufacturing,'' a GSIL manufacturer and its affiliates may employ a maximum of 1,250 employees. The 1,250-employee threshold includes all employees in a business's parent company and any other subsidiaries. The small business subgroup analysis is discussed in section VI.C of this document.

5. Cumulative Regulatory Burden

One aspect of assessing manufacturer burden involves looking at the cumulative impact of multiple DOE standards and the product-specific regulatory actions of other Federal agencies that affect the manufacturers of a covered product. While any one regulation may not impose a significant burden on manufacturers, the combined effects of several existing or impending regulations may have serious consequences for some manufacturers, groups of manufacturers, or an entire industry. Assessing the impact of a single regulation may overlook this cumulative regulatory burden. In addition to energy conservation

standards, other regulations can significantly affect manufacturers' financial operations. Multiple regulations affecting the same manufacturer can strain profits and lead companies to abandon product lines or markets with lower expected future returns than competing products. For these reasons, DOE typically conducts an analysis of cumulative regulatory burden as part of its rulemakings pertaining to appliance efficiency. However, given the tentative conclusion discussed in section V.E, DOE did not conduct a cumulative regulatory burden analysis.

E. Proposed Determination

When considering proposed standards, the new or amended energy conservation standard that DOE adopts for any type (or class) of covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) In determining whether a standard is economically justified, the Secretary must determine whether the benefits of the standard exceed its burdens, considering to the greatest extent practicable the seven statutory factors discussed previously. (42 U.S.C. 6295(o)(2)(B)(i)) The new or amended standard must also ''result in significant conservation of energy.'' (42 U.S.C. 6295(o)(3)(B))

In response to the August 2017 NODA, energy efficiency advocates [48] (EEAs) submitted a comment in support of a standard that eliminates incandescent lamps. EEAs stated that despite falling prices, increased choices, and rising sales of LED lamps, incandescent lamps will retain a large share of the U.S. lighting market unless a standard eliminates them. EEAs noted that historical experience with technology substitution indicates that legacy technologies, like the incandescent light bulb, usually persist in the market long after they stop being a cost-effective choice for consumers. (EEAs, No. 11 at p. 10) [11]

However, NEMA stated the current energy conservation standards for GSILs cannot be amended in accordance with the criteria set forth in 42 U.S.C. 6295(o), and therefore DOE should determine not to amend standards for GSILs. (NEMA, No. 329 at p. 38) [12] GE added that there are only two pathways to achieve significant energy savings for GSILs: (1) Consider a 45 lm/W standard or (2) consider mandating HIR technology. Regarding the first approach, GE concluded that because there are no incandescent or halogen products even close to 45 lm/W on the market, DOE can quickly reach a conclusion that 45 lm/W GSIL products are not technically feasible. DOE agrees with GE's assertion concerning the technological feasibility of a 45 lm/W standard for GSILs. DOE notes that EPCA requires that DOE make a determination whether standards in effect for general service lamps should be amended to establish more stringent standards than certain standards specified in EPCA. 42 U.S.C. 6295(i)(6)(A)(i)(I). In making that determination DOE is not limited to incandescent technologies and DOE must consider a minimum standard applicable to GSLs of 45 lm/W. 42 U.S.C. 6295(i)(6)(A)(ii) DOE will make that determination and will consider a 45 lm/W standard in a subsequent document. Regarding the second approach, GE stated that DOE has already concluded in the 2015 IRL final rule that a standard level mandating HIR technology is not economically justified. GE pointed out that as nothing has changed with this technology, DOE has no reason to believe that the outcome of such an analysis for A-line lamps would produce a different result. (GE, No. 325 at p. 4) [12]

As described previously, when considering proposed standards, the amended energy conservation standard that DOE adopts for any type (or class) of covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Because an analysis of potential economic justification and energy savings first requires an evaluation of the relevant technology, in the following sections DOE first discusses the technological feasibility of amended standards. DOE then addresses the energy savings and economic justification associated with potential amended standards.

1. Technological Feasibility

EPCA mandates that DOE consider whether amended energy conservation standards for GSILs would be technologically feasible. (42 U.S.C. 6295(o)(2)(A)) DOE has tentatively determined that there are design options that would improve the efficacy of GSILs. These design options are being used in similar products (IRLs) that are commercially available and have been used in commercially available GSILs in the past and therefore are technologically feasible. (See sections IV.A.3 and IV.A.4 for further information.) Hence, DOE has tentatively determined that amended energy conservation standards for GSILs are technologically feasible.

2. Significant Conservation of Energy

EPCA also mandates that DOE consider whether amended energy conservation standards for GSILs would result in result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B)) As stated in section III.D.2, DOE has not finalized updates to the Process Rule, in which DOE considers how to determine whether a new or amended standard would result in a significant energy savings. As this rule is not yet finalized, the Department is not relying on that proposed threshold for this determination. However, DOE is still required by statute to issue only such standards as will save a significant amount of energy. (42 U.S.C. 6295(o)(3)(B))

As described above, there are no energy savings or benefits from transitioning to HIR technology. Any energy savings that might result from establishing a standard at that TSL 1 are the result of product shifting as consumers abandon GSIL–HIR products in favor of different product types having different performance characteristics and features. DOE notes that EPCA prohibits DOE from prescribing an amended or new standard if that the standard is likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States at the time of the Secretary's finding. 42 U.S.C. 6295(o)(4)

3. Economic Justification

In determining whether a standard is economically justified, the Secretary must determine whether the benefits of the standard exceed its burdens, considering to the greatest extent practicable the seven statutory factors discussed previously. (42 U.S.C. 6295(o)(2)(B)(i)) One of those seven factors is the savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that

[48] The group described as the ''energy efficiency advocates'' includes the Appliance Standards Awareness Project, American Council for an Energy Efficient Economy, National Consumer Law Center, Consumer Federation of America, Natural Resources Defense Council, Northwest Energy Efficiency Alliance, Northeast Energy Efficiency Partnerships, Alliance to Save Energy, Northwest Power & Conservation Council, and the Southeast Energy Efficiency Alliance.

are likely to result from the standard. This factor is assessed using life cycle cost and payback period analysis, discussed in section III.E.1.b of this NOPD.

Given the high upfront cost and long payback period, these analyses do not anticipate that consumers will benefit from introduction of HIR lamp technology. Additionally, the recent experiences of two manufacturers who attempted and failed to market such a products illustrates that they are not commercially viable. At TSL 1, DOE believes there is uncertainty as to whether manufacturers would spend the capital required to produce HIR lamps given the low probability of recovering those costs as consumers substitute less costly products. Manufacturers could instead choose to forego the investment and produce other lighting products or exit the market entirely.

After considering the analysis and weighing the benefits and the burdens, DOE concluded that, at TSL 1 for GSILs, the benefits of energy savings and positive NPV of consumer benefits would be outweighed by the fact that the covered product PBP exceeds covered product lifetime by nearly a factor of three. Based on the second EPCA factor that DOE is required to evaluate, DOE has tentatively concluded that imposition of a standard at TSL 1 is not economically justified because the operating costs of the covered product are insufficient to recover the upfront cost. Based on these considerations, DOE is not amending energy conservation standards for GSILs.

DOE has presented additional consumer choice analysis anticipating that if it were to establish a standard at TSL 1, most consumers will substitute other available products, such as LEDs, CFLs, and non-GSIL incandescent lamps (the substitution scenario). DOE then estimated the NPV of the total costs and benefits experienced by the Nation in this scenario. (See results in Table V.7 and Table V.8) DOE also conducted an MIA to estimate the impact of amended energy conservation standards on manufacturers of GSILs in this consumer choice scenario. (See results in Table V.9 and Table V.10)

Under the consumer choice analysis, the NPV of consumer benefits at TSL 1 would be $2.241 billion using a discount rate of 7 percent, and $4.173 billion using a discount rate of 3 percent. However, this NPV is based on the anticipated lifecycle costs to consumers who substitute other lamps due to price sensitivity or the unavailability of GSILs. At TSL 1, the average covered product LCC impact is a cost of $4.77 in the residential sector and $16.85 in the commercial sector. The simple payback period is 6.09 years (compared to an average lifetime of 2.0 years) in the residential sector and 2.03 years (compared to an average lifetime of 0.6 years) in the commercial sector. The fraction of GSIL consumers who experience a net LCC cost is 97.7 percent in the residential sector and 99 percent in the commercial sector. At TSL 1, DOE estimates that INPV will decrease between $5.0 million to $3.7 million, or a decrease in INPV of 1.6 to 1.2 percent. However, EPCA prohibits DOE from prescribing an amended or new standard if that the standard is likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States at the time of the Secretary's finding. DOE cannot find economic justification in a standard the purpose of which is to force the unavailability of a product type, performance characteristic or feature in contravention of EPCA.

In this proposed determination, based on the initial determination that amended standards would not be economically justified, and that there would not be any benefits from transitioning to HIR technology at TSL 1, DOE has tentatively determined that energy conservation standards for GSILs do not need to be amended. DOE will consider all comments received on this proposed determination in issuing any final determination.

VI. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

This proposed determination has been determined to be a significant regulatory action for purposes of Executive Order 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (Oct. 4, 1993). As a result, the Office of Management and Budget (OMB) reviewed this proposed determination.

B. Review Under Executive Orders 13771 and 13777

On January 30, 2017, the President issued Executive Order (E.O.) 13771, ''Reducing Regulation and Controlling Regulatory Costs.'' E.O. 13771 stated the policy of the executive branch is to be prudent and financially responsible in the expenditure of funds, from both public and private sources. E.O. 13771 stated it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations.

Additionally, on February 24, 2017, the President issued E.O. 13777, ''Enforcing the Regulatory Reform Agenda.'' E.O. 13777 required the head of each agency to designate an agency official as its Regulatory Reform Officer (RRO). Each RRO oversees the implementation of regulatory reform initiatives and policies to ensure that agencies effectively carry out regulatory reforms, consistent with applicable law. Further, E.O. 13777 requires the establishment of a regulatory task force at each agency. The regulatory task force is required to make recommendations to the agency head regarding the repeal, replacement, or modification of existing regulations, consistent with applicable law. At a minimum, each regulatory reform task force must attempt to identify regulations that:

(1) Eliminate jobs, or inhibit job creation;

(2) Are outdated, unnecessary, or ineffective;

(3) Impose costs that exceed benefits;

(4) Create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;

(5) Are inconsistent with the requirements of Information Quality Act, or the guidance issued pursuant to that Act, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or

(6) Derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.

DOE initially concludes that this proposed determination is consistent with the directives set forth in these executive orders. As discussed in this document, DOE is not proposing to amend energy conservation standards for GSILs and the proposed rule would not yield any costs or cost savings. Therefore, if finalized as proposed, this NOPD is expected to be an E.O. 13771 other action.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IRFA) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities

in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website (*http://energy.gov/gc/office-general-counsel*).

DOE reviewed this proposed determination under the provisions of the Regulatory Flexibility Act and the policies and procedures published on February 19, 2003. Because DOE is proposing not to amend standards for GSILs, if adopted, the determination would not amend any energy conservation standards. On the basis of the foregoing, DOE certifies that the proposed determination, if adopted, would have no significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared an IRFA for this proposed determination. DOE will transmit this certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

D. Review Under the National Environmental Policy Act of 1969

DOE is analyzing this NOPD in accordance with the National Environmental Policy Act of 1969 (NEPA) and DOE's NEPA implementing regulations (10 CFR part 1021). DOE's regulations include a categorical exclusion for actions which are interpretations or rulings with respect to existing regulations. 10 CFR part 1021, subpart D, Appendix A4. DOE anticipates that this action qualifies for categorical exclusion A4 because it is an interpretation or ruling in regards to an existing regulation and otherwise meets the requirements for application of a categorical exclusion. See 10 CFR 1021.410. DOE will complete its NEPA review before issuing the final action.

E. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed determination and has tentatively determined that it 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. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed determination. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) Therefore, no further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this proposed determination meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *http://energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf*.

This proposed determination does not contain a Federal intergovernmental mandate, nor is it expected to require expenditures of $100 million or more in any one year by the private sector. As a result, the analytical requirements of UMRA do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This proposed determination would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

Pursuant to Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (March 15, 1988), DOE has determined that this proposed determination would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this NOPD under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor Executive Order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

Because this proposed determination does not propose amended energy conservation standards for GSILs, it is not a significant energy action, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects.

L. Information Quality

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (OSTP), issued its Final Information Quality Bulletin for Peer Review (the Bulletin). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the bulletin is to enhance the quality and credibility of the Government's scientific information. Under the Bulletin, the energy conservation standards rulemaking analyses are ''influential scientific information,'' which the Bulletin defines as ''scientific information the agency reasonably can determine will have, or does have, a clear and substantial impact on important public policies or private sector decisions.'' *Id.* at 70 FR 2667.

In response to OMB's Bulletin, DOE conducted formal peer reviews of the energy conservation standards development process and the analyses that are typically used and has prepared a report describing that peer review.[49] Generation of this report involved a rigorous, formal, and documented evaluation using objective criteria and qualified and independent reviewers to make a judgment as to the technical/scientific/business merit, the actual or anticipated results, and the productivity and management effectiveness of programs and/or projects. DOE has determined that the peer-reviewed analytical process continues to reflect current practice, and the Department followed that process for developing energy conservation standards in the case of the present action.

VII. Public Participation

A. Attendance at Public Meeting

The time, date and location of the public meeting are listed in the **DATES** and **ADDRESSES** sections at the beginning of this document. If you plan to attend the public meeting, please notify Ms. Regina Washington at (202) 586–1214 or *Regina.Washington@ee.doe.gov*.

Please note that foreign nationals visiting DOE Headquarters are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting, please inform DOE of this fact as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: *Regina.Washington@ee.doe.gov* so that the necessary procedures can be completed.

DOE requires visitors to have laptops and other devices, such as tablets, checked upon entry into the building. Any person wishing to bring these devices into the Forrestal Building will be required to obtain a property pass. Visitors should avoid bringing these devices, or allow an extra 45 minutes to check in. Please report to the visitor's desk to have devices checked before proceeding through security.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS), there have been recent changes regarding ID requirements for individuals wishing to enter Federal buildings from specific States and U.S. territories. DHS maintains an updated website identifying the State and territory driver's licenses that currently are acceptable for entry into DOE facilities at *https://www.dhs.gov/real-id-enforcement-brief*. A driver's license from a State or territory identified as not compliant by DHS will not be accepted for building entry and one of the alternate forms of ID listed below will be required. Acceptable alternate forms of Photo-ID include U.S. Passport or Passport Card; an Enhanced Driver's License or Enhanced ID-Card issued by States and territories as identified on the DHS website (Enhanced licenses issued by these States and territories are clearly marked Enhanced or Enhanced Driver's License); a military ID or other Federal government-issued Photo-ID card.

In addition, you can attend the public meeting via webinar. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: *http://www1.eere.energy.gov/buildings/appliance_standards/product.aspx/productid/41*. Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has plans to present a prepared general statement may request that copies of his or her statement be made available at the public meeting. Such persons may submit requests, along with an advance electronic copy of their statement in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format, to the appropriate address

[49] ''Energy Conservation Standards Rulemaking Peer Review Report.'' 2007. Available at *http://energy.gov/eere/buildings/downloads/energy-conservation-standards-rulemaking-peer-review-report-0*.

shown in the **ADDRESSES** section at the beginning of this NOPR. The request and advance copy of statements must be received at least one week before the public meeting and may be emailed, hand-delivered, or sent by mail. DOE prefers to receive requests and advance copies via email. Please include a telephone number to enable DOE staff to make a follow-up contact, if needed.

C. Conduct of Public Meeting

DOE will designate a DOE official to preside at the public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the public meeting. After the public meeting and until the end of the comment period, interested parties may submit further comments on the proceedings and any aspect of the rulemaking.

The public meeting will be conducted in an informal, conference style. DOE will present summaries of comments received before the public meeting, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will permit, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly and comment on statements made by others. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this rulemaking. The official conducting the public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the public meeting.

A transcript of the public meeting will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this notice. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. The Time and Date of the Public Meeting and Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule before or after the public meeting but no later than the date provided in the **DATES** section at the beginning of this NOPD. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document.

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 itself 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. Otherwise, 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://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 in 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. No telefacsimiles (faxes) will 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, that are written in English, and that are 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. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and 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.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include (1) a description of the items, (2) whether and why such items are customarily treated as confidential within the industry, (3) whether the information is generally known by or available from other sources, (4) whether the information has previously been made available to others without obligation concerning its confidentiality, (5) an explanation of the competitive injury to the submitting person that would result from public disclosure, (6) when such information might lose its confidential character due to the passage of time, and (7) why disclosure of the information would be contrary to the public interest.

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).

E. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

(1) DOE seeks comment on the technology options identified and the ones selected as design options in the screening analysis. See sections IV.A.3 and IV.A.4 of this document.

(2) DOE seeks comment on the performance characteristics of the more efficacious substitute modeled for GSILs. See section IV.B.3 of this document.

(3) DOE welcomes any relevant data and comment on the energy use analysis methodology. See section IV.D of this document.

(4) DOE welcomes any relevant data and comment on the LCC and PBP analysis methodology. See section IV.E of this document.

(5) DOE welcomes any relevant data and comment on the shipments analysis methodology. See section IV.F of this document.

(6) DOE seeks any relevant data and comment on the potential rebound effect for GSILs. See section IV.G.1 of this document.

VIII. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of proposed determination.

Signed in Washington, DC, on August 28, 2019.

Daniel R. Simmons,

Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 2019–18941 Filed 9–4–19; 8:45 am]

BILLING CODE 6450–01–P

FEDERAL REGISTER

Vol. 84 Thursday,

No. 172 September 5, 2019

Part IV

The President

Proclamation 9917—National Alcohol and Drug Addiction Recovery Month, 2019

Proclamation 9918—National Childhood Cancer Awareness Month, 2019

Proclamation 9919—National Preparedness Month, 2019

Proclamation 9920—Labor Day, 2019

Executive Order 13885—Establishing the National Quantum Initiative Advisory Committee

Federal Register
Vol. 84, No. 172
Thursday, September 5, 2019

Presidential Documents

Title 3—

The President

Proclamation 9917 of August 30, 2019

National Alcohol and Drug Addiction Recovery Month, 2019

By the President of the United States of America

A Proclamation

During National Alcohol and Drug Addiction Recovery Month, we raise awareness of substance use disorder and celebrate the millions of Americans who have successfully overcome addiction. Their stories of healing and redemption are a source of hope and encouragement to others battling addiction.

Addiction to alcohol, opioids, and illicit drugs is a public health emergency. For this reason, I have taken aggressive action to combat the scourge of addiction and help those affected by it. My Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand is designed both to reduce the demand for drugs through education, awareness, and the prevention of over-prescription and to cut off the flow of drugs across our borders. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, which I signed into law last year, is the single largest bill dedicated to combating the drug crisis ever passed in the history of our country. This law expands access to evidence-based treatment, protects our communities from illicit drugs, invests more in sustained recovery, brings those in treatment and recovery back into the workforce, and raises public awareness of the dangers of illicitly imported synthetic opioids. My Administration also secured more than $6 billion over 2 years to help Americans affected by addiction to opioids and other drugs have access to the care they need. And we continue working closely with States to waive overly restrictive Federal rules so they have more flexibility to develop and implement innovative solutions to this crisis.

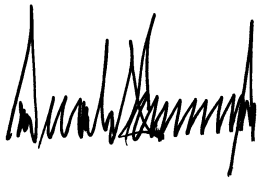
Every American can work to end the crisis of alcohol and drug addiction in our country, which shatters relationships and erodes the strength of our communities. Countless first responders, healthcare professionals, counselors, recovery coaches, spiritual leaders, and volunteers help Americans every day to achieve and sustain recovery through their compassion and dedication. Equally important are the courageous individuals in recovery who have battled stigma, misunderstanding, and the disease of addiction to build a new life. Their struggles, lessons learned, and experiences gained on the road to recovery offer invaluable inspiration to all who fight addiction. Through *The Crisis Next Door* platform launched by the White House last year, Americans whose lives have been tormented by addiction can share their stories and provide a glimpse into the tragic consequences of substance use disorder and the hope, healing, and joy of lives reclaimed through recovery.

This month, we reaffirm our commitment to the critical battle against alcohol and drug addiction, remember the lives lost to this disease, and honor those in recovery. By helping those still struggling find the treatment they need and by welcoming home those who are recovering, we can make our communities and our Nation stronger, healthier, and more prosperous.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim September 2019 as National Alcohol and Drug Addiction Recovery Month. I call upon the

people of the United States to observe this month with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of August, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-fourth.



[FR Doc. 2019–19352
Filed 9–4–19; 11:15 am]
Billing code 3295–F9–P

Presidential Documents

Proclamation 9918 of August 30, 2019

National Childhood Cancer Awareness Month, 2019

By the President of the United States of America

A Proclamation

During National Childhood Cancer Awareness Month, we recognize the brave young Americans who are courageously fighting cancer, and we pause to remember those we have lost to this horrible disease. We also reaffirm our Nation's commitment to developing cures for pediatric cancer, which inflicts terrible pain on children and causes tremendous anguish for parents and loved ones.

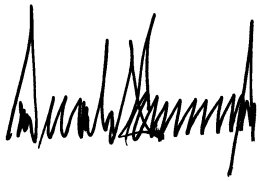
Each year, more than 15,000 children and adolescents under the age of 19 are diagnosed with cancer. Although cancer is the leading cause of post-infancy death among our Nation's young people, there is hope for those afflicted by this disease. In the last half century, the life expectancy of children and adolescents with cancer has greatly increased, with approximately 85 percent now living for at least 5 years after being diagnosed. Building upon this progress, we continue our efforts to find effective and innovative medical procedures to treat and prevent all forms of cancer and to improve the quality of life for childhood cancer survivors.

My Administration is committed to supporting our Nation's dedicated medical professionals, researchers, and innovators as they work to win the fight against childhood cancer. Last year, I signed into law the Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act. This legislation will support research for childhood cancers, explore effective treatments, and help enhance the quality of long-term care for the tenacious young people who have finished treatment and entered into remission. I am also working with the Congress to invest $500 million over the next decade in cancer-related research. This funding will enable our Nation's best scientists and doctors to learn from every child with cancer, creating new opportunities to understand the unique causes of and best cures for childhood cancer.

This month, we honor the more than 400,000 survivors of childhood and adolescent cancers in the United States. Their resilient spirit and immeasurable courage inspire us all. We also express our sincerest gratitude to those who work tirelessly to ensure that all children can live healthy, long, and productive lives.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim September 2019 as National Childhood Cancer Awareness Month. I encourage all Americans to observe this month with appropriate programs and activities that raise awareness of the efforts to find a cure for childhood cancer.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of August, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-fourth.



[FR Doc. 2019–19357
Filed 9–4–19; 11:15 am]
Billing code 3295–F9–P

Presidential Documents

Proclamation 9919 of August 30, 2019

National Preparedness Month, 2019

By the President of the United States of America

A Proclamation

Since the early days of our Nation's history, Americans have always demonstrated perseverance and determination in the face of great challenges. Our Nation's efforts to be prepared for whatever lies ahead have contributed to our ability to consistently rise to the occasion when adversity strikes. During National Preparedness Month, we focus on promoting a culture of preparedness to make our homes, businesses, communities, and Nation more ready and resilient in the face of natural, adversarial, accidental, and technological hazards. We also honor and express our immense appreciation for the brave first responders who risk their lives to help others before, during, and after emergencies.

During the last 2 years, Americans have faced some of the most devastating natural disasters and emergencies in our Nation's history. From the U.S. Virgin Islands to the Hawaiian Islands, we have endured hurricanes, wildfires, floods, blizzards, earthquakes, tornadoes, and other extreme weather and perilous events. Our resolve as a Nation has been tested again and again. More than 50 people lost their lives after record rainfall and strong winds from Hurricane Florence caused catastrophic flooding and structural damage throughout the Carolinas. Hurricane Michael became the strongest hurricane ever to hit the Florida Panhandle, causing major damage to property and tragically taking more lives. And California's Camp Fire, which took the lives of more than 80 people and destroyed thousands of homes, was the deadliest and one of the most destructive wildfires in more than a century.

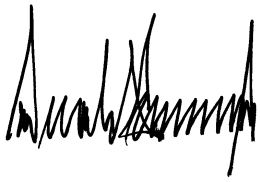
In spite of these tremendous challenges, the American people remain steadfast in their commitment to overcoming any adversity. While Federal, State, local, tribal, and territorial offices, as well as non-governmental organizations, coordinate with first responders and emergency personnel before, during, and after an emergency, the most integral part of an effective recovery following a disaster is preparedness at every level of government, in the private sector, and especially among our citizens. Maintaining readiness starts by having an emergency plan in place before disaster strikes. Signing up for alerts sent to mobile devices is crucial. These alerts provide critical early warnings, enabling people to get to safety before disaster strikes. An emergency fund can help cover unexpected costs for basic needs like food, water, lodging, gas, and insurance deductibles. It is also crucial to designate an out-of-town contact person that family members can call in case of an emergency. And parents and guardians should talk with their children about how to be prepared for unexpected emergencies at home or at school. The Federal Emergency Management Agency's *Ready Campaign* outlines simple, cost-effective, and life-saving measures you can take to prepare yourself, your family, and your property. Taking these simple steps can make a big difference during a crisis or natural disaster.

This month, as Hurricane Dorian bears down on the Florida coast, I encourage all Americans to take action to be ready and resilient. While we cannot always know when the next disaster or emergency will confront us, we must remain ready. Together, we can ensure that all Americans have the

information and resources they need to safeguard themselves and their loved ones from crisis or disaster.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim September 2019 as National Preparedness Month. I encourage all Americans, including Federal, State, tribal, and local officials, to take action to be prepared for disaster or emergency by making and practicing their emergency response plans. Each step we take to become better prepared makes a real difference in how our families and communities will respond and persevere when faced with the unexpected.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of August, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-fourth.



[FR Doc. 2019–19365
Filed 9–4–19; 11:15 am]
Billing code 3295–F9–P

Presidential Documents

Proclamation 9920 of August 30, 2019

Labor Day, 2019

By the President of the United States of America

A Proclamation

On Labor Day, we recognize the remarkable American workers who comprise the greatest labor force in the world. American workers are the heart and soul of our Nation's economic resurgence. Since my first day in office, I have followed through on my promise to fight for an agenda that puts American workers first.

My Administration's pro-growth policies have enabled countless Americans to reclaim the dignity of work and reap the rewards of our thriving economy. Since my election, the American economy has added more than 6 million new jobs, and for the past 17 months, the unemployment rate has held near record lows. In 2017, as the unemployment rate decreased, the rates of injuries and illnesses in the workplace also declined. Additionally, employers are paying higher wages, which are rising at the fastest pace in a decade. Jobs are consistently becoming available faster than people can fill them.

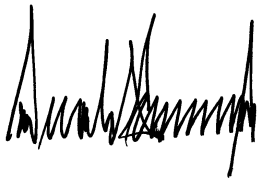
As the 21st century global economy evolves, my Administration is making it a priority to prepare the American workforce of tomorrow. Last year, I signed an Executive Order establishing the President's National Council for the American Worker to ensure that students and workers have access to the affordable, practical, and innovative education and job training they need to be successful across high-demand industries. We are asking companies to sign our Pledge to America's Workers and commit to expanding programs that educate, train, or re-skill employees. In July, as of the 1-year anniversary of our pledge, more than 300 companies and organizations had already joined us in this effort, committing to more than 12 million new education and training opportunities for American students and workers. We are also promoting expanded access to apprenticeships through the Industry-Recognized Apprenticeship Program, which will enable associations, unions, educational institutions, and non-profit organizations to partner and create exceptional opportunities for apprentices to earn and learn through their careers. Additionally, we are seeking to expand Pell Grant program eligibility for high-quality, short-term education and training programs in popular career fields.

My Administration has been working tirelessly to renegotiate one-sided trade agreements to obtain fairer terms for American companies and workers. With the signing of the United States-Mexico-Canada Agreement (USMCA), we took bold and needed action to replace the outdated and unbalanced North American Free Trade Agreement. Once approved by the Congress, the USMCA will support higher-paying jobs for American workers by enhancing the freedom of all American businesses across all sectors of our economy. We also significantly updated one of our most consequential trade deals, the United States-Korea Free Trade Agreement, bringing real benefits to American workers. And we are aggressively enforcing the well-established trade laws of the United States to protect American workers and businesses from unfair trade practices that harm them.

Today, we honor those Americans whose contributions have turned our country into an economic powerhouse, and we renew our commitment to create an environment that continues to foster and promote opportunity.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim September 2, 2019, as Labor Day. I call upon all public officials and people of the United States to observe this day with appropriate programs, ceremonies, and activities that honor the contributions and resilience of working Americans.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of August, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-fourth.



[FR Doc. 2019–19366
Filed 9–4–19; 11:15 am]
Billing code 3295–F9–P

Presidential Documents

Executive Order 13885 of August 30, 2019

Establishing the National Quantum Initiative Advisory Committee

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 104(a) of the National Quantum Initiative Act (Public Law 115–368) (Act), and section 301 of title 3, United States Code, and in order to ensure continued American leadership in quantum information science and technology applications, it is hereby ordered as follows:

Section 1. *Establishment.* The National Quantum Initiative Advisory Committee (Committee) is hereby established. The Committee shall consist of the Director of the Office of Science and Technology Policy or the Director's designee (Director) and not more than 22 members appointed by the Secretary of Energy (Secretary). Committee members shall represent industry, universities, Federal laboratories, and other Federal Government agencies. Committee members must be qualified to provide advice and information on quantum information science and technology research, development, demonstrations, standards, education, technology transfers, commercial application, and national security economic concerns. The Director shall serve as a Co-Chair of the Committee. The Secretary shall designate at least one of the Committee members to serve as Co-Chair with the Director.

Sec. 2. *Functions.* (a) The Committee shall advise the Secretary and the Subcommittee on Quantum Information Science of the National Science and Technology Council (Subcommittee) and make recommendations to the Secretary to consider when reviewing and revising the National Quantum Initiative Program (Program) established pursuant to section 101 of the Act. The Committee shall also carry out all responsibilities set forth in section 104 of the Act.

(b) The Committee shall meet at least twice a year and shall:

(i) respond to requests from the Co-Chairs of the Committee for information, analysis, evaluation, or advice relating to quantum information science and technology applications;

(ii) solicit information and ideas from a broad range of stakeholders on quantum information science in order to inform policy making. Stakeholders include the research community, the private sector, universities, national laboratories, executive departments and agencies (agencies), State and local governments, foundations, and nonprofit organizations; and

(iii) respond to requests from the Subcommittee.

Sec. 3. *Administration.* (a) The heads of agencies shall, to the extent permitted by law, provide the Committee with information concerning quantum information science and supporting technologies and applications when requested by a Co-Chair of the Committee.

(b) In consultation with the Director, the Committee may create standing subcommittees and ad hoc groups, including technical advisory groups, to assist and provide preliminary information to the Committee.

(c) The Director may request that members of the Committee, its standing subcommittees, or ad hoc groups who do not hold a current clearance for access to classified information, receive appropriate clearances and access determinations pursuant to Executive Order 13526 of December 29, 2009

(Classified National Security Information), as amended, or any successor order.

(d) The Department of Energy shall provide such funding and administrative and technical support as the Committee may require.

(e) Committee members shall serve without any compensation for their work on the Committee, but may receive travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the Government service (5 U.S.C. 5701–5707).

Sec. 4. *General Provisions.* (a) Insofar as the Federal Advisory Committee Act, as amended (5 U.S.C. App.) (FACA), may apply to the Committee, any functions of the President under the FACA, except for those in section 6 of the FACA, shall be performed by the Secretary of Energy, in consultation with the Director, in accordance with the guidelines and procedures established by the Administrator of General Services.

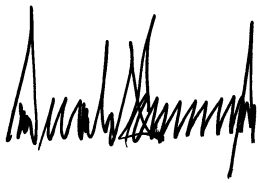
(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
August 30, 2019.

[FR Doc. 2019–19367
Filed 9–4–19; 11:15 am]
Billing code 3295–F9–P

Reader Aids

Federal Register

Vol. 84, No. 172

Thursday, September 5, 2019

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, SEPTEMBER

45873–46418 3
46419–46652 4
46653–46874 5

CFR PARTS AFFECTED DURING SEPTEMBER

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:
9917 46865
9918 46867
9919 46869
9920 46871

Executive Orders:
13885 46873

5 CFR

1650 46419
1651 46419

6 CFR

37 46423

7 CFR

253 45873
718 45877
1146 46653
1412 45877

Proposed Rules:
3565 45927

8 CFR

Proposed Rules:
103 46040

10 CFR

430 46661

Proposed Rules:
430 ..... 46469, 46830

12 CFR

Proposed Rules:
337 46470

14 CFR

39 ..... 45895, 46426, 46429, 46432, 46434
71 46438

Proposed Rules:
39 46496

15 CFR

Proposed Rules:
922 45929

18 CFR

385 46438

19 CFR

12 46676
24 46678
141 46676

20 CFR

401 45900

21 CFR

Proposed Rules:
216 46688

26 CFR

301 ..... 46440, 46681

30 CFR

906 46184

Proposed Rules:
935 46703

31 CFR

582 46440

32 CFR

318 46681
505 46681

33 CFR

100 ..... 45901, 46682
165 ..... 45903, 45905

Proposed Rules:
165 46498
167 46501

37 CFR

1 45907

40 CFR

52 ..... 45910, 45918
151 46100
300 46684

Proposed Rules:
52 ..... 45930, 45931
63 ..... 46138, 46610

44 CFR

64 46685

Proposed Rules:
62 45933

46 CFR

Proposed Rules:
502 45934
515 45934

47 CFR

73 46920

48 CFR

801 46448
815 46448
816 46448
837 46448
849 46448
852 46448
871 46448

49 CFR

Proposed Rules:
383 45938
384 45938
395 45940

50 CFR

21 45921

219 46788
622 45924
679 ..... 45295, 46457, 46458, 46686

Proposed Rules:
635 45941

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 August 28, 2019

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.