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# Presidential Documents

**Title 3—**

## The President

**Memorandum of October 25, 2018**

## Developing a Sustainable Spectrum Strategy for America's Future

**Memorandum for the Heads of Executive Departments and Agencies**

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

**Section 1.** *Policy.* It is the policy of the United States to use radiofrequency spectrum (spectrum) as efficiently and effectively as possible to help meet our economic, national security, science, safety, and other Federal mission goals now and in the future. To best achieve this policy, the Nation requires a balanced, forward-looking, flexible, and sustainable approach to spectrum management.

The growth in the availability of mobile wireless broadband connectivity over the past decade has reshaped the American experience—the way Americans work, learn, shop, run businesses, transport their families and goods across the Nation, farm, conduct financial transactions, consume entertainment, deliver and receive public safety services, and interact with one another. In the growing digital economy, wireless technologies expand opportunities to increase economic output of rural communities and connect them with urban markets, and offer safety benefits that save lives, prevent injuries, and reduce the cost of transportation incidents. American companies and institutions rely heavily on high-speed wireless connections, with increasing demands on both speed and capacity. Wireless technologies are helping to bring broadband to rural, unserved, and underserved parts of America. Spectrum-dependent systems also are indispensable to the performance of many important United States Government missions. And as a Nation, our dependence on these airwaves is likely to continue to grow.

As the National Security Strategy of 2017 made clear, access to spectrum is a critical component of the technological capabilities that enable economic activity and protect national security. Wireless communications and associated data applications establish a foundation for high-wage jobs and national prosperity. While American industry continues to extract greater and greater value from spectrum, each technological leap also increases demands on its usage. Those demands have never been greater than today, with the advent of autonomous vehicles and precision agriculture, the expansion of commercial space operations, and the burgeoning Internet of Things signaling a nearly insatiable demand for spectrum access. Moreover, it is imperative that America be first in fifth-generation (5G) wireless technologies—wireless technologies capable of meeting the high-capacity, low-latency, and high-speed requirements that can unleash innovation broadly across diverse sectors of the economy and the public sector. Flexible, predictable spectrum access by the United States Government will help ensure that Federal users can meet current and future mission requirements for a broad range of both communications- and non-communications-based systems.

The Nation can and will ensure security and safety through modern technology. America's national security depends on technological excellence and the United States Government must continue to have access to the spectrum resources needed to serve the national interest, from protecting the homeland and managing the national airspace, to forecasting severe weather and exploring the frontiers of space. Technological innovation in

spectrum usage, moreover, occurs in both the private and public sectors. Federal agencies must thoughtfully consider whether and how their spectrum-dependent mission needs might be met more efficiently and effectively, including through new technology and ingenuity. The United States Government shall continue to look for additional opportunities to share spectrum among Federal and non-Federal entities. The United States Government shall also continue to encourage investment and adoption by Federal agencies of commercial, dual-use, or other advanced technologies that meet mission requirements, including 5G technologies. In doing so, we will take appropriate measures to sustain the radiofrequency environment in which critical United States infrastructure and space systems operate.

**Sec. 2.** *Advancing the National Spectrum Strategy.* Within 180 days of the date of this memorandum, and concurrent with development of the National Spectrum Strategy referred to in section 4 of this memorandum:

(a) Executive departments and agencies (agencies) shall report to the Secretary of Commerce (Secretary), working through the National Telecommunications and Information Administration (NTIA), on their anticipated future spectrum requirements for a time period and in a format specified by the Secretary. Additionally, agencies shall initiate a review of their current frequency assignments and quantification of their spectrum usage in accordance with guidance to be provided by the Secretary. Reporting of information under this section shall be subject to existing safeguards protecting classified, sensitive, and proprietary data. The Secretary may release publicly a summary of information provided by agencies, to the extent consistent with applicable law.

(b) The Director of the Office of Science and Technology Policy (OSTP), or the Director's designee, shall submit a report to the President on emerging technologies and their expected impact on non-Federal spectrum demand.

(c) The Director of OSTP, or the Director's designee, shall submit a report to the President on recommendations for research and development priorities that advance spectrum access and efficiency.

**Sec. 3.** Within 180 days of the date of this memorandum, and annually thereafter, the Secretary, working through the NTIA, and in coordination with the Office of Management and Budget (OMB), OSTP, and the Federal Communications Commission (FCC), shall submit to the President, through the Director of the National Economic Council and the Assistant to the President for National Security Affairs, a report (to be made public to the extent practicable and consistent with applicable law) on the status of existing efforts and planned near- to mid-term spectrum repurposing initiatives.

**Sec. 4.** Within 270 days of the date of this memorandum, the Secretary, working through the NTIA, and in consultation with OMB, OSTP, and the FCC, and other Federal entities, as appropriate, shall submit to the President, through the Director of the National Economic Council and the Assistant to the President for National Security Affairs, a long-term National Spectrum Strategy that includes legislative, regulatory, or other policy recommendations to:

(a) increase spectrum access for all users, including on a shared basis, through transparency of spectrum use and improved cooperation and collaboration between Federal and non-Federal spectrum stakeholders;

(b) create flexible models for spectrum management, including standards, incentives, and enforcement mechanisms that promote efficient and effective spectrum use, including flexible-use spectrum licenses, while accounting for critical safety and security concerns;

(c) use ongoing research, development, testing, and evaluation to develop advanced technologies, innovative spectrum-utilization methods, and spectrum-sharing tools and techniques that increase spectrum access, efficiency, and effectiveness;

(d) build a secure, automated capability to facilitate assessments of spectrum use and expedite coordination of shared access among Federal and non-Federal spectrum stakeholders; and

(e) improve the global competitiveness of United States terrestrial and space-related industries and augment the mission capabilities of Federal entities through spectrum policies, domestic regulations, and leadership in international forums.

**Sec. 5.** *Spectrum Strategy Task Force.* The Chief Technology Officer and the Director of the National Economic Council, or their designees, shall co-chair a Spectrum Strategy Task Force that shall include representatives from OMB, OSTP, the National Security Council, the National Space Council, and the Council of Economic Advisers. The Spectrum Strategy Task Force shall work with the Secretary and the NTIA in coordinating implementation of this memorandum. In carrying out its coordination functions, the Spectrum Strategy Task Force shall consult with the FCC.

**Sec. 6.** *General Provisions.* (a) Nothing in this memorandum 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 OMB relating to budgetary, administrative, or legislative proposals.

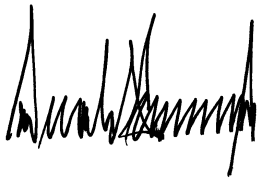
(b) Nothing in this memorandum shall be construed to require the disclosure of classified information, law enforcement sensitive information, proprietary information, or other information that must be protected as required by law or in the interests of national security or public safety.

(c) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This memorandum 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.

(e) The Presidential Memoranda of June 28, 2010 (Unleashing the Wireless Broadband Revolution) and June 14, 2013 (Expanding America's Leadership in Wireless Innovation) are hereby revoked.

(f) The Secretary is authorized and directed to publish this memorandum in the *Federal Register.*



THE WHITE HOUSE,
*Washington, October 25, 2018*

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# Rules and Regulations

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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.

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## FEDERAL RESERVE SYSTEM

### 12 CFR Part 204

**[Regulation D; Docket No. R–1626]**

**RIN 7100–AF19**

## Reserve Requirements of Depository Institutions

**AGENCY:** Board of Governors of the Federal Reserve System.

**ACTION:** Final rule.

**SUMMARY:** The Board is amending Regulation D, Reserve Requirements of Depository Institutions, to reflect the annual indexing of the reserve requirement exemption amount and the low reserve tranche for 2019. The Regulation D amendments set the amount of total reservable liabilities of each depository institution that is subject to a zero percent reserve requirement in 2019 at $16.3 million (up from 16.0 million in 2018). This amount is known as the reserve requirement exemption amount. The Regulation D amendments also set the amount of net transaction accounts at each depository institution (over the reserve requirement exemption amount) that is subject to a three percent reserve requirement in 2019 at $124.2 million (up from $122.3 million in 2018). This amount is known as the low reserve tranche. The adjustments to both of these amounts are derived using statutory formulas specified in the Federal Reserve Act.

The Board is also announcing changes in two other amounts, the nonexempt deposit cutoff level and the reduced reporting limit, that are used to determine the frequency at which depository institutions must submit deposit reports.

**DATES:**

*Effective date:* November 29, 2018.

*Compliance dates:* The new low reserve tranche and reserve requirement exemption amount will apply to the fourteen-day reserve maintenance period that begins January 17, 2019. For depository institutions that report deposit data weekly, this maintenance period corresponds to the fourteen-day computation period that begins December 18, 2018. For depository institutions that report deposit data quarterly, this maintenance period corresponds to the seven-day computation period that begins December 18, 2018. The new values of the nonexempt deposit cutoff level, the reserve requirement exemption amount, and the reduced reporting limit will be used to determine the frequency at which a depository institution submits deposit reports effective in either June or September 2019.

**FOR FURTHER INFORMATION CONTACT:** Sophia H. Allison, Senior Special Counsel (202/452–3565), Legal Division, or Kristen R. Payne, Senior Financial Institution and Policy Analyst (202/452–2872), Division of Monetary Affairs; for users of Telecommunications Device for the Deaf (TDD) only, contact (202/263–4869); Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551.

**SUPPLEMENTARY INFORMATION:** Section 19(b)(2) of the Federal Reserve Act (12 U.S.C. 461(b)(2)) requires each depository institution to maintain reserves against its transaction accounts and nonpersonal time deposits, as prescribed by Board regulations, for the purpose of implementing monetary policy. Section 11(a)(2) of the Federal Reserve Act (12 U.S.C. 248(a)(2)) authorizes the Board to require reports of liabilities and assets from depository institutions to enable the Board to conduct monetary policy. The Board's actions with respect to each of these provisions are discussed in turn below.

### I. Reserve Requirements

Pursuant to section 19(b) of the Federal Reserve Act (Act), transaction account balances maintained at each depository institution are subject to reserve requirement ratios of zero, three, or ten percent. Section 19(b)(11)(A) of the Act (12 U.S.C. 461(b)(11)(A)) provides that a zero percent reserve requirement shall apply at each depository institution to total reservable liabilities that do not exceed a certain amount, known as the reserve requirement exemption amount. Section 19(b)(11)(B) provides that, before December 31 of each year, the Board shall issue a regulation adjusting the reserve requirement exemption amount for the next calendar year if total reservable liabilities held at all depository institutions increase from one year to the next. No adjustment is made to the reserve requirement exemption amount if total reservable liabilities held at all depository institutions should decrease during the applicable time period. The Act requires the percentage increase in the reserve requirement exemption amount to be 80 percent of the increase in total reservable liabilities of all depository institutions over the one-year period that ends on the June 30 prior to the adjustment.

Total reservable liabilities of all depository institutions increased by 2.4 percent, from $7,858 billion to $8,050 billion, between June 30, 2017, and June 30, 2018. Accordingly, the Board is amending Regulation D to set the reserve requirement exemption amount for 2019 at $16.3 million, an increase of $0.3 million from its level in 2018.[1]

Pursuant to section 19(b)(2) of the Act (12 U.S.C. 461(b)(2)), transaction account balances maintained at each depository institution over the reserve requirement exemption amount and up to a certain amount, known as the low reserve tranche, are subject to a three percent reserve requirement. Transaction account balances over the low reserve tranche are subject to a ten percent reserve requirement. Section 19(b)(2) also provides that, before December 31 of each year, the Board shall issue a regulation adjusting the low reserve tranche for the next calendar year. The Act requires the adjustment in the low reserve tranche to be 80 percent of the percentage increase or decrease in total transaction accounts of all depository institutions over the one-year period that ends on the June 30 prior to the adjustment.

Net transaction accounts of all depository institutions increased 2.0 percent, from $2,379 billion to $2,425 billion, between June 30, 2017, and June 30, 2018. Accordingly, the Board is amending Regulation D to set the low reserve tranche for net transaction

[1] Consistent with Board practice, the low reserve tranche and reserve requirement exemption amounts have been rounded to the nearest $0.1 million.

accounts for 2019 at $124.2 million, an increase of $1.9 million from 2018.

The new low reserve tranche and reserve requirement exemption amount will be effective for all depository institutions for the fourteen-day reserve maintenance period beginning Thursday, January 17, 2019. For depository institutions that report deposit data weekly, this maintenance period corresponds to the fourteen-day computation period that begins December 18, 2018. For depository institutions that report deposit data quarterly, this maintenance period corresponds to the seven-day computation period that begins December 18, 2018.

## II. Deposit Reports

Section 11(b)(2) of the Federal Reserve Act authorizes the Board to require depository institutions to file reports of their liabilities and assets as the Board may determine to be necessary or desirable to enable it to discharge its responsibility to monitor and control the monetary and credit aggregates. The Board screens depository institutions each year and assigns them to one of four deposit reporting panels (weekly reporters, quarterly reporters, annual reporters, or nonreporters). The panel assignment for annual reporters is effective in June of the screening year; the panel assignment for weekly and quarterly reporters is effective in September of the screening year.

In order to ease reporting burden, the Board permits smaller depository institutions to submit deposit reports less frequently than larger depository institutions. The Board permits depository institutions with net transaction accounts above the reserve requirement exemption amount but total transaction accounts, savings deposits, and small time deposits below a specified level (the ''nonexempt deposit cutoff'') to report deposit data quarterly. Depository institutions with net transaction accounts above the reserve requirement exemption amount and with total transaction accounts, savings deposits, and small time deposits greater than or equal to the nonexempt deposit cutoff are required to report deposit data weekly. The Board requires certain large depository institutions to report weekly regardless of the level of their net transaction accounts if the depository institution's total transaction accounts, savings deposits, and small time deposits exceeds or is equal to a specified level (the ''reduced reporting limit''). The nonexempt deposit cutoff level and the reduced reporting limit are adjusted annually, by an amount equal to 80 percent of the increase, if any, in total transaction accounts, savings deposits, and small time deposits of all depository institutions over the one-year period that ends on the June 30 prior to the adjustment.

From June 30, 2017, to June 30, 2018, total transaction accounts, savings deposits, and small time deposits at all depository institutions increased 3.6 percent, from $12,157 billion to $12,599 billion. Accordingly, the Board is increasing the nonexempt deposit cutoff level by $29.1 million to $1.029 billion for 2019 (up from $1.000 billion in 2018). The Board is also increasing the reduced reporting limit by $60.7 million to $2.147 billion for 2019 (up from $2.086 billion in 2018).[2]

Beginning in 2019, the boundaries of the four deposit reporting panels will be defined as follows. Those depository institutions with net transaction accounts over $16.3 million (the reserve requirement exemption amount) or with total transaction accounts, savings deposits, and small time deposits greater than or equal to $2.147 billion (the reduced reporting limit) are subject to detailed reporting, and must file a Report of Transaction Accounts, Other Deposits and Vault Cash (FR 2900 report) either weekly or quarterly. Of this group, those with total transaction accounts, savings deposits, and small time deposits greater than or equal to $1.029 billion (the nonexempt deposit cutoff level) are required to file the FR 2900 report each week, while those with total transaction accounts, savings deposits, and small time deposits less than $1.029 billion are required to file the FR 2900 report each quarter. Those depository institutions with net transaction accounts less than or equal to $16.3 million (the reserve requirement exemption amount) and with total transaction accounts, savings deposits, and small time deposits less than $2.147 billion (the reduced reporting limit) are eligible for reduced reporting, and must either file a deposit report annually or not at all. Of this group, those with total deposits greater than $16.3 million (but with total transaction accounts, savings deposits, and small time deposits less than $2.147 billion) are required to file the Annual Report of Deposits and Reservable Liabilities (FR 2910a) report annually, while those with total deposits less than or equal to $16.3 million are not required to file a deposit report. A depository institution that adjusts reported values on its FR 2910a report in order to qualify for reduced reporting will be shifted to an FR 2900 reporting panel.

## III. Regulatory Analysis

*Administrative Procedure Act*

The provisions of 5 U.S.C. 553(b) relating to notice of proposed rulemaking have not been followed in connection with the adoption of these amendments. The amendments involve expected, ministerial adjustments prescribed by statute and by the Board's policy concerning reporting practices. The adjustments in the reserve requirement exemption amount, the low reserve tranche, the nonexempt deposit cutoff level, and the reduced reporting limit serve to reduce regulatory burdens on depository institutions. Accordingly, the Board finds good cause for determining, and so determines, that notice in accordance with 5 U.S.C. 553(b) is unnecessary.

*Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) does not apply to a rulemaking where a general notice of proposed rulemaking is not required.[3] As noted previously, the Board has determined that it is unnecessary to publish a general notice of proposed rulemaking for this final rule. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply.

*Paperwork Reduction Act*

In accordance with the Paperwork Reduction Act of 1995,[4] the Board reviewed this final rule. No collections of information pursuant to the Paperwork Reduction Act are contained in the final rule.

**List of Subjects in 12 CFR Part 204**

Banks, banking, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Board is amending 12 CFR part 204 as follows:

## PART 204—RESERVE REQUIREMENTS OF DEPOSITORY INSTITUTIONS (REGULATION D)

■ 1. The authority citation for part 204 continues to read as follows:

**Authority:** 12 U.S.C. 248(a), 248(c), 461, 601, 611, and 3105.

■ 2. Section 204.4 is amended by revising paragraph (f) to read as follows:

[2] Consistent with Board practice, the nonexempt deposit cutoff level has been rounded to the nearest $0.1 million, and the reduced reporting limit has been rounded to the nearest $1 million.

[3] 5 U.S.C. 603 and 604.

[4] 44 U.S.C. 3506; 5 CFR part 1320.

**§ 204.4 Computation of required reserves.**

* * * * *

(f) For all depository institutions, Edge and Agreement corporations, and United States branches and agencies of foreign banks, required reserves are computed by applying the reserve requirement ratios below to net transaction accounts, nonpersonal time deposits, and Eurocurrency liabilities of the institution during the computation period.

| Reservable liability | Reserve requirement |
|---|---|
| Net Transaction Accounts: | |
| $0 to reserve requirement exemption amount ($16.3 million) | 0 percent of amount. |
| Over reserve requirement exemption amount ($16.3 million) and up to low reserve tranche ($124.2 million). | 3 percent of amount. |
| Over low reserve tranche ($124.2 million) | $3,237,000 plus 10 percent of amount over $124.2 million. |
| Nonpersonal time deposits | 0 percent. |
| Eurocurrency liabilities | 0 percent. |

By order of the Board of Governors of the Federal Reserve System, acting through the Director of the Division of Monetary Affairs under delegated authority, October 24, 2018.

**Ann E. Misback,**

*Secretary of the Board.*

[FR Doc. 2018–23608 Filed 10–29–18; 8:45 am]

BILLING CODE 6210–01–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 71

**[Docket No. FAA–2018–0219; Airspace Docket No. 17–AGL–23]**

**RIN 2120–AA66**

## Amendment of Air Traffic Service (ATS) Routes in the Vicinity of Mattoon and Charleston, IL

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule, delay of effective date.

**SUMMARY:** This action changes the effective date of a final rule published in the **Federal Register** on September 7, 2018, amending VHF Omnidirectional Range (VOR) Federal airways V–72 and V–429 in the vicinity of Mattoon and Charleston, IL. The FAA is delaying the effective date to coincide with the expected completion and flight check of enroute and terminal procedures associated with the planned decommissioning of the Mattoon, IL, VOR.

**DATES:** The effective date of the final rule published on September 7, 2018 (83 FR 45337) is delayed from November 8, 2018 to January 3, 2019. The Director of the Federal Register approved this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

**FOR FURTHER INFORMATION CONTACT:** Colby Abbott, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

**SUPPLEMENTARY INFORMATION:**

### Background

The FAA published a final rule in the **Federal Register** for Docket No. FAA–2018–0219 (83 FR 45337, September 7, 2018), amending VOR Federal airways V–72 and V–429 in the vicinity of Mattoon and Charleston, IL. The effective date for that final rule is November 8, 2018. The FAA expects to complete and flight check the enroute and terminal procedures associated with the planned decommissioning of the Mattoon, IL, VOR by January 3, 2018; therefore the rule amending V–72 and V–429 is delayed to coincide with that date.

VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.11C dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airways listed in this document will be subsequently published in the Order.

### Good Cause for No Notice and Comment

Section 553(b)(3)(B) of Title 5, United States Code, (the Administrative Procedure Act) authorizes agencies to dispense with notice and comment procedures for rules when the agency for ''good cause'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without seeking comment prior to the rulemaking. The FAA finds that prior notice and public comment to this final rule is unnecessary due to the brief length of the extension of the effective date and the fact that there is no substantive change to the rule.''

### Delay of Effective Date

■ Accordingly, pursuant to the authority delegated to me, the effective date of the final rule, Airspace Docket 17–AGL–23, as published in the **Federal Register** on September 7, 2018 (83 FR 45337), FR Doc. 2018–19347, is hereby delayed from November 8, 2018 to January 3, 2019.

**Authority:** 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., P. 389.

Issued in Washington, DC, on October 24, 2018.

**Rodger A. Dean Jr.,**

*Manager, Airspace Policy Group.*

[FR Doc. 2018–23563 Filed 10–29–18; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

### 15 CFR Part 744

**[Docket No. 181010930–8930–01]**

**RIN 0694–AH67**

## Addition of an Entity to the Entity List

**AGENCY:** Bureau of Industry and Security, Commerce.

**ACTION:** Final rule.

**SUMMARY:** In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) by adding one entity to the Entity List. The entity that is added to the Entity List has been determined by the U.S. Government to pose a significant risk of becoming involved in activities contrary to the national security or foreign policy interests of the United States. This entity will be listed under the destination of China.

**DATES:** *Effective Date:* This rule is effective October 30, 2018.

**FOR FURTHER INFORMATION CONTACT:** Chair, End-User Review Committee, Office of the Assistant Secretary, Export

Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–5991, Fax: (202) 482–3911, Email: *ERC@bis.doc.gov.*

**SUPPLEMENTARY INFORMATION:**

## Background

The Entity List (15 CFR, Subchapter C, part 744, Supplement No. 4) identifies entities reasonably believed to be involved, or to pose a significant risk of being or becoming involved, in activities contrary to the national security or foreign policy interests of the United States. The Export Administration Regulations (EAR) (15 CFR, Subchapter C, parts 730–774) imposes additional license requirements on, and limits the availability of most license exceptions for, exports, reexports, and transfers (in-country) to listed entities. The license review policy for each listed entity is identified in the ''License review policy'' column on the Entity List, and the impact on the availability of license exceptions is described in the relevant **Federal Register** notice adding entities to the Entity List. BIS places entities on the Entity List pursuant to part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and all decisions to remove or modify an entry by unanimous vote.

## ERC Entity List Decision

### *Addition to the Entity List*

Under § 744.11(b) (Criteria for revising the Entity List) of the EAR, persons for whom there is reasonable cause to believe, based on specific and articulable facts, have been involved, are involved, or pose a significant risk of being or becoming involved in, activities that are contrary to the national security or foreign policy interests of the United States, and those acting on behalf of such persons, may be added to the Entity List.

Pursuant to 744.11(b) of the EAR, the ERC determined that Fujian Jinhua Integrated Circuit Company poses a significant risk of becoming involved in activities that could have a negative impact on the national security interests of the United States. The ERC determined that the conduct of this entity raises sufficient concern that prior review of exports, reexports, or transfers (in-country) of items subject to the EAR involving this entity, and the possible imposition of license conditions or license denials on shipments to the entity, will enhance BIS's ability to prevent activities contrary to the national security interests of the United States.

For the one entity added to the Entity List in this final rule, BIS imposes a license requirement for all items subject to the EAR and a license review policy of presumption of denial. In addition, no license exceptions are available for exports, reexports, or transfers (in-country) to the person being added to the Entity List in this rule. The acronym ''a.k.a.'' (also known as) is used in entries on the Entity List to identify aliases, thereby assisting exporters, reexporters and transferors in identifying entities on the Entity List.

This final rule adds the following entity to the Entity List:

## China

(1) *Fujian Jinhua Integrated Circuit Company, Ltd.,* a.k.a., the following one alias: -JHICC.

Sanchuang Park, Century Avenue, Jinjiang City, Fujian Province, China.

### *Savings Clause*

Shipments of items removed from eligibility for a License Exception or export or reexport without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export or reexport, on October 30, 2018, pursuant to actual orders for export or reexport to a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export or reexport without a license (NLR).

## Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (Title XVII, Subtitle B of Pub. L. 115–232), which provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule. As set forth in section 1768 of ECRA, all delegations, rules, regulations, orders, determinations, licenses, or other forms of administrative action that have been made, issued, conducted, or allowed to become effective under the Export Administration Act of 1979 (50 U.S.C. 4601 *et seq.*) (as in effect prior to August 13, 2018, and as continued in effect pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) and Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 8, 2018, 83 FR 39871 (August 13, 2018)), or the Export Administration Regulations, and are in effect as of August 13, 2018, shall continue in effect according to their terms until modified, superseded, set aside, or revoked under the authority of ECRA.

## Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications, and carries a burden estimate of 43.8 minutes for a manual or electronic submission.

Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to *Jasmeet_K._Seehra@omb.eop.gov,* or by fax to (202) 395–7285.

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

4. Pursuant to section 1762 of the Export Control Reform Act of 2018 (Title XVII, Subtitle B of Pub. L. 115–232), which was included in the John S. McCain National Defense Authorization Act for Fiscal Year 2019, this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.

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

**List of Subjects in 15 CFR Part 744**

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

## PART 744—[AMENDED]

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

**Authority:** Pub. L. 115–232, Title XVII, Subtitle B. 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 18, 2017, 82 FR 43825 (September 19, 2017); Notice of November 6, 2017, 82 FR 51971 (November 8, 2017); Notice of January 17, 2018, 83 FR 2731 (January 18, 2018); Notice of August 8, 2018, 83 FR 39871 (August 13, 2018).

■ 2. Supplement No. 4 to part 744 is amended by adding in alphabetical order, under CHINA, PEOPLE'S REPUBLIC OF, one Chinese entity, ''Fujian Jinhua Integrated Circuit Company, Ltd.'' to read as follows:

**Supplement No. 4 to Part 744—Entity List**

* * * * *

| Country | Entity | License requirement | License review policy | Federal Register citation |
|---|---|---|---|---|
| * * | * * | * | * | * |
| CHINA, PEOPLE'S REPUBLIC OF ..... | * * | * * | * | * |
| | Fujian Jinhua Integrated Circuit Company, Ltd., a.k.a., the following one alias: -JHICC.<br>Sanchuang Park, Century Avenue, Jinjiang City, Fujian Province, China. | For all items subject to the EAR. (See § 744.11 of the EAR). | Presumption of denial. | 83 FR [INSERT FR PAGE NUMBER] 10/30/2018. |
| | * * | * * | * | * |
| * * | * * | * | * | * |

Dated: October 25, 2018.

**Richard E. Ashooh,**

*Assistant Secretary for Export Administration.*

[FR Doc. 2018–23693 Filed 10–29–18; 8:45 am]

**BILLING CODE 3510–33–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Parts 271 and 272

**[EPA–R08–RCRA–2018–0084; FRL–9982–08–Region 8]**

## North Dakota: Authorization of State Hazardous Waste Management Program Revisions and Incorporation by Reference of Approved State Hazardous Waste Management Program

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is granting final authorization to the hazardous waste program revisions submitted by North Dakota on September 20, 2016 and March 24, 2017. The EPA published a proposed rule on June 5, 2018, and provided for public comment. The comment period ended on July 5, 2018. No comments were received for this rulemaking. No further opportunity for comment will be provided. This final rule also codifies and incorporates by reference the authorized provisions of the North Dakota regulations in the Code of Federal Regulations.

**DATES:** This final rule is effective on October 30, 2018. The incorporation by reference of authorized provisions in the North Dakota regulations contained in this rule is approved by the Director of the Federal Register as of October 30, 2018, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA–R08–RCRA–2018–0084. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at: EPA Region 8, from 8:00 a.m. to 4:00 p.m., 1595 Wynkoop Street, Denver, Colorado 80202–1129, contact: Moye Lin, phone number (303) 312–6667, or the North Dakota Department of Health (NDDH) from 9:00 a.m. to 4:00 p.m., 918 East Divide Avenue, 3rd Floor, Bismarck, North Dakota 58501–1947, phone number (701) 328–5166. The public is advised to call in advance to verify business hours.

**FOR FURTHER INFORMATION CONTACT:** Moye Lin, Resource Conservation and Recovery Program, EPA Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129; phone number (303) 312–6667; Email address: *lin.moye@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Authorization of Revisions to North Dakota's Hazardous Waste Program and Clarification

North Dakota submitted a final complete program revision application on September 20, 2016, and March 24, 2017, seeking authorization of their changes in accordance with 40 CFR 271.21. We now make a final decision that North Dakota's hazardous waste program revisions satisfy all of the requirements necessary to qualify for final authorization. For a list of rules that become effective with this final rule, please see the proposed rule published in the June 5, 2018 **Federal Register** at 83 FR 25986. The EPA is making one clarification to the proposed rule with respect to the impact of the vacatur of certain provisions of the Revisions to the Definition of Solid Waste (DSW) Rule published on January 13, 2015 (80 FR 1694), by the U.S. Court of Appeals for the District of Columbia Circuit, *Am. Petroleum Inst.* v. *EPA,* 862 F.3d 50 (D.C. Cir. 2017) and *Am. Petroleum Inst.* v. *EPA,* No. 09–1038 (D.C. Cir. Mar. 6, 2018). On May 30, 2018 (83 FR 24664; Response to Vacatur of Certain Provisions of the Definition of Solid Waste Rule), the EPA published a final which determined that for states such as North Dakota that had adopted the 2015 DSW rule, those state provisions will be considered broader in scope than the federal program as it pertains to the specific vacated provisions.

## II. Incorporation by Reference

In the proposed rule published on June 5, 2018 (83 FR 25986), the EPA also proposed to codify the EPA's authorization of North Dakota's base hazardous waste management program and the state's revisions to that program. In this action, the EPA is amending 40 CFR 272.1751 to incorporate by reference North Dakota's authorized hazardous waste statutes and regulations. In accordance with the requirements of 1 CFR 51.5, the EPA is incorporating by reference North Dakota's authorized hazardous waste statutes and regulations as described in Section I, above. The EPA has made, and will continue to make, these materials generally available electronically through *http://www.regulations.gov* and in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information). Copies of the regulations that are incorporated by reference are also available from the North Dakota Department of Health (NDDH) from 9:00 a.m. to 4:00 p.m., 918 East Divide Avenue, 3rd Floor, Bismarck, North Dakota 58501–1947, phone number (701) 328–5166. The public is advised to call in advance to verify business hours.

Section 272.1751 also references material which is not being incorporated by reference, but which the EPA considered in determining the adequacy of North Dakota's program. Section 272.1751(c)(2) references the demonstration of adequate authority, including procedural and enforcement provisions, which provides the legal basis for the state's implementation of the hazardous waste management program. In addition, § 272.1751(c)(5), (c)(6), and (c)(7) reference the Memorandum of Agreement, the Attorney General's Statements, and the Program Description, respectively. These documents are evaluated as part of the approval process of the hazardous waste management program in accordance with subtitle C of RCRA but are not part of the material to be incorporated by reference. The public is reminded that some provisions of North Dakota's hazardous waste program are not part of the federally-authorized state program. These non-authorized provisions include:

1. Provisions that are not part of the RCRA subtitle C program because they are ''broader in scope'' than RCRA subtitle C (see 40 CFR 271.1(i));
2. Federal rules for which North Dakota is not authorized, but which have been incorporated into the state regulations because of the way the state adopted federal regulations by reference;
3. State procedural and enforcement authorities which are necessary to establish the ability of the state's program to enforce compliance, but which do not supplant the federal statutory enforcement and procedural authorities.
4. Federal rules which North Dakota adopted, but which were vacated by the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Cir. No. 09–1038, rulings dated July 7, 2017, and March 6, 2018).

State provisions that are ''broader in scope'' than the federal program are not incorporated by reference in 40 CFR part 272. For reference and clarity, the EPA lists in 40 CFR 272.1751(c)(3) the North Dakota statutory provisions that are ''broader in scope'' than the federal program, and which are not part of the authorized program being incorporated by reference. While ''broader in scope'' provisions are not part of the authorized program and cannot be enforced by the EPA, the state may enforce such provisions under state law.

North Dakota has adopted, but is not authorized for, the federal rules published in the **Federal Register** on April 12, 1996 (61 FR 16290); October 22, 1998 (63 FR 56710), and January 8, 2010 (75 FR 1235). Therefore, these federal amendments included in North Dakota's adoption by reference at section 33–24–06–16.5 of the North Dakota Administrative Code, are not part of the state's authorized program and are not part of the incorporation by reference. The June 5, 2018 proposed rule provides details about state provisions which are not part of this amendment to the CFR, as well as the effect of North Dakota's codification on enforcement and on federal requirements promulgated under the Hazardous and Solid Waste Amendments of 1984 (HSWA).

## III. Administrative Requirements

The Office of Management and Budget (OMB) has exempted this action from the requirements of Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). This action authorizes and codifies state requirements for the purpose of RCRA section 3006 and imposes no additional requirements beyond those imposed by state law. Therefore, this action is not subject to review by OMB. This action is not subject to Executive Order 13771 (82 FR 9339, February 3, 2017) because today's authorization and codification of North Dakota's revised hazardous waste program under RCRA is exempted under Executive Order 12866. Accordingly, I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action authorizes and codifies pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538). For the same reason, this action also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have substantial direct effects on the states, on the relationship between the national

government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely authorizes and codifies state requirements as part of the state RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA.

This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant, and it does not make decisions based on environmental health or safety risks. This action is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

Under RCRA 3006(b), the EPA grants a state's application for authorization as long as the state meets the criteria required by RCRA. It would thus be inconsistent with applicable law for the EPA, when it reviews a state authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this action, the EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation and provide a clear legal standard for affected conduct. The EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the action in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). ''Burden'' is defined at 5 CFR 1320.3(b).

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. Because this rule authorizes and codifies pre-existing state rules which are at least equivalent to, and no less stringent than existing federal requirements, and imposes no additional requirements beyond those imposed by state law, and there are no anticipated significant adverse human health or environmental effects, the rule is not subject to Executive Order 12898.

The Congressional Review Act, 5 U.S.C. 801–808, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this document and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This action will be effective October 30, 2018.

**List of Subjects**

*40 CFR Part 271*

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

*40 CFR Part 272*

Environmental protection, Hazardous materials transportation, Hazardous waste, Incorporation by reference, Intergovernmental relations, Water pollution control, Water supply.

**Authority:** This rule is issued under the authority of Sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: October 24, 2018

**Douglas Benevento,**

*Regional Administrator, EPA Region 8.*

For the reasons set forth in the preamble, under the authority at 42 U.S.C. 6912(a), 6926, and 6974(b), EPA is granting final authorization under part 271 to the State of North Dakota for revisions to its hazardous waste program under the Resource Conservation and Recovery Act and is amending 40 CFR part 272 as follows:

## PART 272—APPROVED STATE HAZARDOUS WASTE MANAGEMENT PROGRAMS

■ 1. The authority citation for part 272 continues to read as follows:

**Authority:** Sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

■ 2. Revise § 272.1751 to read as follows:

### § 272.1751 North Dakota State-administered program: Final authorization.

(a) *History of the State of North Dakota authorization.* Pursuant to section 3006(b) of RCRA, 42 U.S.C. 6926(b), North Dakota has final authorization for the following elements as submitted to the EPA in North Dakota's base program application for final authorization which was approved by the EPA effective on October 19, 1984. Subsequent program revision applications were approved effective on August 24, 1990, July 6, 1992, June 6, 1994, March 20, 2000, November 25, 2005, April 14, 2008, and October 30, 2018.

(b) *Enforcement authority.* The State of North Dakota has primary responsibility for enforcing its hazardous waste management program. However, the EPA retains the authority to exercise its inspection and enforcement authorities in accordance with sections 3007, 3008, 3013, 7003 of RCRA, 42 U.S.C. 6927, 6928, 6934, 6973, and any other applicable statutory and regulatory provisions, regardless of whether the state has taken its own actions, as well as in accordance with other statutory and regulatory provisions.

(c) *State Statutes and Regulations*—(1) *Incorporation by reference.* The North Dakota statutes and regulations cited in paragraph (c)(1)(i) of this section are incorporated by reference as part of the hazardous waste management program under Subtitle C of RCRA, 42 U.S.C. 6921 *et seq.* This incorporation by reference is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of the North Dakota regulations that are incorporated by reference in this paragraph from the North Dakota Legislative Council, Second Floor, State Capitol, 600 E Boulevard Avenue, Bismarck, North Dakota 58505, phone (701) 328–2916. You may inspect a copy at EPA Region 8, 1595 Wynkoop Street,

Denver, Colorado, phone number (303) 312–6231, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http:/www.archives.gov/federal-register/cfr/ibr-locations.html.*

(i) The Binder entitled ''EPA-Approved North Dakota Statutory and Regulatory Requirements Applicable to the Hazardous Waste Management Program,'' dated April 2018.

(ii) [Reserved]

(2) *Legal basis.* The EPA considered the following statutes and regulations in evaluating the state program but is not incorporating them herein for enforcement purposes:

(i) North Dakota Century Code (NDCC), Volume 13A, 2012 Replacement, North Dakota Constitution, Article XI: Sections 5 and 6.

(ii) North Dakota Century Code, Volume 4A, 2012 Replacement. Chapter 23–01 ''State Department of Health,'' Section 23–01–04.1; Chapter 23–20.3 ''Hazardous Waste Management,'' Sections 23–20.3–01, 23–20.3–02 introductory paragraph, (2), (3) through (8), (10), (13) through (16), and (18); 23–20.3–03; 23–20.3–04; 23–20.3–05(3), (5), (6), and (8); 23–20.3–06 through 23–20.3–10; and Chapter 23–29 ''Solid Waste Management and Land Protection,'' Section 23–29–04.

(iii) North Dakota Century Code, Volume 4A, 2015 Pocket Supplement. Chapter 23–01 ''State Department of Health,'' Section 23–01–36.

(iv) North Dakota Century Code, Volume 5, 2012 Replacement. Chapter 28–32 ''Administrative Agencies Practice Act,'' Section 28–32–21.1 ''Actions against administrative agencies—Attorney's fees and costs.''

(v) North Dakota Century Code, Volume 6, 2012 Replacement. Chapter 32–40 ''Environmental Law Enforcement,'' Sections 32–40–03 through 32–40–11.

(vi) North Dakota Century Code, Volume 9A, 2012 Replacement, as amended by the 2015 Pocket Supplement. Chapter 44–04 ''Duties, records and meetings,'' Sections 44–04–18 through 19.1.

(vii) North Dakota Administrative Code (NDAC), Article 33–24, Hazardous Waste Management, as amended through January 1, 2016. Sections 33–24–01–15; 33–24–01–16; 33–24–06–05, except .2.c; 33–24–06–06.2; 33–24–06–09; 33–24–06–15.1.6 through .3.b; 33–24–07–03.4; 33–24–07–04 through 33–24–07–14; 33–24–07–25 through 33–24–07–27; and 33–24–07–40 through 33–24–07–54.

(3) *Related legal provisions.* The following statutory and regulatory provisions are broader in scope than the federal program, are not part of the authorized program, are not incorporated by reference, and are not federally enforceable:

(i) North Dakota Century Code, 2012 Replacement, Volume 4A, Chapter 23–01 ''State Department of Health,'' Section 23–01–04.1(6).

(ii) North Dakota Century Code, Volume 4A, 2012 Replacement. Chapter 23–20.3 ''Hazardous Waste Management,'' Sections 23–20.3–02(1); 23–20.3–05.1; 23–20.3–05.2; and 23–20.3–05.3.

(iii) North Dakota Administrative Code, Article 33–24, ''Hazardous Waste Management,'' as amended through January 1, 2016, Sections 33–24–01–09.4; 33–24–01–10.4; 33–24–01–19.1.d; 33–24–02–04.1.y; 33–24–03–03.4; 33–24–04–02.3; 33–24–05–02 second sentence; 33–24–06–14.3.a(4); and 33–24–06–21.

(iv) North Dakota's hazardous waste regulations set forth additional transporter requirements including permit requirements at 33–24–04–02. The transporter permit requirements are broader in scope than the federal program.

(4) *Unauthorized State amendments and provisions.* (i) North Dakota has partially or fully adopted, but is not authorized to implement, the federal rule published in the **Federal Register** on October 22, 1998, titled Standards Applicable to Owners and Operators of Closed and Closing Hazardous Waste Management Facilities: Post-Closure Permit Requirement and Closure Process; Final Rule (HSWA/non-HSWA). The EPA will continue to implement the federal HSWA requirements for which North Dakota is not authorized until the state receives specific authorization for those requirements.

(ii) The following federal rules are not delegable to states. North Dakota has adopted these provisions and left the authority to the EPA for implementation and enforcement: Imports and Exports of Hazardous Waste: Implementation of OECD Council Decision C(92)39 Concerning the Control of Transfrontier Movements of Wastes Destined for Recovery Operations, published April 12, 1996; and Revisions to the Requirements for: Transboundary Shipments of Hazardous Wastes Between OECD Member Countries, Export Shipments of Spent Lead-Acid Batteries, Submitting Exception Reports for Export Shipments of Hazardous Wastes, and Imports of Hazardous Wastes, published January 8, 2010.

(iii) North Dakota has adopted the following federal provisions from the *Revisions to the Definition of Solid Waste Rule,* published January 13, 2015, which have since been vacated by the U.S. Court of Appeals for the District of Columbia Circuit in *Am. Petroleum Inst.* v. *EPA,* 862 F.3d 50 (D.C. Cir. 2017) and *Am. Petroleum Inst.* v. *EPA,* No. 09–1038 (D.C. Cir. Mar. 6, 2018) (vacating both the Factor 4 Legitimacy Test and the Verified Recycler Exclusion aspects of the 2015 DSW Rule): One criterion in the determination of whether recycling is legitimate at 40 CFR 260.43(a)(4); the verified recycler exclusion, which allowed generators to send their hazardous secondary materials to certain reclaimers at 40 CFR 261.4(a)(24); and the associated provisions at 40 CFR 260.30(d) and 260.31(d), which address the criteria in the variance determination for exceptions to the classification of hazardous secondary materials as a solid waste. As a result, those state provisions will be considered broader in scope than the federal program, as it pertains to the specific vacated provisions, and are listed in § 272.1751(c)(3)(iii) with the rest of North Dakota's broader in scope regulatory provisions).

(5) *Memorandum of Agreement.* The Memorandum of Agreement between the EPA Region 8 and the State of North Dakota, signed by the Environmental Health Section of the North Dakota Department of Health on July 18, 2016, although not incorporated by reference, is referenced as part of the authorized hazardous waste management program under subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

(6) *Statement of Legal Authority.* ''Attorney General's Statement: Hazardous Waste Management Program'' signed by the Attorney General of North Dakota on June 8, 1984, and revisions, supplements, and addenda to that Statement dated February 22, 1989, February 11, 1984, October 13, 1999, April 23, 2004, August 19, 2004, and December 5, 2016, although not incorporated by reference, are referenced as part of the authorized hazardous waste management program under subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

(7) *Program Description.* The Program Description and any other materials submitted as supplements, although not incorporated by reference, are referenced as part of the authorized hazardous waste management program under subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

■ 3. Appendix A to part 272 is amended by revising the listing for ''North Dakota'' to read as follows:

## Appendix A to Part 272—State Requirements

* * * * *

### North Dakota

(a) The statutory provisions include: North Dakota Century Code (NDCC), Volume 4A, 2012 Replacement. Chapter 23–20.3 ''Hazardous Waste Management,'' Sections 23–20.3–05(1), (2), (4), (7), and (9). Copies of the North Dakota statutes that are incorporated by reference are available from Matthew Bender & Company Inc., 701 E Water Street, Charlottesville, VA 22902–5389, phone number: (800) 833–9844.

(b) The regulatory provisions include: North Dakota Administrative Code (NDAC), Article 33–24, as revised January 1, 2016, except reserved provisions.

Chapter 33–24–01—General provisions: Sections 33–24–01–01 through 33–24–01–04, 33–24–01–05, except .2.k and .7.a; 33–24–01–06 through 33–24–01–09; 33–24–01–10, except .4.f; 33–24–01–11 through 33–24–01–14; 33–24–01–17; 33–24–01–18; and 33–24–01–19, except .1.d.

Chapter 33–24–02—Identification and Listing of Hazardous Waste: Sections 33–24–02–01 through 33–24–02–03; 33–24–02–04, except .1.y; 33–24–02–05; 33–24–02–06, except .1.e; 33–24–02–07 through 33–24–02–10; 33–24–02–11, except the phrase ''or a miniflash continuously closed cup tester, using the test method specified in American Society for Testing and Material D6450–99 (incorporated by reference in section 33–24–01–05)'' in paragraph .1.a; 33–24–02–12 through 33–24–02–19; 33–24–02–25 through 33–24–02–27; 33–24–02–33 through 33–24–02–42; 33–24–02–50 through 33–24–02–70; 33–24–02–120 through 33–24–02–129; 33–24–02–170 through 33–24–02–175; 33–24–02–180 through 33–24–02–194; 33–24–02–200 through 33–24–02–209; and Appendices I, IV, and V.

Chapter 33–24–03—Standards for Generators: Sections 33–24–03–01, except .4; 33–24–03–02; 33–24–03–03.1 and .2; 33–24–03–03.3 except the phrase ''and a transporter permit''; 33–24–03–04 through 33–24–03–24; 33–24–03–30; 33–24–03–40; 33–24–03–60 through 33–24–03–77; and Appendix I.

Chapter 33–24–04—Standards for Transporters: Sections 33–24–04–01, except .4 and Note following paragraph .3.b; 33–24–04–02.1, except the phrase '', a transporter permit, and a registration certificate''; 33–24–04–02.2, except the phrases ''and a registration certificate, or a transporter permit,'' in the first sentence, and ''and issue a registration certificate'' in the second sentence; and 33–24–04–03 through 33–24–04–08.

Chapter 33–24–05—Standards for Treatment, Storage, and Disposal Facilities and for the Management of Specific Hazardous Waste and Specific Types of Hazardous Waste Management Facilities: Sections 33–24–05–01; 33–24–05–02, except the second sentence; 33–24–05–03, except 33–24–05–03.1; 33–24–05–04 through 33–24–05–10; 33–24–05–15 through 33–24–05–20; 33–24–05–26 through 33–24–05–31; 33–24–05–37; 33–24–05–38, except .1.c and .4; 33–24–05–39 through 33–24–05–44; 33–24–05–47 through 33–24–05–69; 33–24–05–74 through 33–24–05–81; 33–24–05–89 through 33–24–05–98; 33–24–05–103 through 33–24–05–115; 33–24–05–118 through 33–24–05–128; 33–24–05–130 through 33–24–05–138; 33–24–05–144 through 33–24–05–151; 33–24–05–160 through 33–24–05–170; 33–24–05–176 through 33–24–05–188; 33–24–05–201 through 33–24–05–204; 33–24–05–230, except .2.c; 33–24–05–235, except .1/Table entries (6) and (7); 33–24–05–250 through 33–24–05–253; 33–24–05–256; 33–24–05–258; 33–24–05–265; 33–24–05–266; 33–24–05–270 through 33–24–05–281; 33–24–05–282, except .2; 33–24–05–283; 33–24–05–284.8 through .13; 33–24–05–285; 33–24–05–286; 33–24–05–288 through 33–24–05–290; 33–24–05–300 through 33–24–05–303; 33–24–05–400 through 33–24–05–406; 33–24–05–420 through 33–24–05–435; 33–24–05–450 through 33–24–05–460; 33–24–05–475 through 33–24–05–477; 33–24–05–501 through 33–24–05–506; 33–24–05–525 through 33–24–05–537; 33–24–05–550 through 33–24–05–555; 33–24–05–600; 33–24–05–610 through 33–24–05–612; 33–24–05–620 through 33–24–05–624; 33–24–05–630 through 33–24–05–632; 33–24–05–640 through 33–24–05–647; 33–24–05–650 through 33–24–05–667; 33–24–05–670 through 33–24–05–675; 33–24–05–680; 33–24–05–681; 33–24–05–701 through 33–24–05–705; 33–24–05–708 through 33–24–05–720; 33–24–05–730 through 33–24–05–740; 33–24–05–750 through 33–24–05–756; 33–24–05–760 through 33–24–05–762; 33–24–05–770, except .4; 33–24–05–780; 33–24–05–781; 33–24–05–800 through 33–24–05–802; 33–24–05–820 through 33–24–05–826; 33–24–05–850; 33–24–05–855 through 33–24–05–857; 33–24–05–860; 33–24–05–865; 33–24–05–866; 33–24–05–870; 33–24–05–875; 33–24–05–880; 33–24–05–885; 33–24–05–890; 33–24–05–895 through 33–24–05–900; 33–24–05–905; 33–24–05–910; 33–24–05–915; 33–24–05–916; 33–24–05–950; 33–24–05–951; 33–24–05–960; 33–24–05–961; 33–24–05–963 through 33–24–05–968; 33–24–05–980 through 33–24–05–986; 33–24–05–990 through 33–24–05–998; 33–24–05–1010 through 33–24–05–1016; 33–24–05–1020; 33–24–05–1031; 33–24–05–1040 through 33–24–05–1043; 33–24–05–1045 through 33–24–05–1047; 33–24–05–1060 through 33–24–05–1063; 33–24–05–1067; 33–24–05–1068; 33–24–05–1071; 33–24–05–1080 through 33–24–05–1087; 33–24–05–1100 through 33–24–05–1114; 33–24–05–1130 through 33–24–05–1138; and Appendices I through VIII, X through XIII, XV through XXIV, and XXVI through XXIX.

Chapter 33–24–06—Permits: Sections 33–24–06–01; 33–24–06–02, 33–24–06–03, except Note following paragraph .1.a.(2); 33–24–06–04; 33–24–06–05.2.c; 33–24–06–06.1; 33–24–06–07; 33–24–06–08; 33–24–06–10 through 33–24–06–13; 33–24–06–14, except .3.a.(4); 33–24–06–15 introductory paragraph through .1.a; 33–24–06–16.5 through .7; 33–24–06–17 through 33–24–06–20; 33–24–06–30 through 33–24–06–35; 33–24–06–45; 33–24–06–48; 33–24–06–52; 33–24–06–56; 33–24–06–57; 33–24–06–62; 33–24–06–65; 33–24–06–70; 33–24–06–73; 33–24–06–76; 33–24–06–80; 33–24–06–85; 33–24–06–100; and Appendix I to Section 33–24–06–14.

Chapter 33–24–07—Permitting Procedures: Sections 33–24–07–01; 33–24–07–02; and 33–24–07–03, except .4.

Copies of the North Dakota regulations that are incorporated by reference are available from North Dakota Legislative Counsel, Second Floor, State Capitol, 600 East Boulevard Avenue, Bismarck, North Dakota 58505, phone number: (701) 328–2916.

* * * * *

[FR Doc. 2018–23633 Filed 10–29–18; 8:45 am]

BILLING CODE 6560–50–P

# Proposed Rules

Federal Register
Vol. 83, No. 210
Tuesday, October 30, 2018

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 573

**[Docket No. FDA–2014–F–1184]**

### Zinpro Corp.; Filing of Food Additive Petition (Animal Use)

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification; petition for rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that Zinpro Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of silicon dioxide as an anticaking agent for the use with zinc-L-selenomethionine as a feed component.

**DATES:** The food additive petition was filed on July 29, 2014.

**ADDRESSES:** For access to the docket, 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:** Carissa Doody, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6283, *Carissa.doody@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2285) has been filed by Zinpro Corp., 10400 Viking Dr., Suite 240, Eden Prairie, MN 55344. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 (21 CFR part 573) *Food Additives Permitted in Feed and Drinking Water of Animals* to provide for the safe use of silicon dioxide as an anticaking agent for the use with zinc-L-selenomethionine as a feed component. In an earlier notice of petition (79 FR 49465, August 21, 2014), the use of silicon dioxide was omitted.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(r) because it is of a type that does not individually or cumulatively have a significant effect on the human environment. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: October 25, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–23672 Filed 10–29–18; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 573

**[Docket No. FDA–2015–F–2712]**

### Adisseo France S.A.S.; Filing of Food Additive Petition (Animal Use)

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification; petition for rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that Adisseo France S.A.S. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of silicon dioxide as a carrier for selenomethionine hydroxy analogue at a level not to exceed 95 percent of the selenomethionine hydroxy analogue in its packaged form.

**DATES:** The food additive petition was filed on June 18, 2015.

**ADDRESSES:** For access to the docket, 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:** Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6729, *Chelsea.Trull@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2291) has been filed by Adisseo France S.A.S., Immeuble Antony Parc II, 10 Place du Général de Gaulle, 92160 Antony, France. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 (21 CFR part 573) *Food Additives Permitted in Feed and Drinking Water of Animals* to provide for the safe use of silicon dioxide as a carrier for selenomethionine hydroxy analogue at a level not to exceed 95 percent of the selenomethionine hydroxy analogue in its packaged form. In an earlier notice of petition (80 FR 48471, August 13, 2015), the use of silicon dioxide was omitted.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(r) because it is of a type that does not individually or cumulatively have a significant effect on the human environment. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: October 25, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–23671 Filed 10–29–18; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

**[REG–104397–18]**

**RIN 1545–BO74**

## Additional First Year Depreciation Deduction; Hearing

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Proposed rule; notice of hearing.

**SUMMARY:** This document provides a notice of public hearing on proposed regulations relating to guidance regarding the additional first year depreciation deduction under section 168(k) of the Internal Revenue Code.

**DATES:** The public hearing is being held on Wednesday, November 28, 2018, at 10:00 a.m. The IRS must receive speakers' outlines of the topics to be discussed at the public hearing by Thursday, November 15, 2018.

**ADDRESSES:** The public hearing is being held in the IRS Auditorium, Internal Revenue Service Building, 1111 Constitution Avenue NW, Washington, DC 20224. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present a valid photo identification to enter the building.

Send Submissions to CC:PA:LPD:PR (REG–104397–18), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday to CC:PA:LPD:PR (REG–104397–18), Couriers Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224 or sent electronically via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–104397–18).

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulations, Elizabeth R. Binder, (202) 317–7005; concerning submissions of comments, the hearing and/or to be placed on the building access list to attend the hearing, Regina Johnson at (202) 317–6901 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:** The subject of the public hearing is the notice of proposed rulemaking (REG–104397–18) that was published in the **Federal Register** on Wednesday, August 8, 2018 (83 FR 39292).

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing that submitted written comments by October 9, 2018, must submit an outline of the topics to be addressed and the amount of time to be devoted to each topic by Thursday, November 15, 2018.

A period of 10 minutes is allotted to each person for presenting oral comments. After the deadline for receiving outlines has passed, the IRS will prepare an agenda containing the schedule of speakers. Copies of the agenda will be made available, free of charge, at the hearing or by contacting the Publications and Regulations Branch at (202) 317–6901 (not a toll-free number).

Because of access restrictions, the IRS will not admit visitors beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this document.

**Martin V. Franks,**

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

[FR Doc. 2018–23636 Filed 10–29–18; 8:45 am]

**BILLING CODE 4830–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 60

**[EPA–HQ–OAR–2018–0695; FRL–9985–94–OAR]**

**RIN 2060–AU33**

## Adopting Subpart Ba Requirements in Emission Guidelines for Municipal Solid Waste Landfills

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** In this action, the Environmental Protection Agency (EPA) proposes to amend the 2016 Emission Guidelines and Compliance Times for Municipal Solid Waste Landfills (''MSW Landfills EG''). The requirements for state and federal plans implementing the MSW Landfills EG were adopted from 1975 regulations, referred to herein as the ''old implementing regulations,'' which are cross-referenced in the MSW Landfill EG. In a separate regulatory proposal published in the **Federal Register** in August 2018, the EPA proposed changes to modernize the old implementing regulations governing emission guidelines under a new subpart. This action proposes to update the cross-references to the old implementing regulations in the MSW Landfills EG to harmonize with the proposed new timing and completeness requirements for state and federal plans.

**DATES:**

*Comments.* Comments must be received on or before December 14, 2018.

*Public hearing.* If anyone contacts us requesting a public hearing on or before November 5, 2018, we will hold a hearing. Additional information about the hearing, if requested, will be published in a subsequent **Federal Register** document and posted at *https://www.epa.gov/stationary-sources-air-pollution/municipal-solid-waste-landfills-new-source-performance-standards.* See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

**ADDRESSES:**

*Comments.* Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2018–0695 at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. See **SUPPLEMENTARY INFORMATION** for detail about how the EPA treats submitted comments. *Regulations.gov* is our preferred method of receiving comments. However, the following other submission methods are also accepted:

- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2018–0695 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2018–0695.
- *Mail:* To ship or send mail via the United States Postal Service, use the following address: U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2018–0695, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand/Courier Delivery:* Use the following Docket Center address if you are using express mail, commercial delivery, hand delivery, or courier: EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. Delivery verification signatures will be available only during regular business hours.

**FOR FURTHER INFORMATION CONTACT:** For questions about this proposed action, contact Andrew Sheppard, Sector Policies and Programs Division (E143–03), Office of Air Quality Planning and Standards, U.S. Environmental

Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4161; fax number: (919) 541–0516; and email address: *sheppard.andrew@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

*Public hearing.* Please contact Virginia Hunt at (919) 541–0832 or by email at *hunt.virginia@epa.gov* to request a public hearing, to register to speak at the public hearing, or to inquire as to whether a public hearing will be held.

*Docket.* The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2018–0695. All documents in the docket are listed in *Regulations.gov.* Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *Regulations.gov* or in hard copy at the EPA Docket Center, Room 3334, EPA WJC West Building, 1301 Constitution Avenue NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

*Instructions.* Direct your comments to Docket ID No. EPA–HQ–OAR–2018–0695. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *https://www.regulations.gov* or email. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

The *https://www.regulations.gov* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

*Submitting CBI.* Do not submit information containing CBI to the EPA through *https://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that include information claimed as CBI, you must submit a copy of the comments that do not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2018–0695.

*Preamble Acronyms and Abbreviations.* We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

CAA Clean Air Act
CBI Confidential Business Information
CFR Code of Federal Regulations
EG Emission Guidelines
EPA Environmental Protection Agency
MSW Municipal Solid Waste
NAICS North American Industry Classification System
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
PRA Paperwork Reduction Act
RFA Regulatory Flexibility Act
SIP State Implementation Plan
UMRA Unfunded Mandates Reform Act
U.S.C. United States Code

*Organization of this Document.* The information in this preamble is organized as follows:

I. General Information
A. Does this action apply to me?
B. Where can I get a copy of this document and other related information?
II. Background
III. What actions are we proposing?
IV. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs
C. Paperwork Reduction Act (PRA)
D. Regulatory Flexibility Act (RFA)
E. Unfunded Mandates Reform Act (UMRA)
F. Executive Order 13132: Federalism
G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
J. National Technology Transfer and Advancement Act (NTTAA)
K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

## I. General Information

### *A. Does this action apply to me?*

Table 1 of this preamble lists the source categories that may be affected

by this proposal. Table 1 is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. The proposed amendment, once promulgated, will be applicable to the affected sources.

TABLE 1—SOURCE CATEGORIES AFFECTED BY THIS PROPOSED ACTION

| Source category | NAICS code [1] | Examples of affected sources |
|---|---|---|
| State, local, and tribal government agencies | 924119 | Administration of air and water resource and solid waste management programs. |

[1] North American Industry Classification System.

*B. Where can I get a copy of this document and other related information?*

In addition to being available in the docket, an electronic copy of this action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/stationary-sources-air-pollution/municipal-solid-waste-landfills-new-source-performance-standards.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal and key technical documents at this same website.

## II. Background

On August 29, 2016, the EPA published a final rule titled ''Emission Guidelines and Compliance Times for Municipal Solid Waste Landfills'' (the ''MSW Landfills EG''), under Clean Air Act (CAA) section 111(d) (81 FR 59276). Section 111(d) is the provision of the CAA that governs the establishment of performance standards for existing sources. The MSW Landfills EG, which was promulgated as a new subpart at 40 CFR part 60, subpart Cf, updated the control requirements and monitoring, reporting, and recordkeeping provisions for existing MSW landfill sources. The MSW Landfills EG incorporates by cross-reference or direct adoption certain requirements for state and federal plans as specified in 40 CFR part 60, subpart B. Subpart B at 40 CFR part 60 contains the historic regulations, initially promulgated in 1975 to implement CAA section 111(d), that established generally applicable procedural and substantive requirements for CAA section 111(d) regulations (the ''old implementing regulations''). Under the old implementing regulations at 40 CFR 60.23(a) as adopted by the MSW Landfills EG, state plans were due 9 months after the August 29, 2016, publication date of the MSW Landfills EG. Thus, states were required to submit their plans to the EPA by May 30, 2017. *See* 40 CFR 60.30f(b). Under the old implementing regulations as incorporated by the MSW Landfills EG, the EPA had 4 months to approve or disapprove a state plan after receipt of a plan or plan revision, 40 CFR 60.27(b), and 6 months to issue federal plans for states that failed to submit approved plans after the due date for state plans, 40 CFR 60.27(c)–(d).

On August 31, 2018, as part of the proposed Affordable Clean Energy (ACE) rule (a CAA section 111(d)-rule addressing greenhouse gas emissions from fossil-fuel-fired electric generating units), the EPA proposed revisions to the old implementing regulations for all CAA section 111(d) emission guidelines (83 FR 44746). Specifically, the proposed ACE rule included a new regulation at 40 CFR part 60, subpart Ba (''proposed new implementing regulations'') that would, among other things, change the timing requirements for the submission of state plans, the EPA's review of state plans, and the issuance of federal plans to more closely align the procedures to that provided under CAA section 110 as specified in CAA section 111(d)(1).[1] In addition, the proposed new implementing regulations would include new completeness criteria also modeled after those that apply to state implementation plans (SIPs) submitted under CAA section 110 (83 FR 44803–44807).

## III. What actions are we proposing?

In the proposed ACE rule, the EPA proposed to apply the 40 CFR part 60, subpart Ba timing requirements to all ''ongoing'' emission guidelines already published under CAA section 111(d) (83 FR 44769). However, the EPA recognizes that, without further action, the promulgation of the proposed new implementing regulations would not be sufficient to change the timing requirements for the MSW Landfills EG, even though it is an ongoing CAA section 111(d) action. This is because the MSW Landfills EG includes a cross-reference to the old implementing regulations, as well as a specific deadline for the submission of state plans that was based on the timing requirements in the old implementing regulations. The EPA is proposing to amend the cross-references and deadline in the MSW Landfills EG to align with the proposed timing requirements in 40 CFR part 60, subpart Ba.[2] The EPA notes that, because this proposal is predicated on the proposed timing requirements in 40 CFR part 60, subpart Ba, the EPA will have to finalize the relevant sections of 40 CFR part 60, subpart Ba that pertain to this rule either prior to or concurrently with finalizing this rule.

Specifically, the EPA is proposing to amend the MSW Landfills EG regulatory text in 40 CFR part 60, subpart Cf to adjust the state plan due date from May 30, 2017, to August 29, 2019, which aligns with the proposed new timing requirements in 40 CFR part 60, subpart

[1] CAA section 111(d) provides: ''The Administrator shall prescribe regulations which shall establish a procedure similar to that provided by section 7410 of this title under which each State shall submit to the Administrator a plan which (A) establishes standards of performance for any existing source for any air pollutant (i) for which air quality criteria have not been issued or which is not included on a list published under section 7408(a) of this title or emitted from a source category which is regulated under section 7412 of this title but (ii) to which a standard of performance under this section would apply if such existing source were a new source, and (B) provides for the implementation and enforcement of such standards of performance.''

[2] 40 CFR part 60, subpart Cf would continue to cross-reference 40 CFR part 60, subpart B, except that it would now cross-reference 40 CFR part 60, subpart Ba with respect to the implementing regulation's timing requirements. Accordingly, the requirements of 40 CFR 60.23 (Adoption and submittal of State plans; public hearings) and 40 CFR 60.27 (Actions by the Administrator) would be replaced by the requirements proposed in 40 CFR 60.23a and 40 CFR 60.27a, respectively. However, the proposed text in 40 CFR 60.23a(a)(1) and 60.27a(e)(1) refer to a notice of availability of a final guideline document that was published under 40 CFR 60.22a(a). Because the MSW Landfills EG were published under 40 CFR 60.22(a), for purposes of this amendment, the proposed requirements of 40 CFR 60.23a(a)(1) and 40 CFR 60.27a(e)(1) will refer to the final guideline document that was published under 40 CFR 60.22(a). Additionally, the provisions of 40 CFR 60.27a(e)(2) that specify when the EPA may apply less stringent emission standards or longer compliance schedules will continue to reference 40 CFR 60.24(f) instead of 40 CFR 60.24a(f).

Ba.[3] For state plans submitted to the EPA prior to promulgation of these amendments, the EPA is taking comment on whether to amend the MSW Landfills EG regulatory text in 40 CFR part 60, subpart Cf to require those states to resubmit their plans in accordance with the provisions of the proposed new implementing regulations. This would ensure consistent treatment of all states and state plans, avoid confusion regarding deadlines, and allow the EPA to undertake a completeness review for state plans already submitted to the EPA. Alternatively, the EPA solicits comment on whether the Agency should not require the resubmission of state plans submitted prior to promulgation of these amendments, and, if not, whether the EPA should still evaluate the already-submitted plans for compliance with the proposed new completeness criteria.

As explained in the proposed ACE rule, CAA section 111(d)(1) directs the EPA to promulgate regulations establishing a procedure ''similar to'' that under CAA section 110 (governing the development, submission, and EPA review of SIPs to address National Ambient Air Quality Standards) for states to submit plans to the EPA that establish standards of performance for existing sources (*see* 83 FR 44771). The old implementing regulations at 40 CFR part 60, subpart B were promulgated in 1975 (*see* 40 FR 53346) and have not been significantly revised since their original promulgation. Notably, the implementing regulations do not reflect CAA section 111(d) in its current form as amended by Congress in 1977, and do not reflect CAA section 110 in its current form as amended by Congress in 1990. As discussed more fully in the ACE proposal, the EPA has determined that certain portions of the implementing regulations do not appropriately align with the direction in CAA section 111(d) that the EPA's regulations be ''similar'' to the provisions under CAA section 110.[4] Due to the amount of work, effort, and time required for developing state plans, the EPA has determined that extending the submission date of state plans from 9 months to 3 years is appropriate. Because states have considerable flexibility in implementing CAA section 111(d), this change would allow states more time to interact and work with the EPA in the development of state plans and minimize the chance of unexpected issues arising that could slow down eventual approval of state plans (83 FR 44769–44771).

Separate and apart from the interaction between the text of CAA section 111(d) and the 1990 amendments to CAA section 110, the EPA's experience also has shown that states need more time to submit a plan than provided for in the old implementing regulations at 40 CFR part 60, subpart B. When the EPA proposed the MSW Landfills EG, some commenters objected to the 9-month period to submit a state plan as not being achievable for a number of reasons, such as the amount of time needed for rule development, public outreach, public notice, and to hold a public hearing for rule adoption. Commenters recommended allowing states varying amounts of time, from 12 to 24 months, to submit a state plan. (*See https://www.epa.gov/stationary-sources-air-pollution/responses-public-comments-epas-standards-performance-municipal,* at pages 30–33.) In response, the EPA declined to extend the deadline because we thought at that time that a majority of the states would be able to submit a plan within the prescribed 9-month period and because, ''[f]or states that do not submit a state plan, the CAA gives the EPA express authority to implement a federal plan.'' (*Id.* at page 30–31.) On further consideration, the EPA has determined that its response to comments requesting a longer period of time to submit state plans was inadequate. The Congressional intent underlying CAA section 111(d) is clear, and is strengthened by the reference to CAA section 110: Implementation of CAA section 111(d) is intended to be primarily a state-driven process, and the existence of federal backstop authority is not a sufficient reason to decline to provide a longer period of time for states to develop and submit their plans. The EPA further notes that almost all of the states, rather than just a minority, did not submit a state plan within the prescribed 9-month period by May 30, 2017.[5]

In addition, as explained in the proposed ACE rule, CAA section 111(d)(2)(A) authorizes the EPA to prescribe a plan for a state ''in cases where the State fails to submit a satisfactory plan.'' The EPA, therefore, is charged with determining whether state plans developed and submitted under CAA section 111(d)(1) are ''satisfactory.'' The EPA reiterates the position in the proposed ACE rule that, given the flexibilities that CAA section 111(d) and emission guidelines generally accord to states, and the EPA's prior experience on reviewing and acting on SIPs under CAA section 110, it is appropriate to extend the period for the EPA's review and approval or disapproval of plans from the 4-month period provided in 40 CFR part 60, subpart B, to the 12-month period (after a determination of completeness, either affirmatively by the EPA or by operation of law) provided in the proposed new implementing regulations. This timeline would provide adequate time for the EPA to review plans and follow notice-and-comment rulemaking procedures to ensure an opportunity for public comment on the EPA's proposed action on a state plan (*see* 83 FR 44771). Because the EPA is proposing to apply the completeness criteria that are included in the proposed new implementing regulations to state plans submitted to implement the MSW Landfills EG, it is important that the EPA have the opportunity to undertake a completeness review for all state plans.[6] Therefore, the EPA is taking comment on whether the states that have already submitted state plans to implement the MSW Landfills EG should resubmit their plans in accordance with the proposed requirements in 40 CFR part 60, subpart Ba.

[3] The EPA notes that the proposed regulatory text for 40 CFR 60.27a in the proposed ACE rule has a typographical error. The proposed requirements in 40 CFR 60.27a(g)(2)(vi) and (vii) reference 40 CFR 60.23 instead of the proposed requirements in 40 CFR 60.23a. *See* 83 FR 44807. Assuming 40 CFR 60.27(g)(2) is finalized, the error will be corrected in the final rule.

[4] The EPA acknowledges that the procedural and substantive requirements established by Congress for the SIP process under CAA section 110 are considerably more detailed than the corresponding requirements established by Congress for the state existing-source performance standards plans under CAA section 111(d). Accordingly, the EPA does not interpret the Congressional direction under CAA section 111(d) to promulgate regulations establishing a state-plan procedure ''similar to'' that under CAA section 110 as requiring the EPA to establish an *identical* scheme for the two provisions. Rather, the EPA interprets the ''similar to'' direction as requiring it to carefully consider the major structural features of CAA section 110 and, where appropriate, adopt similar provisions in its regulations implementing CAA section 111(d). For the reasons proposed in the ACE rule, the EPA has determined that the timeline promulgated in the old implementing regulations (as incorporated by the MSW Landfills EG) is inappropriately short and that a timeline more in harmony with CAA section 110, as amended in 1990, is more appropriate.

[5] At the present, only California, Arizona, and New Mexico have submitted a state plan to the EPA.

[6] The ACE proposal states: ''In the case of SIPs under CAA section 110(k)(1), EPA promulgated completeness criteria in 1990 at Appendix V to 40 CFR part 51 (55 FR 5830; February 16, 1990). EPA proposes to adopt criteria similar to the criteria set out at section 2.0 of Appendix V for determining the completeness of submissions under CAA section 111(d). EPA notes that the addition of completeness criteria in the framework regulations does not alter any of the submission requirements states already have under any applicable emission guideline.'' 83 FR 44746, 44772.

Finally, for this proposed action, the EPA is reiterating the rationale in the proposed ACE rule for extending the timing from 6 months to 2 years for the EPA to promulgate a federal plan for states that fail to submit an approvable state plan in response to the MSW Landfills EG. This 2-year timeline is consistent with the federal implementation plan deadline under CAA section 110(c) (*see* 83 FR 44771) and would be beneficial to the EPA. Whenever the EPA promulgates a federal plan, it must follow the rulemaking requirements in CAA 307(d). This involves a number of potentially time-consuming steps, including coordination with many offices, developing a comprehensive record, and considering comments submitted on a proposed plan. In addition, when states fail to submit a plan as required under the MSW Landfills EG, we typically promulgate a single federal plan that applies to a number of states. Unlike a federal plan developed for a single state, the federal plan developed here may be more complex and time-intensive since it must be tailored to meet the needs of many states.

In summary, under this proposed rule, which would adopt the timing requirements in proposed 40 CFR part 60, subpart Ba, states would have until August 29, 2019, to submit their state plans (3 years from the effective date of the MSW Landfills EG). After a state has submitted its plan, the EPA would have 6 months to determine if the plan is complete. If the EPA does not make a determination of completeness within that period of time, the state plan would be deemed complete by operation of law, and the EPA would have 12 additional months to approve or disapprove the state plan. If the EPA determines that the plan is complete, the EPA would have 12 months from the date of that determination to approve or disapprove the state plan. If the EPA determines that the plan is incomplete, the EPA would have 2 years to promulgate a federal plan. Similarly, if the EPA disapproves a state plan (even one that met the completeness requirements), the EPA would have 2 years to promulgate a federal plan. However, a state would always be able to submit a revised state plan that corrects the deficiencies, and, depending on the timing, the EPA could either approve that plan before promulgating a federal plan or, if a federal plan had already been promulgated, approve it and withdraw the federal plan.

Although the costs and benefits of harmonizing the timing requirements of state plans cannot be quantified due to inherent uncertainties, the EPA believes that they will be minimal and requests comment on this. Some facilities may have an incentive to install landfill gas collection systems. Landfill gas can be recovered and used as an energy source, either offsetting existing energy costs or providing a source of revenue. This offers financial advantages for some facilities to install landfill gas collection systems early in the development of the project (*i.e.,* prior to the regulatory requirement date resulting from a state or federal plan implementing the MSW Landfills EG). If facilities have already installed controls, then shifting the date by which states must submit plans may not have any impact on the actual collection and control of landfill gas. On the other hand, some sources may choose to wait until requirements are enacted prior to installing controls. While this would not impact the cost of installing controls, it could impact the amount of landfill gas captured over the life of the project and increase the net cost.

For states, the costs of complying with the new timing requirements, which include the new completeness criteria, are likely minimal.[7] The proposed completeness criteria in 40 CFR part 60, subpart Ba are based on the criteria in 40 CFR part 51, appendix V that states already follow when developing SIPs under CAA section 110. Given that the majority of state planning occurs under CAA section 110, it is likely that many states simply comply with the completeness criteria in 40 CFR part 51, appendix V when developing their CAA section 111(d) state plans, while any states that do not would need to make only minimal adjustments to apply their CAA section 110 SIP process in the context of CAA section 111(d) state planning.

In summary, the purpose of this proposal is to amend the MSW Landfills EG to align the timing requirements in the EG, which were adopted from the old implementing regulations, with the timing and completeness checklist requirements in the proposed new implementing regulations at 40 CFR part 60, subpart Ba (*see* 83 FR 44803 *et seq.*). The EPA is taking comment on amending the cross-references in the MSW Landfills EG to refer to the timing and completeness requirements in the proposed new implementing regulations, requiring states that have already submitted state plans to resubmit their plans and impacts of this proposal.[8]

## IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

### *A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

### *B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs*

This action is not expected to be subject to Executive Order 13771 because this proposed rule is expected to result in no more than *de minimis* costs.

### *C. Paperwork Reduction Act (PRA)*

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2060–0720. Because the burden to prepare and submit a state plan have been fully incorporated into the 2016 MSW Landfills EG, and this action does not change any of the requirements associated with the stringency of the rule, there are no changes to the previously estimated information collection burden.

### *D. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action proposes a technical amendment to the MSW Landfills EG promulgated in 2016, which was determined not to impose any requirements on small entities due to the fact that emission guidelines established under CAA section 111(d) do not impose any requirements on regulated entities and, thus, will not have a significant economic impact

[7] Sources owned or operated by federal, state, local, and tribal government entities will not be significantly affected by this action because it does not address substantive underlying control requirements. It merely addresses the date by which states must submit plans.

[8] The current proposal is separate and distinct from the ongoing reconsideration proceeding related to the MSW Landfills EG, which is scheduled to be proposed in spring 2019. (*See https://www.epa.gov/sites/production/files/2017-05/documents/signed_-_letter_-_municipal_solid_waste_landfills.pdf.*)

upon a substantial number of small entities. *See* 81 FR 59309–9310 for additional discussion. We have, therefore, concluded that this action similarly will have no net regulatory burden for all directly regulated small entities.

*E. Unfunded Mandates Reform Act (UMRA)*

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

The action implements mandate(s) specifically and explicitly set forth in 40 CFR part 60, subpart Ba without the exercise of any policy discretion by the EPA.

*F. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

*G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications, as specified in Executive Order 13175. The MSW Landfills EG recognized that one tribe had three landfills that may potentially be subject to the emission guidelines, but noted that these landfills have already met requirements under the previous new source performance standards/emission guidelines framework as promulgated in 1996 (*see* 81 FR 59311). However, this action does not have a substantial direct effect on that tribe since it is merely a procedural change amending timing requirements for states to submit plans to the EPA and for the EPA to promulgate a federal plan. Thus, Executive Order 13175 does not apply to this action.

*H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This regulatory action is a procedural change and does not have any impact on human health or the environment. Thus, it will not disproportionately affect children.

*I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Further, we have concluded that this action is not likely to have any adverse energy effects because it is a procedural change and does not have any impact on energy supply, distribution, or use.

*J. National Technology Transfer and Advancement Act (NTTAA)*

This rulemaking does not involve technical standards.

*K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This regulatory action is a procedural change and the EPA does not anticipate that it will have any material impact on human health or the environment.

**List of Subjects in 40 CFR Part 60**

Environmental protection, Administrative practice and procedures, Emission guidelines, Landfills, Reporting and recordkeeping requirements, State plan.

Dated: October 23, 2018.

**Andrew R. Wheeler,**

*Acting Administrator.*

For the reasons stated in the preamble, the Environmental Protection Agency proposes to amend part 60 of title 40, chapter I, of the Code of Federal Regulations as follows:

## PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

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

## Subpart Cf—Emission Guidelines and Compliance Times for Municipal Solid Waste Landfills

■ 2. Section 60.30f is amended by revising paragraphs (a) and (b) to read as follows:

### § 60.30f Scope and delegated authorities.

* * * * *

(a) If you are the Administrator of an air quality program in a state or United States protectorate with one or more existing municipal solid waste landfills that commenced construction, modification, or reconstruction on or before July 17, 2014, you must submit a state plan to the U.S. Environmental Protection Agency (EPA) that implements the Emission Guidelines contained in this subpart. The requirements for state and federal plans are specified in 40 CFR part 60, subpart B with the exception that §§ 60.23 and 60.27 will not apply. The following requirements apply instead:

(1) Notwithstanding the provisions of § 60.20a(a) in 40 CFR part 60, subpart Ba, the requirements of §§ 60.23a and 60.27a will apply for state and federal plans, except that the requirements of § 60.23a(a)(1) will apply to a notice of availability of a final guideline document that was published under § 60.22(a); and

(2) The requirements of § 60.27a(e)(1) will refer to a final guideline document that was published under § 60.22(a) and the requirements of § 60.27a(e)(2) will refer to § 60.24(f).

(b) You must submit a state plan to the EPA by August 29, 2019.

* * * * *

[FR Doc. 2018–23700 Filed 10–29–18; 8:45 am]

BILLING CODE 6560–50–P

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 60, 61, 63, 70 and 72

**[EPA–R08–OAR–2018–0299; FRL–9985–72–Region 8]**

## Proposed Approval of Recodification and Revisions to State Air Pollution Control Rules; North Dakota; Proposed Interim Approval of Title V Program Recodification and Revisions; Proposed Approval of Recodification and Revisions To State Programs and Delegation of Authority To Implement and Enforce Clean Air Act Section 111 and 112 Standards and Requirements

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA or the ''Agency'') has reviewed changes to the North Dakota Air Pollution Control Rules. Concluding review of those changes, the EPA is proposing interim approval of revisions to the North Dakota operating permit program for stationary sources subject to title V of the Clean Air Act (CAA or the ''Act'') and recodification of the title V program under a new title of the North Dakota Administrative Code (NDAC). This document also proposes approval

of North Dakota's revision and recodification of the State's programs for implementing and enforcing delegated requirements under certain sections of the Act, and consequentially the means for the Agency's proposed approval of a revised delegation arrangement between the EPA and the State of North Dakota for transfer of authority to regulate sources under those sections. Upon final approval of this rulemaking action North Dakota will receive delegation of authority to implement and enforce CAA section 111 New Source Performance Standards (NSPS) and section 112 National Emission Standards for Hazardous Air Pollutants (NESHAP), including Maximum Achievable Control Technology (MACT) requirements within the state, excluding Indian country, exactly as the requirements were promulgated by EPA (*i.e.,* ''straight delegation''). Straight delegation of sections 111 and 112 authorities does not include those authorities reserved by the EPA Administrator or otherwise reserved by the EPA, nor the authority to implement and enforce regulations not incorporated unchanged into state code, and does not include those regulations unincorporated by North Dakota and omitted from the State's request for delegation. Upon finalization of this rulemaking, North Dakota will also continue to be eligible for future automatic delegation of incorporated, unchanged federal requirements, without need for request of Agency approval on a case-by-case basis. The proposed action effects the transfer of title V program administration and delegated authority to implement and enforce sections 111 and 112 requirements from the North Dakota Department of Health (NDDH) to the newly created North Dakota Department of Environmental Quality (NDDEQ or the ''Department''). The EPA is taking these actions pursuant to sections 501–506, 111 and 112 of the Act.

**DATES:** Written comments must be received on or before November 29, 2018.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R08–OAR–2018–0299 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *www.regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

*Docket:* All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at *www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. The EPA requests that, if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Gregory Lohrke, Air Program, EPA, Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129; (303) 312–6396; *lohrke.gregory@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background Information

The North Dakota Century Code (NDCC) currently designates the NDDH as the primary state environmental agency (NDCC 23–01). The North Dakota health department's authority to administer and implement the North Dakota Air Pollution Control Rules is codified in NDAC Article 33–15. On April 7, 2017, the Governor of North Dakota signed legislation to amend the NDCC for the creation of the NDDEQ and initiate the transfer of all authority, powers and duties of the NDDH related to environmental quality to the new Department.[1] The migration of legal and implementation authority, from the NDDH and to the new Department, required North Dakota to revise the NDAC to codify the NDDEQ's source of legal, jurisdictional and enforcement authority, and to define the programs and regulations that the NDDEQ will implement. The creation of the NDDEQ also requires the State to seek EPA approval for the migration of these authorities and all amendments to related programs and agreements. On August 6, 2018, North Dakota, having recodified the state environmental regulations,[2] submitted to the Acting Administrator a request for approval of the revision and transfer of the State's CAA programs as they will be administrated by the NDDEQ. Among the duties of the new NDDEQ is the implementation and enforcement of the North Dakota Operating Permits Program and programs implemented via that program including the Act's section 111 and 112 standards and a program for implementation of Title IV of the Act, all of which the EPA had previously approved and delegated to the State in prior rulemaking actions. In these prior actions we determined that NDDH met, among other things, the relevant statutory and regulatory authority and the ability to implement and enforce the operating permits program.

After the EPA receives a program revision, the Administrator shall approve or disapprove program revisions based on the requirements of part 70 and the Act.[3] In addition to the recodifications to the State's title V permitting program, the State's submittal includes recodifications of the programs for implementation and enforcement of delegated section 111 and 112 standards and requirements. The recodification and minor revisions to North Dakota's section 111 and 112 programs also requires the EPA to determine whether to make minor revisions to the delegation arrangements concerning those programs. North Dakota's rules authorizing the NDDEQ to administer the State's environmental programs only become effective after the State receives the necessary federal approvals.[4] North Dakota's operating

[1] North Dakota Session Laws 2017, Ch. 199. § 1 (Senate Bill 2327).

[2] For reference here and throughout today's notice concerning the renumbering and recodification of NDCC and NDAC provisions relevant to the transfer of CAA authorities to the NDDEQ, see the general guidance document, ''Crosswalk on Recodifications of Relevant NDCC and NDAC Sections,'' available in the docket for today's notice.

[3] 40 CFR 70.4(i)(2).

[4] EPA's proposed approval actions on North Dakota's submittal to transfer its Title V Program approval and its delegated authority for the NESHAP, MACT and NSPS from the North Dakota Department of Health to the North Dakota Department of Environmental Quality does not

Continued

permit and source requirements become federally enforceable on the effective date of final approval of this rulemaking action.

## II. Summary of North Dakota's Title V Program Recodification and Revisions

### *A. Introduction*

Title V of the 1990 CAA amendments directed the EPA to develop and promulgate rules that define the necessary elements of an approvable state operating permits program and the necessary standards and procedures by which the EPA will approve, oversee, and, when necessary, withdraw approval of a state's permitting authority under such programs. These operating permit program requirements are codified at 40 CFR part 70 (part 70). Title V also directs states to develop and submit to the EPA approvable programs for the issuance of operating permits to all major stationary sources and to certain other sources within the state's jurisdiction. Part 70 includes the procedure for state requests to the EPA for approval of revisions to the state's operating permit program (§ 70.4(i)), and for EPA approvals of partial or complete transferal of permitting authority from one state agency to another (§ 70.4(i)(2)).

North Dakota received interim approval of its operating permit program effective on August 7, 1995 (60 FR 35335). The State later received final, full approval effective on August 16, 1999 (64 FR 32433). On August 6, 2018, the State of North Dakota submitted to the EPA a formal request for approval of all operating permit program recodifications and revisions, for transferal of permitting authority to the NDDEQ, along with requests for approvals of delegations of authority for other related programs under the Act (*See* sections III and IV of this notice).[5] The submittal included a modified program description, documentation of rulemaking procedures followed, including public comment documentation, and copies of the relevant sections of recodified and revised state regulations.[6] This submittal was supplemented on August 16, 2018, with an Attorney General's opinion describing the NDDEQ's legal authority to administer and enforce aspects of the operating permit program under part 70 and title V of the Act.[7] North Dakota is not resubmitting the operating permit program, rather the State is only updating the numbering of its operating permits program and related amendments that have previously been approved by the EPA. Therefore, except for the minor changes to the regulations analyzed in Section II.B.4, this notice proposes action on the recodification and amendments as appropriate and consistent with the transfer of authority and change in name and does not re-approve the substantive State regulations.

### *B. Analysis of State Submittal*

The EPA finds the State of North Dakota's modified operating permits program submittal to be administratively complete for requesting approval of recodification and revisions to the State's program and the transfer of all authorities related to the permitting program to the newly created NDDEQ. This determination was made with reference to the criteria for administrative completeness found in 40 CFR part 70. An accounting of specific, required submittal elements for revisions to state operating permit programs and transfers of authority to new state agencies are in 40 CFR 70.4(i)(2). This section specifies the submittal requirements for any state-initiated program revision as being: (1) A modified program description; (2) an Attorney General's statement; and (3) such other documents as EPA determines to be necessary (70.4(i)(2)(i)). Additional evaluation criteria specific to initial program submittals, used as supplemental criteria in the EPA's review of the necessary submittal elements, are found under § 70.4(b).

#### 1. Program Description

As required under 40 CFR 70.4(i)(2)(i), the State of North Dakota included in its request for approval of revisions to its operating permit program a description of how the NDDEQ intends to carry out its responsibilities under part 70 and title V of the CAA (see criteria for program descriptions at § 70.4(b)(1)). The State's program description outlines both the basis for operating permit program implementation and the organizational structure of the NDDEQ's Division of Air Quality. The program description also includes job classification descriptions for all staff positions responsible for carrying out the operating permits program under the NDDEQ's air quality division. Implementation of the North Dakota title V program will be based on implementation authority granted by the relevant sections of NDAC article 33.1–15, as submitted to the EPA for review.[8] The NDDEQ also provides that it will generate guidance and policy documents to clarify the bounds and details of this implementation authority.[9] The Department's organizational structure is explained within the submittal in both narrative and graphical form.[10] The Division is equivalent in form and substance to, and entirely replaces, the Environmental Section of the NDDH, which the EPA previously approved (64 FR 32433). The State has historically also demonstrated adequate resources and capabilities for implementation and enforcement of the State title V program, and identified no new divisions of relevant authorities created by the transfer of powers to the NDDEQ (§ 70.4(i)(2)). Therefore, we propose to approve the program description information as appropriate and consistent with the transfer of authority.

#### 2. Attorney General's Statement

Title 40 CFR 70.4(b)(3) enumerates the necessary elements of the Attorney General's statement required for program revisions covered by § 70.4(i)(2)(i). These elements are necessary to ensure that the State operating permit authority receiving transfer of the title V program has the complete legal authority to carry out the requirements of a part 70 program. This includes, but is not limited to, the authority to: Issue permits and assure source compliance with each applicable requirement and requirement of part 70; incorporate monitoring, recordkeeping, reporting and compliance certification

extend to Indian country as defined in 18 U.S.C. 1151. Indian country generally includes (1) lands within the exterior boundaries of the following Indian reservations located within North Dakota: The Fort Berthold Indian Reservation, the Spirit Lake Reservation, the Standing Rock Sioux Reservation, and the Turtle Mountain Reservation; (2) any land held in trust by the United States for an Indian tribe; and (3) any other areas that are ''Indian country'' within the meaning of 18 U.S.C. 1151. The EPA, or eligible Indian tribes, as appropriate, will retain responsibilities under CAA Sections 501–506, 111, and 112 for air quality in Indian country.

[5] The submittal package, ''Title V Permit to Operate, MACT, NESHAPs and NSPS Programs for Department of Environmental Quality, Division of Air Quality,'' is available for public review in the docket for today's notice.

[6] For purposes of cross-referencing a recodified provision of the NDAC air pollution control rules with its previous version, we note that the recodification followed a consistent scheme: All rules previously codified as 33–15–xx–xx are now codified as 33.1–15–xx–xx. For example: All Title V Permit to Operate provisions previously codified under NDAC section 33–15–14–06 are now codified at corresponding subsections of NDAC section 33.1–15–14–06.

[7] The Attorney General's statement, ''Attorney General's Opinion Operating Permits Program,'' is available for public review in the docket for today's notice.

[8] See submittal package document, ''Title V Permit to Operate, MACT, NESHAPs and NSPS Programs for Department of Environmental Quality, Division of Air Quality'' at section 1.A.

[9] *Ibid.*

[10] *Ibid.* at sections 1.B and 1.C.

requirements into permits; incorporate into permits all applicable requirements and part 70 requirements; terminate, modify, or revoke and reissue permits for cause; enforce permits, permit fee requirements, and the requirement to obtain a permit; make available to the public any permit application contents: Compliance plan, permit, and monitoring and compliance certification report; not issue a permit if the Administrator objects to its issuance in a timely manner or, if the permit has not already been issued, to public petitions to the EPA; and insure the opportunity for judicial review of permit actions under the conditions outlined in part 70 (40 CFR 70.4(b)(3)(i)–(xiii)).

North Dakota's Attorney General's statement provides descriptions of the legal authority under the recodified laws and regulations of the State to carry out all aspects of an operating permits program, including the authority to carry out each of these preceding elements.[11] The statement includes citations to the relevant State laws and regulations that grant these authorities, that provide the corresponding requirements of the Act and federal regulations of part 70.

During North Dakota's review of the NDAC for recodification and submittal to the EPA, the State discovered limitations on the opportunity for judicial review in State courts. The EPA regulation for state operating permit programs outlines the conditions and requirements for granting affected parties the opportunity to appeal for judicial review in state courts (40 CFR 70.4(b)(3)(x)–(xii)). The Attorney General's opinion explains that while State law provides for opportunity for judicial review for most of the requirements in 40 CFR 70.4(b)(3)(x)–(xii), the provisions are overly limited. The opinion explains that the State intends to revise its rules to remedy the limitations on judicial review:

> Forthcoming Department rules will provide that if the final permit action being challenged is the Department's failure to take final action, a petition for judicial review may be filed at any time before the Department denies the permit or issues the final permit; and that where petitions for judicial review are based solely on grounds arising after the 30-day deadline for judicial review, such petitions may be filed no later than 30 days after the new grounds for review arise.[12]

The statement concludes by explaining that ''an addendum to the opinion will be submitted once these rules are adopted.'' Therefore, while State law grants the Department authority to grant petitioners the right to some opportunities for judicial review, Department rules limit the full authority required under 40 CFR 70.4(b)(3)(x)–(xii) (NDCC §§ 23.1–01–11, 23.1–06–04(1)(l), 28–32–42; NDAC § 33.1–15–14–06(8)). The EPA proposes to find that the Attorney General's statement is appropriate and consistent with the transfer of authority, except for the limitations on judicial review under title V and § 70.4(b)(3)(x)–(xii) described in the Attorney General's opinion. The effects of these limitations on the EPA's proposed action are discussed in section II.C of this document.

3. Supporting Documents

The transfer of permitting program authorities to the newly created Department will be accompanied by a transfer of all related program operations as they have existed under the authority of the NDDH. Since the North Dakota title V program is reasonably assumed to operate in the future as it has since full program approval in 1999, the EPA asked for no additional supporting documents, such as would be required for initial program submittals under 40 CFR 70.4(b)(4)–(16), except for the relevant NDCC and NDAC sections as revised and recodified for program transfer. With the exception to the revisions needed to the regulations discussed in section II.B.4 of this notice, we propose to find that the recodified regulations are substantively equal to those the EPA previously approved for implementation and enforcement of the State's operating permit program, the structure and operations of the implementing authority can be assured to continue in a similar, adequate manner as they did under the NDDH, and the relevant NDCC and NDAC sections are appropriate and consistent with the transfer of authority.

4. Analysis of the State's Prior Unapproved Amendments to NDAC 33–15–14–06

Since the full approval of North Dakota's title V operating permit program in 1999 (64 FR 32433), the State has made several minor changes to the section of North Dakota regulations that provide the legal authority to implement and enforce such a program. North Dakota made most of these amendments to NDAC section 33–15–14–06 to bring its regulations into alignment with the federal part 70 operating permit program requirements as amended between 1999 and the present.[13] The EPA proposes to approve the State's previously unconsidered program amendments as listed below for the following reasons:

- Under subsection 1 (''Definitions''), three paragraphs were added to reflect the EPA's amendments to 40 CFR 70.2. Two paragraphs add new definitions for ''Approved replicable methodology (ARM)'' [14] and ''Alternative operating scenario (AOS),'' [15] in accordance with the EPA's 2009 revisions to the part 70 regulations (74 FR 51417). The third paragraph was added to account for the EPA's 2010 addition of a definition for ''Subject to regulation'' [16] to § 70.2 (75 FR 31513). The State made conforming amendments to its Definitions to incorporate these additions (*e.g.,* when the new definition for AOS was added, by inserting 33–15–14–06.1.d, with all of the subsequent definitions amended to maintain alphabetical order: 33–15–14–06.1.d became 33–15–14–06.1.e, and so forth). North Dakota has also amended the definition of ''Major source'' under this subsection to reflect the exact 2001 EPA revisions to the major source definition under 40 CFR 70.2 (66 FR 59161);
- Under subsection 4 (''Permit applications''), several paragraphs, along with specific language, were removed relating to the timeline for initial title V permit applications, which the State explains no longer apply to any source in North Dakota and are no longer necessary. Two paragraphs were added to specify requirements for a description and compliance schedule for source requirements associated with a proposed AOS, to be included in the compliance plan for all title V sources submitting operating permit applications (paragraphs 4.c.(8)(b)[4] and (c)[4]). The State made these additions, as well as limited revisions to various paragraphs (33–15–14–06.4.c(2), (3)(c) and (7)) under this subsection,[17] to

[11] For purposes of representing the necessary elements of an acceptable Attorney General's opinion (§ 70.4(b)(3)(i)–(xiii)), and how the submitted Opinion presents those elements and demonstrates the State's legal authority through the recodified, relevant sections of its NDCC and NDAC, please reference the documents, ''Attorney General's Opinion Operating Permits Program,'' and, ''AG Opinion Review,'' found in the docket for today's notice.

[12] *Ibid.*

[13] For the purposes of cross-referencing pre-submittal revisions to NDAC 33–15–14–06 (title V program) with the recodification of those revisions under NDAC 33.1–15–14–06, and a comparison of how these revisions reflect the EPA's amendment of 40 CFR part 70 during the years between initial, full approval of North Dakota's title V program and the present, please see the document, ''Post-1999 Amendments to North Dakota Title V Program,'' in the docket for today's notice.

[14] NDAC 33.1–15–14–06.1.f.

[15] 33.1–15–14–06.1.d.

[16] 33.1–15–14–06.1.cc.

[17] Docket item: ''Post-1999 Amendments to North Dakota Title V Program.''

accommodate permit applications from sources with an AOS after the EPA's 2009 revisions to part 70 regulations (74 FR 51417). The limited revisions to these three paragraphs were made to reflect the changed language of their federal regulation corollaries (40 CFR 70.5(c)(2), (3)(iii) and (7)) after the 2009 CFR revisions;

• Under subsection 5 (''Permit content''), North Dakota revised the language of paragraphs a.(1) and a.(9) to account for the EPA's revisions to various part 70 requirements attendant to the addition of definitions for ARM and AOS. These changes were made in accordance with the EPA's 2009 revisions to part 70 regulations (74 FR 51417). These two paragraphs incorporate paragraphs 40 CFR 70.6(a)(1) and (a)(9), as revised in 2009 with minor terminology changes to accommodate reference to the North Dakota Program instead of a generalized state program. The State also revised language under paragraph c.(5)(c)[2] of this subsection to clarify and update compliance certification requirements in accordance with the EPA's 2014 revisions to section 70.6 (79 FR 43661). This paragraph incorporates 40 CFR 70.6(c)(5)(iii)(B), as revised in 2014 with minor terminology changes to accommodate reference to the North Dakota Program and the State's air quality control rules instead of a generalized state program and the CFR;

• Under subsection 8 (''Judicial review of title V permit to operate decisions''), the State added the subsection by adding paragraphs 8.a through 8.e to codify most of the legal authority to provide judicial review of permit decisions as required of state operating permit programs and described under section 70.4(b)(3)(x)–(xii); and

• Under subsection 10 (''Compliance assurance monitoring''), North Dakota incorporated by reference the compliance assurance monitoring (CAM) regulations of 40 CFR part 64 with minor revisions to three definitions used in part 64 to insure the State's delegated implementation and enforcement authority regarding those regulations.

• Additionally, the EPA promulgated amendments to the part 70 regulations that North Dakota has not adopted and the EPA proposes to find that is was not necessary for the State to adopt these amendments.[18]

North Dakota's revised title V program submittal includes all amendments to NDAC section 33–15–14–06 as they have been incorporated into the recodification of North Dakota's title V permitting regulations at NDAC 33.1–15–14–06. These amendments were made to either directly reflect the EPA's amendments to the federal part 70 regulations during the years since North Dakota's full program approval (64 FR 32433) or as North Dakota-specific amendments. All of the State's amendments, except for those to NDAC subsection 33–15–14–06.8 and its successor, the limitations of which are discussed in section II.B.2 of today's notice, are found to be approvable. Many of these changes were made to bring state regulations into accord with the EPA's changes to part 70 requirements over that time period. The remaining changes to NDAC 33–15–14–06 were not in response to modified federal regulations; however, the State's changes do not create an operating permits program any less stringent than is required under 40 CFR part 70. We propose to find that all previously unapproved amendments to the North Dakota Program between full approval and the transfer of authority to the NDDEQ, as they have been recodified under NDAC 33.1–15–14–06, are approvable for the purposes of part 70 program implementation and enforcement.

5. Transfer of the Acid Rain Program

North Dakota's request for transfer of the title V operating permit program includes the request to transfer associated State responsibilities for the CAA title IV Acid Rain Program (40 CFR parts 72, 75 and 76).[19] 40 CFR 70.4(b)(3)(xiii) specifies that the attorney general's legal opinion ensure that the authority of the state permitting agency is not used to modify the acid rain program requirements. The EPA issued guidance to clarify the primary criteria for approval of state submittals to carry out the acid rain portion of the operating permits program.[20] The Attorney General opinion assures that ''State law is consistent with, and cannot be used to modify, the Acid Rain Program requirements of 40 CFR part 72.''[21] NDCC 23.1–06–04(1)(l); NDAC 33.1–15–21. Additionally, North Dakota's revised title V program submittal demonstrates adequate legal and regulatory authority to issue permits that reflect the requirements of title IV of the Act.[22] North Dakota will continue to implement an acid rain program through the NDDEQ substantively equal to the program approved with the original interim title V program approval (*See* 60 FR 20945). Because of the substantively equal authorities and capabilities of the NDDH and the NDDEQ, North Dakota has reasonably assured the EPA of its ability to meet the requirements related to title IV of the Act, through the issuance and enforcement of title V operating permits. Therefore, we propose to approve the transfer of the acid rain program as appropriate and consistent with the transfer of authority.

*C. Proposed Action*

North Dakota's program meets the minimum requirements and otherwise substantially meets the part 70 requirements,[23] but is not fully approvable because as described in section II.B.2 the Attorney General Opinion explains that the State's rules lack full authority required for judicial review.[24] Therefore, the EPA proposes interim approval of the State's operating permit program under 40 CFR 70.4(d) and CAA section 502(g). An interim approval of North Dakota's operating permit program would solely be to allow the State to make minor revisions to NDAC 33.1–15–14–06.8, and update the Attorney General's opinion to reflect revised legal authorities, as a precursor to full approval of the State's operating permit program (See discussion in section II.B.2 of this notice). The EPA will act as expeditiously as possible to finalize full approval of North Dakota's title V program once the revised State rules and Attorney General's opinion are submitted to the EPA. Proposed interim approval shall not be construed as approving any deviation from the implementation and enforcement requirements under part 70 or as an approval of a program less stringent than that described by part 70 requirements. Under section 70.4(d) the EPA proposes to set an expiration date for interim approval, not to exceed 2 years after such an approval and non-

[18] A table of these EPA 40 CFR part 70 revisions and justification for North Dakota, not including the revisions in the State's operating permits program, may be found in the document, ''EPA Amendments to Part 70 Not Adopted,'' included in the docket for this action.

[19] Title V Permit to Operate, MACT, NESHAPs and NSPS Programs for Department of Environmental Quality, Division of Air Quality; see Governor's letter and section 1.B.

[20] EPA Memorandum, ''Title IV-Title V Interface Guidance for States,'' from Lydia Wegman, Deputy Director, Office of Air Quality Planning and Standards and Paul Stolpmann, Acting Director, Office of Atmospheric Programs, to EPA Air Division Directors, included in the docket for today's notice.

[21] Attorney General's Opinion Operating Permit Program, August 16, 2018, p. 9.

[22] *Ibid.*, and throughout.

[23] 40 CFR 70.4(d)(3).

[24] As explained in the Attorney General's Opinion, forthcoming State rules will remedy this limitation and an addendum to the opinion will be submitted once the rules are adopted.

renewable upon expiration. If the EPA finalizes an interim approval of North Dakota's title V program, the interim approval's expiration date will be set for no later than January 1, 2021.

## III. Delegation of NESHAP and MACT Requirements

### *A. Introduction*

Section 112 of the CAA authorizes the EPA to develop and periodically revise a list of all categories and subcategories of major sources and area sources of hazardous air pollutants (HAP). To reduce HAP emissions from these sources, this section of the Act also authorizes the EPA to promulgate federally enforceable NESHAP and MACT requirements for source categories. The NESHAP and MACT requirements are promulgated in parts 61 and 63 of title 40 of the CFR. Section 112(l) of the Act provides a mechanism for approval of programs and delegation of authority to the states to implement and enforce these federal standards and requirements. A state's program may provide for partial or complete delegation of the Agency's authorities and responsibilities to implement and enforce section 112 standards and requirements, so long as those authorities are carried out by an approvable state program with standards and requirements no less stringent than those promulgated by the EPA. The regulations found in 40 CFR part 63, subpart E establish procedures consistent with section 112(l) for the approval of state rules, programs, or other requirements, as well as procedures for the delegation of authority to states to implement and enforce all section 112 federal rules as promulgated, without changes, after their incorporation into state code (40 CFR 63.91).

North Dakota first received straight delegation of authority to implement and enforce NESHAP and MACT requirements on July 7, 1995 (60 FR 35335) upon the parallel interim approvals of the State's section 112 implementation and enforcement plan and the State's title V program.[25] The EPA subsequently informed North Dakota of the procedures for NESHAP and MACT automatic delegation.[26] An automatic delegation arrangement with a state allows for prospective approval of all delegations of authority to implement and enforce future section 112 standards and requirements without case-by-case approval, so long as the standards and requirements are incorporated unchanged into state code. North Dakota was operating under an automatic delegation arrangement prior to recodification of the State's section 112 program and the planned transfer of authority to implement and enforce state environmental regulations from the NDDH to the NDDEQ.[27]

The NDDH's planned transfer of authorities pursuant to State law to a new State agency required minor revisions and the recodification of State rules and its section 112 program for implementation and enforcement of NESHAP and MACT requirements. The recodification of the State's program requires the State provide the Agency with a copy of the revised authorities and a formal request for approval measured against the criteria for approval found under 40 CFR 63.91(d) and any additional relevant approval criteria in 40 CFR part 63, subpart E.

In a letter dated August 6, 2018, North Dakota submitted to the EPA final revisions to the State's Air Pollution Control Rules pertaining to administration, implementation and enforcement of CAA section 112 emissions standards and requirements by the new NDDEQ. This letter included a request to approve straight delegation of all NESHAP and MACT requirements incorporated unchanged into the recodified State regulations, and a submittal package justifying the approvability of the State's revised section 112 program. The EPA reviewed the State's program and recodified incorporations of federal requirements (NDAC chapters 33.1–15–12 and 33.1–15–22) for equivalency to the formerly approved implementation and enforcement program and former codification of federal requirements (NDAC chapters 33–15–12 and 33–15–22). The EPA also evaluated the submittal for approvability on the program's own merits as measured against the approval criteria found in subpart E of 40 CFR part 63. Additionally, we evaluated North Dakota's request for section 112 program approval based on the nine elements in the EPA's 1983 ''Good Practices Manual for Delegation of NSPS and NESHAPs'': (1) Emission limits consistent with Federal regulations; (2) test methods consistent with federal regulations; (3) reporting and monitoring requirements; (4) enforcement; (5) waiver procedures; (6) surveillance; (7) public notification and disclosure of information; (8) resources; and (9) reporting to EPA.[28] [29]

### *B. Analysis of State Submittal*

Referring to a state's title V program final approval would normally satisfy the common approval criteria set forth for straight delegation of section 112 authorities to the state (40 CFR 63.91(d)(3)). However, North Dakota's title V program also underwent recodification during the proposed transfer of authority to the NDDEQ and was revised since EPA's final approval. Notice of proposed rulemaking action on the recodifications and revisions to North Dakota's title V program is found in Section II of today's proposed rulemaking document. Due to the concurrent nature of the title V revisions and recodifications and section 112 program recodifications and of the EPA's simultaneous review of those revisions, the EPA evaluates the section 112 program recodifications against the criteria for stand-alone up-front completeness and approvability.

The North Dakota request for section 112 program approval was measured for completeness against all up-front approval criteria found under 40 CFR 63.91(d). These criteria as they were fulfilled by the State of North Dakota are: (1) A written finding by the State Attorney General that the NDDEQ has the necessary legal authority to implement and enforce the State's rules and source requirements upon program approval and to assure compliance by all sources within the State of North Dakota with each applicable section 112 standard or requirement (§ 63.91(d)(3)(i)); [30] (2) a copy of all NDCC and NDAC statutes and regulations relevant to the implementation and enforcement by the NDDEQ of section 112 standards and requirements upon final program approval (§ 63.91(d)(3)(ii)); [31] (3) a narrative and graphical description of the NDDEQ, the agency's organization and the adequacy of its institutional

[25] Appendix A to 40 CFR part 70. *North Dakota* (b).

[26] *See* letter addressed to Director Jeff Burgess, Division of Environmental Engineering, North Dakota Department of Health from Director Richard R. Long, EPA Region 8 Air and Radiation Program, May 16, 2000, ''Delegation Procedures for Section 112 Requirements,'' in the docket for today's notice.

[27] *Ibid.*

[28] For reference, this document may be found in the docket for today's notice.

[29] For a detailed demonstration of North Dakota's program adequacy following the program elements in the EPA's 1983 ''Good Practices Manual for Delegation of NSPS and NESHAPs,'' see the NESHAP and MACT Program Descriptions, included in the submittal document, ''Title V Permit to Operate, MACT, NESHAPs and NSPS Programs for Department of Environmental Quality, Division of Air Quality,'' please refer to section 2–3 (PDF pages 32–39), found in the docket for today's notice.

[30] See submittal package document, ''Attorney General's Opinion.''

[31] See submittal package document, ''Title V Permit to Operate, MACT, NESHAPs and NSPS Programs for Department of Environmental Quality, Division of Air Quality'' at sections 6 and 7.

resources to implement and enforce all aspects of the section 112 program upon approval (§ 63.91(d)(3)(iii)); [32] (4) a schedule demonstrating immediate implementation of the section 112 program upon final approval (§ 63.91(d)(3)(iv)); and, (5) a plan for expeditious compliance by all affected sources subject to the NDDEQ section 112 program upon final approval (§ 63.91(d)(3)(v)).

North Dakota provides the required items of 40 CFR 63.91(d)(3), and so fulfills the section 112 program submittal criteria set out by that section and the EPA's 1983 Manual, as outlined below.

1. With respect to the State's legal authority to implement and enforce a section 112 program in the manner required under § 63.91(d)(3)(i): Sections VI, VII, XIV and XXII of the Attorney General's Opinion provides reference to the statutory source of the State's implementation and enforcement authority for administering a section 112 program.[33] As the transfer of authorities from the NDDH to the NDDEQ is almost exclusively a recodification of state laws and regulations, the EPA also refers to its previous determination that these legal authorities are adequate to carry out a section 112 program to determine that this legal authority is maintained by the NDDEQ.

2. Pursuant the requirement of § 63.91(d)(3)(ii) that the submittal include a copy of all statutes, regulations, and requirements containing the appropriate provisions granting the authority to implement and enforce the state's section 112 program, including the related requirements in the EPA's 1983 Good Practices Manual (program elements 1–7) [34] the State has included such a copy of all relevant, recodified statutes and regulations. As there were no substantive modifications to these authorizing statutes and regulations, the EPA refers to its previous determination in the 1995 title V interim program approval that the NDDEQ has adequate authority to implement and enforce a section 112 program, just as the NDDH had before these recodifications.

3. Pursuant the requirement of § 63.91(d)(3)(iii) that the State show adequate resources to implement and enforce all aspects of a section 112 program, the State notes in its submittal that the NDDEQ will be funded and staffed at the same level as the Environmental Health Division of the NDDH which previously carried out all aspects of the section 112 program.[35]

4. Pursuant to the requirements of §§ 63.91(d)(3)(iv) and (v), which require a demonstration of planned expeditious implementation and enforcement of the section 112 program, the State's submittal quotes a specific provision of Senate Bill 2327 that specifies that all ''orders, determinations, and permits'' made by the NDDH before the transfer of authority remain in effect. The NESHAPs and MACT Program Descriptions provide additional details regarding program implementation. As there will be a continuity in the orders, determinations and permit conditions that compose the section 112 program, there is no further need for implementation schedules or compliance plans as would be needed in an initial program approval. Pursuant to the EPA's 1983 Best Practices Manual program element for reporting to the EPA, the NESHAP and MACT Program Descriptions explain that the DEQ will report to the EPA as required by the Performance Partnership Agreement (PPA) [36] and Appendix A to part 61 (incorporated by reference in NDAC 33.1–15–13). The State's Descriptions further explain that the DEQ will work with the EPA to provide information on NESHAP and MACT sources that is requested by the EPA.

*C. What NESHAPs are we proposing to delegate?*

North Dakota's request included NESHAP in 40 CFR part 61 as they existed on July 2, 2010, and in 40 CFR part 63 as they existed through July 1, 2015.[37] This proposed delegation affects only the implementation and enforcement authority for those standards which had been previously delegated to the State under the previously approved program, and which have now been incorporated unchanged into the State's revised air pollution control rules.

The NDDEQ would maintain primary responsibility for the enforcement of the delegated section 112 standards within the State. If the NDDEQ determines that such enforcement is not feasible and so notifies the EPA, or on the occasion of the NDDEQ acting in a manner incongruous with the terms of this delegation arrangement, the EPA may exercise its parallel enforcement authority pursuant section 113 of the CAA with respect to sources within North Dakota subject to the section 112 hazardous air pollutant standards.

Additionally, some portions of the NESHAP/MACT standards and the associated general provisions may not be delegated to a state. The EPA retains authority over those portions of the section 112 standards and associated general provisions which may not be delegated. In general, the EPA will delegate to a state the authority to make decisions which are not likely to be nationally significant or to alter the stringency of the underlying standard. Pursuant to this goal, the EPA has codified those part 63 general provisions which may, and may not, be delegated to a state in 40 CFR 63.91(g). The EPA's complete reasoning for defining those provisions which are and are not delegable may be found in EPA's July 10, 1998 memorandum [38] or in the related **Federal Register** notice from January 12, 1999 (64 FR 1880). In addition, some portions of the section 112 requirements, by their own terms, may not be delegated to a state. The EPA Administrator retains authority of those sections of individual subparts that require: (1) Approving equivalency determinations and alternate test methods; (2) decision-making to ensure national consistency; and (3) EPA rulemaking in order to implement. The document titled ''Delegation of CAA Authorities Overview'' in the docket for this proposal provides a list of example sections in 40 CFR parts 61 and 63 that may not be delegated. Additionally, this action does not propose delegation of any authority under section 112(r), the accidental release program. Accordingly, the EPA is retaining authority over those portions of the section 112 requirements that cannot be delegated.

If this delegation is finalized, all questions concerning implementation and enforcement of the excluded standards in the State of North Dakota

[32] *Ibid.* at sections 2, 3 and 5.

[33] The NESHAP and MACT Program Descriptions in the submittal package document, ''Title V Permit to Operate, MACT, NESHAPs and NSPS Programs for Department of Environmental Quality, Division of Air Quality,'' Sections 2 and 3 include information that meets several program elements in the EPA's 1983 Best Practices Manual, including, program elements 1, 2, 3, 4, 5, and 7.

[34] See the NESHAP and MACT Program Descriptions in the submittal package document, ''Title V Permit to Operate, MACT, NESHAPs and NSPS Programs for Department of Environmental Quality, Division of Air Quality,'' Sections 1, 2 and 3.

[35] See submittal package document, ''Title V Permit to Operate, MACT, NESHAPs and NSPS Programs for Department of Environmental Quality, Division of Air Quality'' at sections 1, 2, 3, and 5.

[36] See document titled, ''ND PPA 2018–2019,'' in the docket for today's notice.

[37] See NDAC 33.1–15–13–01.1; 33.1–15–22–01.

[38] Memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, ''Delegation of 40 CFR part 63 General Provisions Authorities to State and Local Air Pollution Control Agencies,'' available online at: (*https://www3.epa.gov/airtoxics/112(l)/delauth9.pdf*).

should be directed to the EPA Region 8 Office.

*D. How will statutory and regulatory interpretations be made?*

If this NESHAP delegation is finalized, the State will obtain concurrence from the EPA on any matter involving the interpretation of section 112 of the CAA or 40 CFR parts 61 and 63 to the extent that implementation or enforcement of these provisions have not been covered by prior EPA determinations or guidance.

*E. What authority does the EPA have?*

The EPA retains the right, as provided by CAA section 112(l)(7) and 40 CFR 63.90(d)(2), to enforce any applicable emission standard or requirement under section 112. In addition, the EPA may enforce any federally approved state rule, requirement, or program under 40 CFR 63.90(e) and 63.91(c)(1)(i). The EPA also has the authority to make certain decisions under the General Provisions (subpart A) of parts 61 and 63. In addition, the EPA may review and disapprove state determinations and subsequently require corrections. *See* 40 CFR 63.91(g)(1)(ii). The EPA also has the authority to review a state's implementation and enforcement of approved rules or programs and to withdraw approval if we find inadequate implementation or enforcement. *See* 40 CFR 63.96. Furthermore, the Agency retains any authority in an individual emission standard that may not be delegated according to provisions of the standard.

*F. What information must the State provide to the EPA?*

In addition to the information identified in the Performance Partnership Agreement, the State must provide any additional compliance related information to the EPA Region 8 Air Program within 45 days of a request under 40 CFR 63.96(a). In receiving delegation for specific General Provisions authorities, the State must submit to the EPA Region 8 on a semi-annual basis, copies of determinations issued under these authorities. *See* 40 CFR 63.91(g)(1)(ii). For part 63 standards, these determinations include: § 63.1, Applicability Determinations; § 63.6(e), Operation and Maintenance Requirements—Responsibility for Determining Compliance; § 63.6(f), Compliance with Non-Opacity Standards—Responsibility for Determining Compliance; § 63.6(h), Compliance with Opacity and Visible Emissions Standards—Responsibility for Determining Compliance; § 63.7(c)(2)(i) and (d), Approval of Site-Specific Test Plans; § 63.7(e)(2)(i), Approval of Minor Alternatives to Test Methods; § 63.7(e)(2)(ii) and (f), Approval of Intermediate Alternatives to Test Methods; § 63.7(e)(iii), Approval of Shorter Sampling Times and Volumes When Necessitated by Process Variables or Other Factors; § 63.7(e)(2)(iv), (h)(2) and (3), Waiver of Performance Testing; § 63.8(c)(1) and (e)(1), Approval of Site-Specific Performance Evaluation (Monitoring) Test Plans; § 63.8(f), Approval of Minor Alternatives to Monitoring; § 63.8(f), Approval of Intermediate Alternatives to Monitoring; § 63.9 and 63.10, Approval of Adjustments to Time Periods for Submitting Reports; § 63.10(f), Approval of Minor Alternatives to Recordkeeping and Reporting; and § 63.7(a)(4), Extension of Performance Test Deadline.

*G. What is the EPA's oversight role?*

The EPA oversees a state's decisions to ensure the delegated authorities are being adequately implemented and enforced. We will integrate oversight of the delegated authorities into the existing mechanisms and resources for oversight currently in place. If, during oversight, we determine that the State made decisions that decreased the stringency of the delegated standards, then the State shall be required to take corrective actions and the source(s) affected by the decisions will be notified, as required by 40 CFR 63.91(g)(1)(ii) and (b). We will initiate withdrawal of the program or rule if the corrective actions taken are insufficient.

*H. Should sources submit notices to the EPA or the State?*

For the delegated NESHAP standards and authorities covered by this proposed action, if finalized, sources would submit all of the information required pursuant to the general provisions and the relevant subpart(s) of the delegated NESHAP (40 CFR parts 61 and 63) directly to the State. The State is the primary point of contact with respect to delegated NESHAPs. Sources do not need to send a copy to the EPA. The EPA Region 8 proposes to waive the requirement that notifications and reports for delegated standards be submitted to the EPA in addition to the State in accordance with 40 CFR 63.9(a)(4)(ii) and 63.10(a)(4)(ii).[39] For those standards and authorities not delegated as discussed above, sources must continue to submit all appropriate information to the EPA.

*I. How will unchanged authorities be delegated to the State in the future?*

As stated in previous NESHAP delegation actions, the EPA has approved North Dakota's mechanism of incorporation by reference of NESHAP standards into the State regulations, as they apply to both part 70 and non-part 70 sources. *See, e.g.,* the EPA's 2000 memo to Director Jeff Burgess, Division of Environmental Engineering, NDDH. All future section 112 requirements incorporated by reference (IBR) into the State rules will become effective on the date the requirement goes into effect according to the State's updated rules and regulations. In the case of future adoption of section 112 requirements, the EPA requests that North Dakota send notice of the its intention to receive delegation of the requirements within 60 days of the State's incorporation of those requirements into the State's rules and regulations. The notification should include an official copy of the regulation stamped, dated and signed by the appropriate official, with the date of adoption and the effective date in North Dakota. Within 30 days of receipt of North Dakota's notification, the EPA will reply with an acknowledgment of the delegation and will change the relevant Region 8 electronic delegations of authority table (found under the ''Delegations of Authority'' link at: *http://www2.epa.gov/region8/air-program*) to reflect the new delegation of authority. If there is a change in the effective date for the section 112 requirement, North Dakota must notify the EPA as soon as possible. If the delay extends beyond the section 112 requirement compliance date, the EPA will implement and enforce the requirement until North Dakota has fully incorporated the requirement and the final effective date has passed.

The State also has the option of receiving partial delegation of a section 112 requirement, and the option to cancel the delegation of authority to implement and enforce previously adopted requirements. Automatic partial delegation of severable portions of any standard requires that the state: (1) Clearly define the separable subcategory in the particular standard, or the specific separable subset of affected sources in the specific standard so that regulated sources and the public know who is the implementing and enforcing authority; and (2) the applicable portions of the federal standard must be adopted by IBR into the state regulations or rules with an additional, clear explanation of what

[39] This waiver only extends to the submission of *copies* of notifications and reports; the EPA does not waive the requirements in delegated standards that require notifications and reports be submitted to an electronic database (*e.g.,* 40 CFR part 63, subpart HHHHHHH).

portions of the standard are not included in the standard's adoption into the State rule. If the State does not want to use automatic delegation for any of its previously adopted section 112 requirements, then the State may provide a list of those requirements which have been adopted and which the State wants to exclude from the delegation process to the EPA.

*J. Proposed Action*

The EPA proposes to approve North Dakota's program for receiving delegated authority to implement and enforce emissions standards and other requirements for air pollutants subject to section 112 of the CAA as recodified by the State. The EPA also proposes approval of revisions to the section 112 automatic delegation arrangement between the EPA and the State of North Dakota to accommodate the transfer of environmental regulatory programs from the NDDH to the NDDEQ. The proposed approval of recodification of federal NESHAP and MACT requirements and legal authorities to implement and enforce section 112 requirements, and the recognition of the NDDEQ's ability to receive delegated federal authority to administer the State's section 112 program will affect the transfer from the NDDH to the NDDEQ of the authority to implement and enforce all incorporated, unchanged federal NESHAP and MACT requirements.

## IV. Delegation of NSPS

*A. Introduction*

Section 111 of the CAA authorizes the EPA to establish a list of source categories which contribute significantly to air pollution and authorizes the Agency to publish regulations establishing federal performance standards for new sources within such categories. Section 111 performance standards for new sources are categorically referred to as NSPS and may individually be found in 40 CFR part 60.

Section 111(c) of the Act establishes that the EPA may find a state program as ''adequate'' for purposes of implementing and enforcing the NSPS and delegate these authorities to the state. Delegation of authority confers upon the state primary implementation and enforcement responsibility; however, the EPA also retains concurrent authority to enforce the standards, and sole authority over those portions of the standards that may not be delegated. The usual method for establishing adequacy of a state's program is to verify both the existence of an approved state title V permitting program and that the part 60 federal NSPS requirements are IBR in the state's code. If these two program features can be positively verified, the state is considered capable of implementing and enforcing the section 111 standards and the state may request delegation of authority to administer the NSPS requirements for sources within the state. After section 111 program approval, a state and the EPA may reach an agreement to ''automatically'' delegate future NSPS requirements to the state, if the future requirements are IBR in the state's code. Automatic delegation arrangements allow the state to administer the NSPS as they are updated or introduced without need for case-by-case approvals from the EPA. North Dakota and the EPA currently maintain such an arrangement.

The EPA last affirmed delegation of NSPS to North Dakota in a letter dated February 27, 2014,[40] which was subsequently published for public notice in the **Federal Register** on October 9, 2014 (79 FR 60993). Due to North Dakota's creation of the NDDEQ by act of legislature, and revision and recodification of portions of the NDCC and NDAC to grant the Department legal authority to implement and enforce the State's air pollution control rules, the EPA finds it necessary to revise the automatic delegation arrangement between the Agency and the State.

As North Dakota is seeking approval of the transfer of its title V program to the NDDEQ concurrent with the State's revisions to its section 111 program, the EPA requested that the State demonstrate the adequacy of its program and resources for implementing and enforcing NSPS requirements independent of a fully approved operating permits program. The EPA evaluated the State's section 111 program based on the minimum program elements recommended in the Agency's 1983 ''Good Practices Manual for Delegation of NSPS and NESHAPs.'' [41] The requirements set forth by this document are a state's demonstrations of: (1) Emission limits consistent with federal regulations; (2) test methods consistent with federal regulations; (3) reporting and monitoring requirements; (4) enforcement authority against noncomplying sources; (5) waiver procedures; (6) a source surveillance program; (7) a protocol for public notification and information disclosure; (8) adequate program resources; and (9) a communication protocol between a state and the EPA. North Dakota has included in its request for section 111 program approval a NSPS program description that seeks to demonstrate adequacy of the program with respect to each of the nine key program elements listed in this paragraph.

*B. Analysis of State Submittal*

The EPA reviewed North Dakota's section 111 program adequacy demonstration with reference to the ''Good Practices'' manual for NSPS delegations. The requirements of emission limits and test methods consistent with federal regulations, as well as the requirement of adequate source reporting and monitoring requirements, have been met with the IBR of federal NSPS requirements in the State air pollution control rules. The State updated all IBR citations as necessary. The EPA reviewed the State's incorporations and finds them substantively equivalent to incorporations as they existed at the time of the 2014 approval of NSPS delegation of authority to the State during the NDDH's administration of North Dakota's environmental regulations.[42] The State has made an adequate demonstration of enforcement authority in their program description and has provided a State Attorney General's opinion certifying the fullness of NDDEQ's enforcement authority and the adequacy of its source waiver and public notification and disclosure of information procedures. The EPA reviewed the relevant sections of State code related to enforcement and public notification, and finds them substantively equivalent to incorporations as they existed at the time the title V program received full approval. The State also made a sufficient demonstration of adequate program resources for the implementation and enforcement of the NSPS as they will have the same resources that were previously allocated by the State legislature that the EPA approved. The State's submittal also commits to reporting requirements under the Performance Partnership Agreement between the North Dakota and the EPA, as well as working with

[40] See letter to Terry O'Clair, Director, Division of Air Quality, North Dakota Department of Health, ''Automatic Delegation of Clean Air Act (CAA) Section 111 Requirements,'' from Carl Daly, Director, Air Program, February 27, 2014.

[41] For reference, this document may be found in the docket for today's notice.

[42] For cross-referencing North Dakota's unchanged incorporations of federal NSPS requirements both before and after the transfer of authorities from the NDDH to the NDDEQ, see the document, ''North Dakota NSPS Recodifications,'' included in the docket for today's notice.

the EPA to provide information to the Agency.[43]

*C. What NSPSs are we proposing to delegate?*

North Dakota's request included NSPS in 40 CFR part 60 as they existed through July 1, 2015.[44] This proposed delegation affects only the implementation and enforcement authority for those standards which had been previously delegated to the State under the previously approved automatic delegation program, and which have now been incorporated unchanged into the State's revised air pollution control rules.

The NDDEQ would maintain primary responsibility for the enforcement of the delegated section 111 standards within the State. If the NDDEQ determines that such enforcement is not feasible and so notifies the EPA, or on the occasion of the NDDEQ acting in a manner incongruous with the terms of this delegation arrangement, the EPA may exercise its parallel enforcement authority pursuant section 113 of the CAA with respect to sources within North Dakota subject to the section 111 new source performance standards.

There are some section 111 standards that may not be delegated to a state and which are not included in this automatic delegation arrangement. The emission guidelines (EG) found in 40 CFR part 60, subparts Cb, Cc, Cd, Ce, Cf, BBBB, DDDD, FFFF, and MMMM require states to develop implementation plans for 'existing' facilities of certain source categories, which are then approved under a separate process pursuant to section 111(d) of the CAA.

In addition, some portions of the section 111 standards and the associated general provisions of part 60, by their own terms, may not be delegated to a state. The EPA Administrator retains authority to implement those sanctions that require: (1) Approving equivalency determinations and alternate test methods; (2) decision making to ensure national consistency; and (3) EPA rulemaking in order to implement. 40 CFR 60.4(d) also contains certain NSPS authorities that are not delegated to state and local agencies. Additionally, the document titled ''INSERT'' in the docket for this proposal contains a list of example sections in 40 CFR part 60 that may not be delegated to a state. Accordingly, EPA retains authority over those portions of the CFR part 60 standards that may not be delegated.

If this delegation is finalized, all questions concerning implementation and enforcement of the excluded standards in the State of North Dakota should be directed to the EPA Region 8 Office.

*D. How will statutory and regulatory interpretations be made?*

If this NSPS delegation is finalized, the State will obtain concurrence from the EPA on any matter involving the interpretation of section 111 of the CAA or 40 CFR part 60 to the extent that implementation or enforcement of these provisions have not been covered by prior EPA determinations or guidance.

*E. What authority does the EPA have?*

We retain the right, as provided by CAA section 111(c)(2), to enforce any applicable emission standard or requirement under section 111. We also retain any authority in an individual standard that may not be delegated according to provisions of the standard and retain the authorities stated in the preceding delegation agreement.[45] North Dakota first received approval to operate under an automatic delegation arrangement that was effective on December 8, 2014.[46] (*See* 79 FR 60993). The delegation tables as of now and how it would look if this proposal is finalized may be found in the docket for this action. The docket item ''Delegation of CAA Authorities Overview,'' also lists the authorities that cannot be delegated to any state or local agency.

*F. What information must the State provide to the EPA?*

The State must provide any information identified in the Performance Partnership Agreement to the EPA, in accordance with the terms of the Agreement.

*G. What is the EPA's oversight role?*

The EPA oversees the State's decisions to ensure the delegated authorities are being adequately implemented and enforced. We will integrate oversight of the delegated authorities into the existing mechanisms and resources for oversight currently in place. We will initiate withdrawal of the program or rule if the corrective actions taken are insufficient.

*H. Should sources submit notices to the EPA or the State?*

For the delegated NSPS standards and authorities covered by this proposed action, if finalized, sources would submit all of the information required pursuant to the general provisions and the relevant subparts of the delegated NSPS (40 CFR part 60) directly to the State. The State is the primary point of contact with respect to delegated NSPS. Sources do not need to send a copy to the EPA. For those standards and authorities not delegated as discussed above, sources must continue to submit all appropriate information to the EPA.

*I. How will unchanged authorities be delegated to the State in the future?*

As stated in previous NSPS delegation actions, the EPA has approved North Dakota's mechanism of incorporation by reference of NSPS standards into the State regulations, as they apply to both part 70 and non-part 70 sources. *See, e.g.,* 79 FR 60993. All future section 111 requirements IBR into the State rules will become effective on the date the requirement goes into effect according to the State's updated rules and regulations. In the case of future adoption of section 111 requirements, the EPA requests that North Dakota send notice of the State's intention to receive delegation of the requirements within 60 days of its incorporation of those requirements into the State's rules and regulations. The notification should include an official copy of the regulation stamped, dated and signed by the appropriate official, with the date of adoption and the effective date in North Dakota. Within 30 days of receipt of North Dakota's notification, the EPA will reply with an acknowledgment of the delegation and will change the relevant Region 8 electronic delegations of authority table (found at: *http://www2.epa.gov/region8/air-program*) to reflect the new delegation of authority. If there is a change in the effective date for the section 111 requirement, North Dakota must notify the EPA as soon as possible. If the delay extends beyond the section 111 requirement compliance date, the EPA will implement and enforce the requirement until North Dakota has fully incorporated the requirement and the final effective date has passed.

The State also has the option of receiving partial delegation of a section 111 requirement, and the option to cancel the delegation of authority to

[43] For a detailed demonstration of North Dakota's program adequacy following the program elements in the EPA's 1983 ''Good Practices Manual for Delegation of NSPS and NESHAPs,'' see, ''NSPS Program Description,'' included in the submittal document, ''Title V Permit to Operate, MACT, NESHAPs and NSPS Programs for Department of Environmental Quality, Division of Air Quality,'' found in the docket for today's notice.

[44] NDAC 33.1–15–12–01.1.

[45] *See* the EPA's August 26, 2009 letter to Director Terry O'Clair, Division of Air Quality, North Dakota Department of Health, ''Delegation of Clean Air Act New Source Performance Standards 2009.''

[46] 79 FR 60993; October 9, 2014 (informing the public of EPA authorizing automatic delegation to North Dakota via letter from Carl Daly, Director Air Program, EPA Region 8, to Terry O'Clair, Director, Division of Air Quality, North Dakota Department of Health (February 27, 2014).

implement and enforce previously adopted requirements. Automatic partial delegation of severable portions of any standard requires that the State: (1) Clearly define the separable subcategory in the particular standard, or the specific separable subset of affected sources in the specific standard so that regulated sources and the public know who is the implementing and enforcing authority; and (2) the applicable portions of the Federal standard must be adopted by IBR into the State regulations or rules with an additional, clear explanation of what portions of the standard are not included in the standard's adoption into the State rule. If the State does not want to use automatic delegation for any of its previously adopted section 111 requirements, then the State may provide a list of those requirements which have been adopted and which the State wants to exclude from the delegation process to the EPA.

*J. Proposed Action*

With this notice of proposed rulemaking, the EPA is providing public notice and opportunity for public comment on the Agency's intention to approve revisions to the State of North Dakota's section 111 program for implementation and enforcement of NSPS requirements. The agency is also proposing straight delegation of all applicable implementation and enforcement authorities necessary to regulate section 111 sources covered by the relevant subparts of 40 CFR part 60 incorporated unaltered into State code. This proposed delegation shall not be construed as extending to those part 60 subparts which cover existing sources that require EPA approval of a state plan that affects the implementation and enforcement of federal emissions guidelines for such source categories (section 111(d) sources); nor shall this proposed action be construed as delegating those authorities under section 111 of the Act and part 60 which are reserved by the Administrator of the EPA and not subject to delegation. The EPA is also proposing approval of revisions to the automatic delegation arrangement between the EPA and the State of North Dakota to accommodate the transfer of delegated NSPS implementation and enforcement from the NDDH to the NDDEQ.

## V. Timing of Proposed Effective Dates

All revisions to the title V operating permits program, and section 111 and 112 programs would be federally enforceable as of the effective date of the EPA's approval of the respective revision and recodification of those programs, with the exception of the EPA's grant of interim approval of the part 70 program. The State plans to rely on the date when the EPA signs the final notice for purposes of notifying the state legislature that the EPA has approved these revisions, which will provide for the transfer authority from NDDH to NDDEQ to be effective under State law. Prior to the effective date of this approval, the State intends to take the necessary additional steps as specified in S.L. 2017, ch. 199, Section 1, to ensure that NDDEQ rules and the NDDEQ would become federally enforceable on the effective date of the EPA's approval. Unless and until the NDDEQ rules and agency become fully effective under federal law, for purposes of federal law the EPA recognizes the State's program as currently approved under the North Dakota Department of Health.

## VI. Statutory and Executive Order Review

Under the CAA, the Administrator is required to approve:

- A state permit program submittal that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7661a(d); 40 CFR 70.1(c), 70.4(i). Thus, in reviewing permit program submittals, the EPA's role is to approve state choices, provided they meet the criteria of the CAA and the criteria, standards and procedures defined in 40 CFR part 70;
- A state program for receiving delegated authority to implement and enforce emission standards and other requirements for air pollutants subject to section 112 if such program complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7412(l); 40 CFR part 63, subpart E. Thus, in reviewing section 112 program submittals, the EPA's role is to approve state choices, provided they meet the criteria of the CAA and the criteria, standards and procedures defined in 40 CFR parts 61 and 63; and
- A state program for receiving delegated authority to implement and enforce emission limitations for new stationary sources subject to section 111 if such program complies with the provisions of the Act and applicable federal regulations. 42 U.S.C 7411(c). Thus, in reviewing section 111 program submittals, the EPA's role is to approve state choices, provided they meet the criteria of the CAA and implement the requirements, standards and procedures defined in 40 CFR part 60.

Accordingly, this action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because Operating Permits Program approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this action is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

## List of Subjects in 40 CFR Parts 60, 61, 63, 70 and 72

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations,

Title V, New source performance standards, National emission standards for hazardous air pollutants, Maximum achievable control technology, Delegation of authority.

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

Dated: October 24, 2018.

**Douglas Benevento,**

*Regional Administrator, EPA Region 8.*

[FR Doc. 2018–23631 Filed 10–29–18; 8:45 am]

**BILLING CODE 6560–50–P**

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 192

**[EPA–HQ–OAR–2012–0788; FRL–9985–79–OAR]**

**RIN 2060–AP43**

## Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule; withdrawal.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) is withdrawing its January 19, 2017, proposed rule addressing health and environmental protection standards under the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) that would have applied to byproduct materials produced by uranium in-situ recovery (ISR) and would have subsequently been implemented by the U.S. Nuclear Regulatory Commission and its Agreement States. The EPA is withdrawing the proposed rule for three reasons. First, the EPA, informed in part by feedback received on the proposal, has serious questions as to whether the proposed rule as written is within EPA's authority under UMTRCA. Second, the EPA no longer believes that a national rulemaking to promulgate standards is necessary at this time, as the EPA believes the existing regulatory structures are sufficient to ensure the targeted protection of public health and the environment at existing ISR facilities. Third, present market circumstances suggest that the influx of new ISR license applications that was once anticipated and that was an underlying motive for the proposal is not likely to materialize.

**DATES:** The proposed rule published on January 19, 2017 (82 FR 7400), entitled ''Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings,'', is withdrawn as of October 30, 2018.

**FOR FURTHER INFORMATION CONTACT:** Ingrid Rosencrantz, Office of Radiation and Indoor Air, Radiation Protection Division, Mail Code 6608T, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–343–9290; fax number: 202–343–2304; email address: *radiation.questions@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

On January 19, 2017, the U.S. Environmental Protection Agency (EPA) proposed new health and environmental protection standards under the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) (2017 Proposal).[1] The standards proposed in that action would have applied to byproduct materials produced by uranium in-situ recovery (ISR) facilities and would have subsequently been implemented by the U.S. Nuclear Regulatory Commission (NRC) and NRC Agreement States. The EPA initially proposed new health and environmental protection standards for ISR facilities on January 26, 2015 (2015 Proposal).[2] However, the EPA decided to re-propose the rule on January 19, 2017, and seek additional public comment on changes to the original proposal, including changes in the regulatory framework and approach, based on public comment and new information received from stakeholders. The EPA has not finalized either of these proposals and is not doing so today. Instead, the EPA is withdrawing the 2017 Proposal, which superseded the 2015 Proposal.

### II. Why is the EPA withdrawing the 2017 Proposal?

The EPA has decided to withdraw the 2017 Proposal for three reasons. First, stakeholders, including the NRC, raised significant concerns regarding the EPA's legal authority under UMTRCA to propose these standards. Based on those significant concerns, we now have serious questions concerning whether the EPA has the legal authority under UMTRCA to issue the regulations as developed in the 2017 Proposal.

Second, the EPA no longer believes that a national rulemaking to promulgate standards is currently necessary as the Agency believes the existing regulatory structures are sufficient to ensure the targeted protection of public health and the environment at existing ISR facilities. The NRC stated in its public comments that its ''current regulations, at 10 CFR part 40, Appendix A, and those of the various Agreement States, as supplemented by site-specific license conditions, guidance documents . . . and the operational experience and technical expertise of the regulatory agency staff, *constitute a comprehensive and effective regulatory program* for uranium in situ recovery operations (ISR) facilities.'' (emphasis added).

Third, present market circumstances suggest that the influx of new ISR license applications that was once anticipated, and that was motivation for the proposal, is not likely to materialize. Therefore, there is less need for the rule, which was intended to provide a more workable and efficient approach for addressing these expected new applications, compared to existing mechanisms.

#### *A. The EPA's Legal Authority*

In the 2015 Proposal, the EPA explained that it was ''proposing these new standards'' under its authority in section 206 of UMTRCA which ''authorizes EPA to promulgate general standards for the protection of public health, safety, and the environment from radiological and non-radiological hazards associated with . . . the processing and the possession, transfer, and disposal of byproduct material at sites at which ores are processed primarily for their uranium and thorium source material content or which are used for the disposal of such byproduct material.'' [3] Many commenters stated that this provision does not provide authority for the type of standards that the EPA proposed. Other commenters agreed with the EPA's view that UMTRCA provides authority for proposing these standards. The EPA evaluated and responded to these comments in the 2017 Proposal.[4] Many of these same commenters subsequently submitted comments on the 2017 Proposal, arguing again that the proposed standards exceeded the EPA's authority to establish ''generally applicable standards.'' [5] The NRC also submitted comments stating that it does not believe EPA has the authority to develop standards of the type contained in the 2017 Proposal. Some of these commenters raised new arguments to support their position that the proposed standards exceed the EPA's authority under UMTRCA. In light of the comments provided on the various proposals, including by the NRC, the

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[1] 82 FR 7400.

[2] 80 FR 4156.

[3] 80 FR at 4163; *See also* 42 U.S.C. 2022(b)(1).

[4] 82 FR at 7418–7419, 7421–7422.

[5] 42 U.S.C. 2022(b)(1) uses the phrase ''standards of general application,'' while 42 U.S.C. 2022(b)(2) uses the term ''generally applicable standards.'' We use these terms interchangeably throughout the action.

EPA now has serious questions as to whether we have the legal authority to finalize the standards that were proposed in the 2017 Proposal.

Most of the commenters' objections to the EPA's application of its authority under UMTRCA in the 2015 Proposal centered around the meaning of the phrase ''standards of general application'' in the statutory provision. Commenters opposing the proposed standards stated, ''the proposed rules were legally invalid and felt the EPA was overreaching its authority under UMTRCA by proposing standards that are too detailed and prescriptive.'' [6] These commenters stated that the EPA ''was redefining what UMTRCA established as the EPA's role to set general standards'' since these commenters did not believe UMTRCA provided the EPA with the authority to set standards that included ''any prescriptive implementation requirements.'' [7] Other commenters that supported the 2015 Proposal stated that ''the proposed standards were an appropriate application of the EPA's authority under the UMTRCA.'' [8]

In its response to the many comments opposing the EPA's proposed application of its authority, the EPA in the 2017 Proposal indicated that it ''disagree[d] with those commenters who believe the EPA has redefined its role or overreached its authority in developing the new standards for ISR facilities.'' [9] The EPA stated that ''the new standards proposed in this action would apply the same requirements to all ISR facilities and would establish general requirements . . . [that] the regulatory agency would be responsible for implementing. . .on a site-specific basis through the licensing process and would retain the authority to determine when an ISR license can be terminated.'' [10]

Several stakeholders, including the NRC, subsequently submitted comments on the 2017 Proposal, again stating that the proposed standards could not be reasonably classified as ''generally applicable standards'' under UMTRCA and thus was outside EPA's authority. In the 2017 Proposal, the EPA identified the proposed standards as falling into one of three different categories: (1) ''Constituent concentration standards;'' (2) ''initial stability standards;'' and (3) ''long-term stability standards.'' [11] In its comments, the NRC asserted the initial and long-term stability standards ''are not generally applicable standards but are implementation criteria, and as such, encroach upon NRC's authority and impair the NRC's ability to effectively regulate its ISR licensees.'' [12] The NRC also raised several new significant legal arguments in its comments to support its position that had not been previously raised with EPA.[13] For example, the NRC argues that ''EPA's authority to promulgate generally applicable standards, at least for radiological material, is prescribed by what is essentially EPA's organic authority, namely, the Reorganization Plan No. 3 of 1970 (Reorganization Plan).'' [14] The NRC asserts that ''the Reorganization Plan provided EPA with an express transfer of AEA authority to set generally applicable standards 'for the protection of the general environment from radioactive material,''' and that the Reorganization Plan ''expressly prescribed this standard setting authority by defining the term 'standards' to mean 'limits on radiation exposures or levels, or concentrations or quantities of radioactive material'—essentially, numerical limits.'' [15] NRC further asserts that UMTRCA's legislative history shows that ''Congress was aware of and considered [this standard-setting authority in the Reorganization Plan] when it enacted UMTRCA in 1978'' and that ''Congress structured UMTRCA's grant of authority to the EPA Administrator upon this very provision.'' [16] The NRC points to several excerpts from the legislative history to support its claim that Congress intended ''that EPA's generally applicable standards under UMTRCA, for both radiological and non-radiological materials, be in the form of numerical limits, namely, limits on concentrations of radiological and non-radiological material, quantities of such material, or allowable doses or levels to individuals from such material.'' [17]

Other commenters disputed the EPA's authority to adopt regulatory requirements that they alleged could not reasonably be considered ''generally applicable standards.'' For example, the Uranium Producers of America (UPA) argued that the proposed standards ''exceed[s] EPA's jurisdictional authority as set forth by UMTRCA.'' [18] UPA further criticized the ''new prescriptive post-operational monitoring time and data requirements and new prescriptive post-restoration requirements'' as an ''impermissible attempt by EPA to direct the compliance of ISR operations.'' [19] The Texas Commission on Environmental Quality (TCEQ) raised the same objection, requesting that the EPA withdraw those particular requirements ''because they exceed EPA's authority to promulgate standards.'' [20] TCEQ stated that UMTRCA ''confers the NRC and Agreement State programs . . . , not EPA, with authority to implement and enforce EPA's standards,'' and then asserted the EPA's ''proposed rules . . . go beyond the promulgation of standards and address how those standards should be implemented and enforced.'' [21]

Other stakeholders submitted comments in support of the 2017 Proposal, reiterating their position that they believe the EPA has the authority to propose these types of ''generally applicable standards'' under UMTRCA.

Based on the discussion above, EPA now has serious questions concerning whether we have the legal authority to issue the regulations as proposed in the 2017 Proposal. In conjunction with the grounds for withdrawal discussed below, this uncertainty as to our authority weighs in favor of withdrawing the 2017 Proposal.

*B. Health and Environmental Protection Justification for the Rule*

When EPA initiated this rulemaking, there was already an effective system in place providing environmental oversight of ISR operations. As we explained in the 2015 Proposal, ''in 1983, EPA originally promulgated regulations at 40 CFR part 192, Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings, in response to the statutory requirements of the Atomic Energy Act [AEA] of 1954, as amended by the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA).'' [22] The 2015 Proposal further stated: ''Requirements currently applicable to active uranium processing and disposal sites, including ISR sites (*i.e.,* Title II sites) can be found in subpart D of 40 CFR part 192 (hereafter ''subpart D''). Subpart D contains provisions for managing uranium byproduct materials during and following the processing of uranium ores, and restoration of

[6] 82 FR at 7418.

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] 82 FR 7405.

[12] EPA–HQ–OAR–2012–0788–0312 (comments of the Nuclear Regulatory Commission) at 11.

[13] EPA–HQ–OAR–2012–0788–0312, pp. 8–21.

[14] *Id.* at pg. 12.

[15] *Id.*

[16] *Id.* at pg. 13.

[17] *Id.* at pg. 14.

[18] EPA–HQ–OAR–2012–0788–0380 (comments of Uranium Producers of America) at 7.

[19] *Id.*

[20] EPA–HQ–OAR–2012–0788–0302 (comments of the TCEQ) at 3.

[21] *Id.* at 3–4.

[22] 80 FR 4161.

disposal sites following any such use of those sites.'' [23]

In the 2015 Proposal, under the heading ''Why does EPA believe new standards are necessary?'' the Agency stated: ''We believe that ISR-specific standards are necessary because uranium ISR operations are very different from conventional uranium mills and the existing standards do not adequately address their unique aspects. In particular, we believe it is necessary to take a longer view of groundwater protection than has been typical of current ISR industry practices. Although the presence of significant uranium deposits typically diminishes groundwater quality, current industry practices for restoration and monitoring of the affected aquifer may not be adequate to prevent either the further degradation of water quality or the more widespread contamination of groundwater that is suitable for human consumption.'' [24]

In response to both proposals, the EPA has received numerous comments questioning the need or benefits of the rule. For example, in the 2017 Proposal the EPA noted that ''Industry commenters and others say that there is no need for this rule because the EPA has not identified an instance in which an ISR operation has contaminated a source of drinking water.'' [25] In the 2017 Proposal, the EPA also said: ''Focusing on the area of surrounding or adjacent aquifers, the EPA acknowledges that the Agency does not have sufficient information to document a specific instance of contamination of a public source of drinking water caused by an ISR . . . [however,] the Agency remains concerned that the lack of data does not demonstrate that no contamination is occurring . . . . The monitoring requirements in this proposal address the issue of lack of data.'' [26] (emphasis added). In its comments on the 2017 Proposal, UPA refers to the above statement: ''EPA acknowledges there is *no evidence* of harm. . . . The EPA provides no evidence to contradict [NRC's findings].'' By contrast, the Natural Resources Defense Council (NRDC) asserts that its comments ''demonstrate impacts to ISL mined aquifers . . . such that the groundwater is substantially degraded and there will be long-term harm to crucial natural resources.'' [27] As is evidenced by the comments, the debate is nuanced and complicated and reflects differing views on the available data.

In addition to the public stakeholder comments mentioned above, most importantly, the NRC, the agency tasked with implementing the program, weighed in on the debate, stating in its public comments that ''the NRC staff has concluded that its application of the 10 CFR part 40, Appendix A regulations to ISR facilities meets the AEA standard of 'adequate protection' of public health and safety and the environment. . . .'' [28]

In considering these factors, as well as the presence of an existing program that the NRC (the implementing agency) believes is sufficient, and the lack of expected growth and status of the industry as described further in the next section of this withdrawal action, the EPA believes that the reasonably envisioned public health and environmental benefits of the proposed rulemaking are limited and do not warrant EPA proceeding with its proposed rulemaking. The existing regulatory structures, adequately address the current environmental concerns.

### *C. Current and Anticipated Market Conditions*

Finally, the EPA believes that market forces themselves have lessened the need for such a rule. Initially, several factors, including the expected growth in this industry, led the EPA and the NRC to believe that regulation of ISR activities could be more workable and efficient if the EPA issued standards of general application specific to the ISR facilities that the NRC would incorporate into its own regulations and implement through its licensing activities.[29] When these efforts began, the NRC expected as many as 23 ISR license applications for new facilities, expansions, and restarts.[30] This expected influx of ISR license applications is no longer anticipated.

The NRC is currently reviewing license applications for only three expansions of ISR facilities and, for the next five years, the NRC expects only one license application for an expansion of one ISR facility and one license application for one new ISR facility.[31] Compared to the expected influx of ISR license applications, and the 15 ISR facilities owned by 10 companies at the time of the 2017 Proposal, at the end of 2017 only approximately six ISR facilities were operating,[32] with production down 17% compared to late 2016.[33] According to the U.S. Energy Information Administration (EIA), ''Domestic Uranium Production Report,'' 4th Quarter 2017, there are no ISR facilities reported as operating in Texas, with Alta Mesa, Hobson, La Palangana reported as on ''standby.'' Additional ISR facilities in New Mexico, Texas, and Wyoming have been licensed but have not operated and only one has undergone development.

The proposal of generally applicable national standards by EPA was driven partly by the expectation of a significant number of new facilities (which would have also applied to operating wellfields at existing facilities), making these proposed ISR-specific standards a more immediate prerequisite to achieving the efficiency across all regulatory programs that the NRC acknowledged could be gained by a ''regulatory regime . . . specific to ISRs.'' [34] Today, the EPA questions whether this expected growth in operating ISR facilities is likely to be realized.

Given this change in circumstances, completion of this rule is no longer expected to achieve the regulatory efficiency that was sought when this rulemaking effort began. The NRC and the NRC Agreement States currently regulate, through existing licenses, the limited number of operating ISR facilities and such an approach has been workable in practice for this number of

[23] 80 FR 4163.

[24] 80 FR 4164.

[25] 82 FR 7404.

[26] 82 FR 7404.

[27] EPA–HQ–OAR–2012–0788–0380 at 2; EPA–HQ–OAR–2012–0788–0390 (comments of the NRDC) at 4.

[28] EPA–HQ–OAR–2012–0788–0312 at 1.

[29] EPA–HQ–OAR–2012–0788–0006 (''Regulation of Groundwater Protection at *In Situ* Leach Uranium Extraction Facilities,'' Nuclear Regulatory Commission Memorandum COMJSM–06–0001, January 17, 2006) at 2 (''. . . the recent rapid rise in uranium prices and mining claims would indicate a significant future potential for new ISL facilities.''); 80 FR at 4167 (''In recent years, NRC has recognized the desirability of ISR-specific regulations. . . . [T]he Commission determined in 2006 that the appropriate action was 'initiation of a rulemaking effort specifically tailored to groundwater protection programs at *in situ* leach (ISL) uranium recovery facilities.' ''); 82 FR at 7420 (''In addition, the NRC acknowledges that efficiency could be gained by codifying its longstanding effective regulatory regime into regulations specific to ISRs. As described in the original proposal, this rulemaking was initially prompted by the NRC's conclusion that ISR-specific rules are needed to create a more workable and sustainable regulatory framework for this activity, and is not based on any specific instances of identified contamination.'').

[30] EPA–HQ–OAR–2012–0788–0405 (''Uranium Recovery Licensing Activities,'' Presentation of the Nuclear Regulatory Commission) at 10.

[31] Expectations for number of future licenses based on NRC/EPA telephone conversation on November 28, 2017.

[32] U.S. Energy Information Administration: ''Domestic Uranium Production Report.'' 4th Quarter 2017 (February 8, 2018). The operating facilities are Crow Butte in Nebraska and Lost Creek, Nichols Ranch, Ross, Smith Ranch-Highland and Willow Creek, all in Wyoming. Cameco subsequently curtailed production at the Crow Butte and Smith-Ranch Highland facilities (see *http://www.cameco.com*).

[33] World Nuclear News, 20 November 2017.

[34] 82 FR 7420. *See* footnote 29 for a more complete citation.

facilities. We do not see a need for the EPA to continue investing its resources to complete this rule to develop a ''more workable and sustainable regulatory framework'' as originally anticipated when we proposed these ISR-specific standards, especially where current production is reduced and little or no growth is expected in the near future. The statutory authorities providing for this ongoing regulatory and licensing function remain unchanged. Thus, the appropriate regulatory authorities may decide on a case-by-case basis to revise their own pre-existing regulations based on these authorities if they deem it necessary to assist with their management of ISR facilities in a particular state or local area.

In addition, we find support for our decision to withdraw the proposed rule in the NRC's comments on the 2017 Proposal. As explained above, the EPA developed the proposed standards partly based on its understanding, after consultation with the NRC, that the anticipated growth in the number of ISR facilities highlighted a need for standards specific to ISR facilities, rather than continuing to apply standards that were originally written to address surface disposal of uranium mill tailings.[35] However, the NRC expressed the following view in its public comments on the proposed rulemaking:

> The NRC's current regulations, at 10 CFR part 40, Appendix A, and those of the various Agreement States, as supplemented by site-specific license conditions, guidance documents (*e.g.,* NRC's ''Standard Review Plan for In Situ Leach Uranium Extraction License Applications,'' NUREG–1569), and the operational experience and technical expertise of the regulatory agency staff, constitute a comprehensive and effective regulatory program for uranium in situ recovery operations (ISR) facilities.[36]

Considering the prevailing economic conditions affecting current and projected production, which leads the NRC now to expect significantly fewer future license applications, as opposed to the large increase that it expected at the time the rulemaking process was initiated (which was motivation for the proposal), we conclude that withdrawing this proposal is appropriate.

## III. Statutory Authority

The statutory authority for this notice is provided by section 275 of the Atomic Energy Act (AEA), as added by section 206 of UMTRCA (42 U.S.C. 2022) and the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*).

## IV. Impact Analysis

Because the EPA is not promulgating any regulatory requirements, there are no compliance costs or impacts associated with today's final action.

## V. Statutory and Executive Order Reviews

Today's action does not establish new regulatory requirements. Hence, the requirements of other regulatory statutes and Executive Orders that generally apply to rulemakings (*e.g.,* the Unfunded Mandate Reform Act) do not apply to this action.

Dated: October 18, 2018.

**Andrew R. Wheeler,**

*Acting Administrator.*

[FR Doc. 2018–23583 Filed 10–29–18; 8:45 am]

BILLING CODE 6560–50–P

[35] 82 FR at 7402–3; 80 FR 4164–7.

[36] EPA–HQ–OAR–2012–0788–0312 at 1.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

### 42 CFR Chapter IV

**[CMS–5528–ANPRM]**

**RIN 0938–AT91**

## Medicare Program; International Pricing Index Model for Medicare Part B Drugs

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Advance notice of proposed rulemaking with comment.

**SUMMARY:** We are issuing this advance notice of proposed rulemaking (ANPRM) to solicit public comments on potential options we may consider for testing changes to payment for certain separately payable Part B drugs and biologicals (hereafter called ''drugs''). Specifically, CMS intends to test whether phasing down the Medicare payment amount for selected Part B drugs to more closely align with international prices; allowing private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and changing the 4.3 percent (post-sequester) drug add-on payment in the model to reflect 6 percent of historical drug costs translated into a set payment amount, would lead to higher quality of care for beneficiaries and reduced expenditures to the Medicare program.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 31, 2018.

**ADDRESSES:** In commenting, please refer to file code CMS–5528–ANPRM. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5528–ANPRM, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5528–ANPRM, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Hillary Cavanagh, 410–786–6574 or the IPI Model Team at *IPIModel@cms.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

## I. Executive Summary

### *A. Purpose*

The Medicare program and its beneficiaries currently pay more for many high-cost drugs than many other countries.[1] The Centers for Medicare & Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation (''Innovation Center'') is taking action on President Trump's goal to lower drug costs for Medicare beneficiaries by exploring a potential model that seeks to ensure the Medicare program pays comparable prices for Part B drugs relative to other economically-similar countries. The potential International Pricing Index (IPI) model would have several goals, including: reducing Medicare program selected expenditures and beneficiary cost-sharing for separately payable Part B drugs (for example, drug administered in physician offices and hospital outpatient departments), preserving or enhancing quality of care for beneficiaries, offering comparable pricing relative to international markets, removing providers' financial incentive to prescribe higher-cost drugs while creating revenue stability, minimizing disruption to the current supply chain, and increasing Medicare efficiency and value to reduce federal spending and taxpayer dollars. With this advance notice of proposed rulemaking (ANPRM), the CMS is soliciting public feedback on key design considerations for developing the IPI Model.

The IPI Model aims to drive better quality for Medicare beneficiaries and reduce Medicare drug spending by offering comparable pricing relative to other countries and addressing flawed incentives in the current payment system. Currently, Medicare pays substantially more than other countries for the highest-cost physician administered drugs.[2] In addition, the current Medicare payment system has several features that may be causing greater utilization of higher priced drugs.[3] Under the current system, Medicare pays doctors and hospitals a fee set at 6 percent of the price of the drug so that the dollar amount of the add-on increases with the price of the drug rather than a set payment reflecting the service being performed. The current buy-and-bill system also requires physicians to purchase high-cost Part B drugs and wait for Medicare reimbursement, exposing practices to financial risk and jeopardizing their ability to operate and provide care in their communities.

We are proposing to design the IPI Model to achieve the following: (1) Reduce expenditures while preserving or enhancing the quality of care for beneficiaries; (2) ensure the United States (U.S.) is paying comparable prices for Part B drugs relative to other countries by phasing in reduced Medicare payment for selected drugs based on a composite of international prices; (3) reduce out-of-pocket costs for included drugs for Medicare beneficiaries, and thereby increase access and adherence due to decreased drug costs; (4) maintain relative stability in provider revenue through an alternative drug add-on payment for furnishing drugs that removes the current percentage-based drug add-on payments, which creates incentives for higher list prices and to prescribe higher cost drugs; (5) reduce participating health care providers' burden and financial risk associated with furnishing included drugs by using private-sector vendors to purchase and take title to included drugs; and (6) introduce greater competition into the acquisition process for separately payable Part B drugs.

### *B. Summary of Major Provisions*

In section III. of this ANPRM, we discuss the model concept design for the IPI Model. This IPI Model would focus on selected separately payable Part B drugs and biologicals (hereafter called ''drugs''). Specifically, the IPI Model would initially focus on Part B single source drugs, biologicals, and biosimilars that encompass a high percentage of Part B drug utilization and spending. The Innovation Center would test this model under section 1115A of the Social Security Act (the Act), which authorizes testing models expected to reduce program expenditures, while preserving or enhancing the quality of care furnished to beneficiaries. The model under consideration would include physicians, hospitals, and potentially other providers and suppliers in selected geographic areas. The IPI Model test would include the following components:

- Set the Medicare payment amount for selected Part B drugs to be phased down to more closely align with international prices;
- Allow private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and
- Increase the drug add-on payment in the model to reflect 6 percent of historical drug costs.
- Pay physicians and hospitals the add-on based on a set payment amount structure; CMS would calculate what CMS would have paid in the absence of the model, before sequestration, and redistribute this amount to model participants based on a set payment amount.

These and other components of the potential model are described in greater detail in this ANPRM.

We are considering issuing a proposed rule in the Spring of 2019 with the potential model to start in Spring 2020. The potential model would operate for five years, from Spring 2020 to Spring 2025. Of note, as discussed in section III.I. of this ANPRM, the IPI Model may have an impact on Medicaid drug rebates and payments, which we continue to explore.

With the release of this ANRPM, we solicit public input on our intended model design to inform our ongoing work to develop the IPI Model.

## II. Background

### *A. Overview of Supply Chain*

#### 1. Current Distribution System

In the U.S., Part B drugs that are administered in the outpatient setting usually flow from the manufacturer through drug wholesalers (or specialty distributors) to the provider or supplier. At each step of the process, the drugs are sold to the next entity in the supply chain and that entity takes title to the drug. Distribution management systems are employed to order drugs, track sales and shipments, manage price and customer lists, record financial transactions, and support other industry processes. Figure 1 provides a high-level

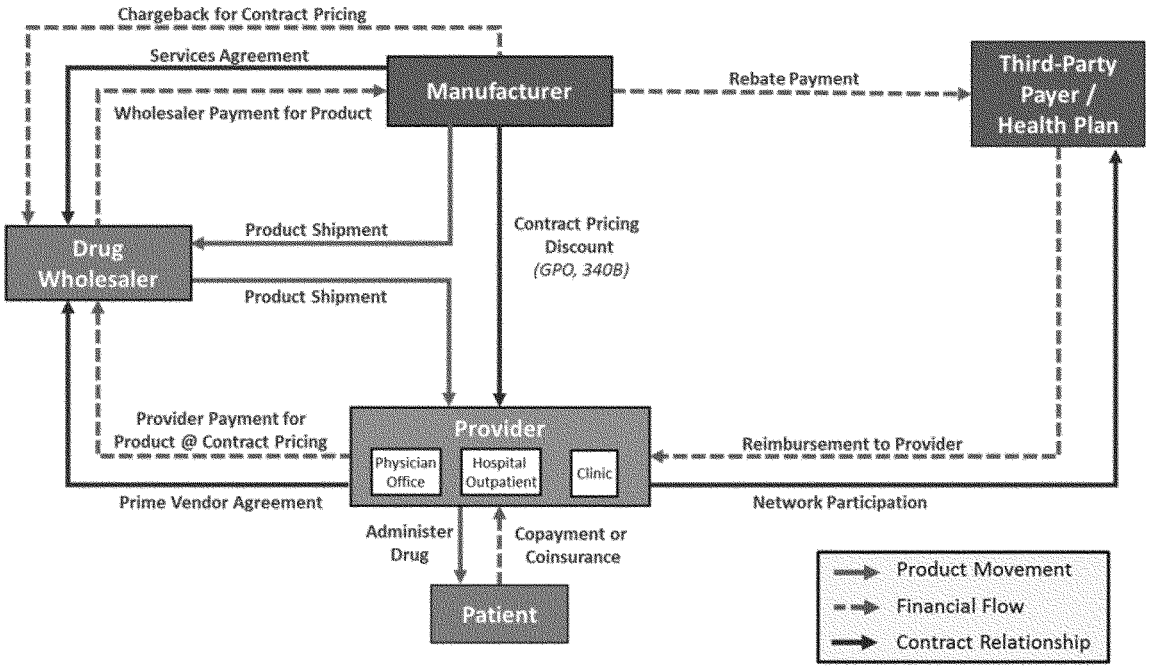
[1] ''Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-spending-medicare-part-b-drugs.*

[2] ''Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-spending-medicare-part-b-drugs.*

[3] ''Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-spending-medicare-part-b-drugs.*

view of this ''buy and bill'' system [4] and existing relationships between the various entities, including product movement, financial flow, and contract relationships.[5]

## FIGURE 1: BUY-AND-BILL SYSTEM FOR DISTRIBUTION AND REIMBURSEMENT OF PROVIDER-ADMINISTERED OUTPATIENT DRUGS




GPO = Group Purchasing Organization; 340B = 340B Drug Pricing Program. Chart illustrates flows for **Provider-Administered, Outpatient Drugs**. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.
Source: Fein, Adam. J., *The 2016–17 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors*, Drug Channels Institute, September 2016, Exhibit 28. Available at http://drugchannelsinstitute.com/products/industry_report/wholesale/.

The role of the health care provider within the buy-and-bill system is to seek out low cost drug suppliers and purchasing mechanisms (for example, by joining a group purchasing organization (GPO)), order, buy (or use financing), receive, and store drugs, administer drugs to patients, file claims to bill insurers for payment, and collect patient cost-sharing. There are many different buying strategies that enable physicians and hospitals to obtain lower drug prices. These strategies include using GPOs, group purchasing arrangements, wholesaler/distributor price lists, the 340B Prime Vendor,[6] and directly negotiated agreements with manufacturers. Similarly, the current drug distribution system accommodates a variety of purchasing mechanisms and specialized distribution processes, for example, cold chain and product tracing compliance.[7]

Physicians generally purchase Part B drugs from a wholesaler, distributor, or specialty pharmacy. Hospitals generally purchase for their outpatient departments through their hospital pharmacy's arrangement with a drug wholesaler. Physicians and hospitals also have arrangements with manufacturers, individually or through their GPOs, for discounts that are tied to prescribing, for example volume discounts based on purchases of drugs for all patients that are treated. Drug wholesalers, distributors, and specialty pharmacies negotiate with manufacturers on the price they will pay to acquire drugs. When applicable, contract pricing controls the price that the health care provider will pay to the wholesaler, distributor, or specialty pharmacy, while shipping and handling and other terms may vary. Through a process called the ''chargeback process,'' manufacturers reduce the final drug prices to wholesalers and other

[4] The ''buy and bill'' system refers to health care providers purchasing drugs for administration to patients followed by the submission of claims to a payer.

[5] Reprinted with permission. Drug Channels, ''Follow the Vial: The Buy-and-Bill System for Distribution and Reimbursement of Provider-Administered Outpatient Drugs,'' October 14 2016, accessed via: *https://www.drugchannels.net/2016/10/follow-vial-buy-and-bill-system-for.html.*

[6] The Health Resources and Services Administration (HRSA) administers the 340B Drug Pricing Program that allows certain hospitals and other health care providers (''covered entities'') to obtain discounted prices on ''covered outpatient drugs'' (as defined at section 1927(k)(2) of the Act) from drug manufacturers. The 340B Prime Vendor is responsible for securing subceiling discounts on outpatient drug purchases and discounts on other pharmacy-related products and services for participating public hospitals, community health centers, and other safety-net health care providers electing to join the 340B program.

[7] A cold chain ensures that a product maintains a desired temperature all the way through the supply chain from manufacturing to delivery/administration. Product tracing allows a user to track every step of the supply chain.

distributors to reflect the contract prices that were applied to health care providers' drug purchases. Increasingly, specialty pharmacies are supplying oncology drugs to health care providers that have chosen to remove themselves from the buy and bill system—or private payers are mandating use of ''white bagging'' or ''brown bagging'' (that is, pharmacy dispensed drugs delivered to the practitioner by the pharmacy or patient) to control drug costs.[8] However, Medicare does not mandate use of or encourage white bagging or brown bagging.[9]

2. Prior Competitive Acquisition Program

Under the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which established section 1847B of the Act, we have authority to implement the ''Competitive Acquisition Program'' or ''CAP'' for Part B drugs that are not paid on a cost or prospective payment basis. The CAP was implemented in the mid-2000s.

The CAP was an alternative to the average sales price (ASP) methodology that is used to pay for the majority of Part B drugs, particularly drugs that are administered during a physician's office visit. Instead of buying drugs for their offices, physicians who chose to participate in the CAP would place a patient-specific drug order with an approved CAP vendor; the vendor would provide the drug to the office and then bill Medicare and collect cost-sharing amounts from the patient. Drugs were supplied in unopened containers (not pharmacy-prepared individualized doses like syringes containing a patient's prescribed dose). When the CAP was in place, most Part B drugs used in participating physicians' offices were supplied by the approved CAP vendor. Unlike the buy and bill process that is still used to obtain many Part B drugs, physicians who participated in the CAP did not buy or take title to the drug. Physician participation in the CAP was voluntary, but physicians had to elect to participate in the CAP. CAP drug claims were processed by a designated carrier.

CMS conducted bidding for CAP vendors in 2005. The first CAP contract period ran from July 1, 2006 until December 31, 2008. One drug vendor participated in the program, providing drugs within approximately 180 Healthcare Common Procedure Coding System (HCPCS) billing codes (including heavily utilized drugs in Part B) to physicians across the United States and its territories. The parameters for the second round of the vendor contract were essentially the same as those for the first round. While CMS received several qualified bids for the subsequent contract period, shortly before the second contract period began, contractual issues with the successful bidders led to the postponement of the program, and the CAP has been suspended since January 1, 2009.

3. Challenges With the Statutory CAP

As described previously, the CAP operated for a brief time from 2006 to 2008. The Part B drug market has changed since that time. Higher cost drugs, particularly biologicals manufactured by sole sources, are driving increasing Part B drug expenditures.[10] Many of the highest price drugs and biologicals available today were not contemplated when the CAP program was established. While distribution channels have remained concentrated, today's providers and suppliers have access to more sophisticated technologies such as electronic ordering systems and virtual inventory management systems.

Since 2009, physicians have faced growing financial risks under the buy and bill approach, as the prices of Part B drugs have increased. Hospitals have varying ability to negotiate discounts, so some hospitals face similar financial challenges for the outpatient drugs they provide. Further, the rising costs of prescription drugs in the Medicare Part B program strain federal resources as well as beneficiaries' wallets.

As envisioned, the CAP had the potential to reduce risk for enrolled physicians and Medicare expenditures. As implemented, the CAP was tied to the ASP payment under section 1847A of the Act and did not achieve savings.[11] In the aggregate, the submitted bids could not exceed a threshold that was based on ''point in time'' ASP data combined with historical utilization data. The submitted bids fed into the composite bid analysis and vendor selection process. These time consuming, imprecise mechanisms, along with other features of the CAP, limited the appeal of the program for vendors. There was no guarantee for the CAP vendors that the CAP payments would cover their drug acquisition and operating costs. Participating physicians reported that CAP requirements were challenging to integrate into efficient practice patterns and treatment regimes, especially for oncologists who prescribe dosages that may change on the day of treatment, and physicians who need to administer antibiotics urgently.

Recently, we have heard from stakeholders, including physician and hospital groups, and beneficiary advocates, that a CAP-like approach with improvements, particularly in regards to onsite availability of drugs, could potentially address concerns about the financial burdens associated with furnishing Part B drugs and their rising costs, and address challenges experienced in the CAP. Stakeholder feedback on the CAP has been considered in the development of the potential IPI Model described in this ANPRM. In addition, comments received on a Request for Information on a potential model to leverage the authority under the CAP for Part B drugs and biologicals that was included in the Calendar Year 2019 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (83 FR 37046) and comments received on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (83 FR 22692) were considered.

*B. Rising Cost of Prescription Drugs*

1. Medicare Spending

Medicare Part B drug expenditures have increased significantly over time. From 2011 to 2016, Medicare FFS drug spending increased from $17.6 billion to $28 billion under Medicare Part B, representing a compound annual growth rate (CAGR) of 9.8 percent, with per capita spending increasing 54 percent, from $532 to $818.[12] The number of Medicare Part B FFS beneficiaries and the number of these beneficiaries who received a Part B drug increased over the 5-year period (2011 through 2016). However, the increase in total Medicare drug spending during this period is more fully explained by increases in the prices of drugs and mix of drugs for those beneficiaries who received them than by increases in Medicare enrollment and drug utilization. The

[8] Robinson and Howell. Specialty Pharmaceuticals: Policy Initiatives to Improve Assessment, Pricing, Prescription, and Use. Health Affairs 2014:33(10);1745–50.

[9] ''Brown bagging'' is a term used when the patient obtains the drug at a pharmacy and then brings it to the physician for administration. ''White bagging'' is a term used when the specialty pharmacy ships directly to the physician office or hospital outpatient department for administration.

[10] Medicare Part B Drug Spending Dashboard accessed via: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB.html.*

[11] Evaluation of the Competitive Acquisition Program for Part B Drugs: Final Report, December 2009, accessed via: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf.*

[12] Spending and Enrollment Data from Centers for Medicare and Medicaid Services Office of Enterprise Data and Analytics.

CAGR in number of Medicare Part B FFS beneficiaries is less than 1 percent between 2011 and 2016.

2. International Prices Relative to U.S. Prices

Drug acquisition costs in the United States exceed those in Europe, Canada, and Japan, according to a Department of Health and Human Services (HHS) analysis [13] of drug acquisition costs for Medicare Part B physician-administered drugs. The HHS analysis compared United States drug acquisition costs for a set of Medicare Part B physician-administered drugs to acquisition costs in 16 other developed economies—Austria, Belgium, Canada, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Japan, Portugal, Slovakia, Spain, Sweden, and the United Kingdom (UK).

Among the 27 products included in the analysis, acquisition costs in the U.S. were 1.8 times higher than in comparator countries.[14] Acquisition cost ratios ranged from U.S. prices being on par with international prices for one drug, to U.S. prices being up to 7 times higher than the international prices. There is variability across the 16 countries in the study as well, with no one country consistently acquiring drugs at the lowest prices. The U.S. has the highest ex-manufacturer prices for 19 of the 27 products.

As a result, Medicare beneficiaries and the Medicare program are bearing unnecessary, potentially avoidable costs for Part B drugs.

## III. Model Concept Design

The potential IPI Model would leverage and improve upon the CAP approach by paying physicians and hospitals for drug-related costs, providing more flexibility for drug ordering and distribution, and by having model vendors compete for business from physicians and hospitals. Through the potential IPI Model, we seek to test ways to remove physicians and hospitals outpatient departments from the buy and bill process, without creating undue disruption to the distribution system.

CMS is considering contracting with a number of private-sector vendors that would supply physicians, hospital outpatient departments, and other included providers and suppliers with the drugs and biologicals that CMS would include in the model in all of the model's selected geographic areas. Similar to the CAP, the model vendors, rather than the health care providers, would take on the financial risk of acquiring the drugs and billing Medicare. Instead of paying the model vendors based on bid amounts, as section 1847B of the Act prescribes for the CAP, under the IPI Model Medicare would pay the vendor for the included drugs based on international prices discussed in section III.D. of this ANPRM, which would be intended to lower the amount Medicare pays for included drugs and beneficiary cost-sharing. The model vendors would have flexibility to offer innovative delivery mechanisms to encourage physicians and hospitals to obtain drugs through the vendor's distribution arrangements, such as electronic ordering, frequent delivery, onsite stock replacement programs, and other technologies. Physicians and hospitals in the model test would select the vendors that best provide customer service and support beneficiary choice of treatments, and would be able to engage with multiple vendors for different drugs and to change vendors. In addition to the Medicare drug administration payment that would still be made to physicians and hospitals, the model would pay physicians and hospitals a ''drug add-on amount'' that would be different from the current drug add-on amount.

Outside of the designated model test areas and for drugs not included in the model, health care providers would continue to use the buy and bill approach and the current Medicare FFS payment policies would apply.

This ANPRM describes features of a potential model in more detail, such as how an international pricing index could be developed and tested. We intend to waive program requirements to the extent necessary to test the model design that we would implement through notice and comment rulemaking. We seek feedback on a number of potential model elements described in the following sections of this ANPRM. These include:

- What limitations would be in place on the entities that could participate as vendors (*e.g.* pharmacies, manufacturers, providers themselves)?
- Which countries should be included in calculating an international pricing index? How frequently should international data be updated?
- What should be the schedule for phasing in the spending target?
- Should we introduce health care provider bonuses to incentivize reductions in cost or utilization relative to a benchmark?

*A. Model Vendors*

1. Testing Alternative to CAP Requirements

As CMS develops the IPI Model, we seek to minimize disruption within the drug distribution system while increasing competition, lowering U.S. drug prices, and removing the incentive for higher list prices. Under the CAP, the CAP vendor had to acquire the CAP drug and ship the drug to the ordering physician after receiving a beneficiary-specific order. Under the IPI Model we are considering, vendors would have the flexibility to offer a variety of delivery options, including beneficiary-specific prescriptions, pre-ordering approaches such as onsite inventory management solutions, and other arrangements that would not require physicians and hospitals to purchase the drugs or face greater buying costs. Physicians and hospitals would select the vendors that offer delivery mechanisms that best meet their patient care needs, practice size and location(s), and support needs. Agreements between the vendors and physicians/hospitals would establish the terms of their arrangements and would include appropriate guardrails to protect all parties, including beneficiaries and the Medicare program. CMS seeks feedback on whether CMS should be a party to and/or regulate these agreements, and whether the agreements should specify obligations to ensure the physical safety and integrity of the included drugs until they are administered to an included beneficiary, how drug disposition would be handled, and data sharing methods, confidentiality requirements, and potentially other requirements.

2. Eligible Vendors

Under the potential IPI Model, we would intend to allow greater flexibility than under the CAP in the types of entities that could be selected as a model vendor (in accordance with applicable laws), and to minimize the impacts on drug distribution processes. Under the CAP, specialty pharmacies were the only entities that met the CAP vendor criteria, and only one such vendor participated in the program. To increase competition, the IPI Model would potentially allow entities such as GPOs, wholesalers, distributors, specialty pharmacies, individual or groups of physicians and hospitals, manufacturers, Part D sponsors, and/or other entities to perform the role of

[13] ''Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-spending-medicare-part-b-drugs.*

[14] Acquisition cost ratios ranged from U.S. prices being on par with international prices for one drug, to U.S. prices being up to 7 times higher than the international prices. There is variability across the 16 countries in the study as well, with no one country consistently acquiring drugs at the lowest prices. The U.S. has the highest acquisition costs for the vast majority of the 27 products.

model vendor as long as they could satisfy the vendor qualification requirements. We are interested in ways to minimize any potential concerns that could arise by allowing a broader set of entities to be vendors, and how health care providers operating as vendors might be able to operate in all geographic areas included in the model. We seek input on the types of entities that would be allowed to be model vendors, the potential for perverse incentives that could be introduced by potentially allowing health care providers to be model vendors and/or allowing model vendors to charge health care providers for distribution-related activities, and whether there should be guardrails in place to prevent perverse incentives.

We would require that model vendors purchase and take title to the included drugs, but to allow for innovative distribution approaches, model vendors would not be required to take physical possession of the drugs. For example, if a manufacturer establishes a limited distribution program, model vendors could negotiate with the manufacturer ways to purchase the drug while the established limited distribution entity would continue to ship the drug to the physician or hospital for administration.

We would expect that all model vendors would operate on a national basis; that is, model vendors potentially would be required to serve all of the selected model geographic areas and supply all included drugs to the physicians and hospitals that enroll with the vendor. The model would promote competition among multiple national vendors; vendors would compete for agreements with physicians and hospitals and other health care providers that would be included in the model. Physicians and hospitals would not be required to use only one vendor; we would encourage model participants to obtain drugs from the most cost effective model vendors. Enrolling with more than one vendor would allow physicians and hospitals more options for obtaining drugs timely, although the minimum requirement would be that model participants maintain enrollment with at least one vendor in order to furnish included drugs to the beneficiaries they serve timely.

Model vendors would operate enrollment for physicians and hospitals and would send periodic enrollment reports and other documentation to CMS to support model operations. In addition, model vendors would be prohibited from paying rebates or volume-based incentive payments to physicians and hospitals.

3. Model Vendor Responsibilities

The model vendors' responsibilities would be based on the responsibilities of the CAP contractor under section 1847B of the Act and would be specified in a model vendor agreement. The model vendors would be responsible for such activities as—

- Negotiating with manufacturers for the vendor's drug acquisition prices for included drugs;
- Establishing mechanisms for the model vendor to take title to, but not necessarily physical possession of, included drugs, and arranging for the distribution of included drugs to participant health care providers for administration to included beneficiaries;
- Establishing mechanisms within the vendor's arrangements with manufacturers, physicians, hospitals, and other included providers and suppliers to receive compensation for vendor services;
- Implementing processes for participant health care providers to enroll with the vendor and to obtain included drugs;
- Meeting applicable licensure requirements in each State in which the vendor would supply included drugs and be enrolled in Medicare as a participating supplier, unless the model vendor distributes included drugs under contract with one or more entities, in which case the vendor must require that such entities meet applicable licensure requirements and be enrolled in Medicare as a participating supplier;
- Establishing mechanisms for physicians and hospitals to notify the vendor of the disposition of an included drug;
- Submitting claims for included drugs in accordance to model billing instructions established by CMS;
- Paying manufacturers for included drugs that were administered;
- Operating vendor-administered payment arrangements, such as indication based pricing, or outcomes-based agreements;
- Developing and implementing program integrity safeguards to ensure that all model requirements and applicable Medicare requirements are followed;
- Participating in model activities, including monitoring and evaluation activities;
- Providing support and technical assistance to participant health care providers; and
- Performing other functions and requirements as specified in the model vendor agreement, such as administrative requirements.

4. Model Vendor Payment

Physicians and hospitals would pay the model vendor for distribution costs and would collect beneficiary cost-sharing, including billing supplemental insurers.[15] Informational drug claims would be submitted to the Medicare Administrative Contractor (MAC) along with claims for drug administration.

In addition, similar to how the CAP operated, under the model, vendors would submit claims to Medicare and would be paid an applicable amount for the Part B drug that was administered to an included beneficiary. The model payment amounts to vendors for included drugs would be updated quarterly. The payment amount is described in section III.D. of this ANPRM. Unlike the CAP, under the potential model CMS would not solicit bid amounts for drugs. To the extent it would be legally allowable, vendors' agreements with physicians and hospitals could include provisions for delivery fees and other vendor costs.[16]

On a periodic basis, for example quarterly, CMS would ensure that payment to the model vendors for administered drugs is substantiated by the physician and hospital submitted claims.

We seek feedback on other options for model vendor payment, including whether payment should include an administration fee from CMS and whether vendors' agreements with physicians and hospitals could include provisions for delivery fees and other vendor costs.

We are considering whether, given the flexibilities that model vendors and physicians and hospitals would have under the model, the model should include dispute resolution support, and if so, what such support should include.

5. Model Vendor Selection

We intend to operate a competitive selection process to identify the model vendors that would participate in the IPI Model. As we solicit applications for potential model vendors, we would encourage a variety of qualified entities to apply, including new business arrangements that could fulfill the vendor role on a national basis. We intend to select three or more model vendors so that physicians and hospitals have a number of vendors from which to obtain drugs and so that model vendors compete on the basis of

[15] We envision that existing Medicare crossover claims processing steps could be leveraged to support billing supplemental insurers.

[16] We envision that model vendors would compete, in part, for physicians and hospitals based on low fees.

customer service and cost, but solicit comment as to whether three vendors is an appropriate floor. The solicitation for model vendors would specify in more detail the model vendor requirements.

The model vendor solicitation would also specify the selection factors, which may include: The ability to negotiate with manufacturers; the ability to ensure product integrity; The ability to establish a customer service/grievance process; financial performance and solvency; record of integrity and the implementation of internal integrity measures; internal financial controls; maintenance of appropriate licensure to purchase drugs and biologicals; and ability to meet the model vendor agreement requirements within 6 months.

We would refuse to establish a model vendor agreement with an entity for reasons including—

- Exclusion of the entity under section 1128 of the Act from participation in Medicare or other Federal health care programs; or
- Past or present violations or misconduct related to the pricing, marketing, distribution, or handling of drugs covered under the Medicare program.

We would similarly include reasons to terminate a model vendor in the model vendor agreement. In addition, to ensure that selected model vendors would be able to perform their responsibilities under the model vendor agreement without influence from parties that have a financial interest related to included drugs or participating health care providers, we are considering including conflict of interest requirements similar to those established for the CAP in 42 CFR 414.912.

6. Requests for Feedback and Information

We are inviting public comment on the factors that would be necessary to allow CMS to identify entities that would most likely perform the responsibilities of a model vendor efficiently and effectively with minimal start up time.

- We seek information about the types of entities that could serve as national vendors for the model. Should CMS require model vendors to enroll any included health care provider? If included physicians and hospitals could be model vendors, should they be required to be a vendor for other health care providers, and should they have to operate on a national basis? Should any vendor be required to provide services on a national basis?
- We are also interested in public comment on the potential guardrails that would be appropriate if manufacturers and/or health care providers could serve as model vendors. Also should CMS receive shared savings based on the difference between a model vendor's negotiated price and CMS' payment amount? If so, how would CMS operationalize this shared savings approach?
- What should be the potential responsibilities of model vendors and model participants (included physicians, hospitals, and potentially other providers and suppliers) under the model. Specifically, are there ways that vendors and model participants could collaborate to enhance quality and reduce costs?
- What would be the ability of the potential types of entities that could be model vendors to negotiate for drug prices that would be at or below the IPI Model payment? Would certain types of entities have advantages or face additional challenges?
- Are there processes that model vendors could use to increase their price negotiation leverage with manufacturers and lower their potential loss exposure without increasing burdens on beneficiaries, physicians, and hospitals?
- Are there unsurmountable challenges related to physicians and hospitals paying for distribution costs and to continue to collect beneficiary cost-sharing, including billing supplemental insurers?
- Should physicians and hospitals receive bad debt payments if beneficiaries fail to satisfy cost-sharing obligations?
- Is there a need for the model to include billing and dispute resolution support, and if so, what should such support include?
- Should CMS pay the model vendors or should providers pay the model vendors for the responsibilities associated with taking title to drugs and distributing drugs? What incentives are established if CMS pays the model vendors?
- What should be the reasons for excluding entities from serving as a model vendor or terminating a model vendor agreement, as well as appropriate conflict of interest requirements?
- Should the role for the model vendors include entering into value-based payment arrangements (for example, indication-based pricing or outcomes-based agreements)? And if so, should there be requirements around these arrangements?

*B. Model Participants, Compensation and Selected Geographic Areas*

1. Model Participants

IPI Model participants would include all physician practices and hospital outpatient departments (HOPDs) that furnish the model's included drugs in the selected model geographic areas. CMS is considering whether to also include durable medical equipment (DME) suppliers, Ambulatory Surgical Centers (ASCs), or other Part B providers and suppliers that furnish the included drugs. Model participation would be mandatory for the physician practices, HOPDs, and potentially other providers and suppliers, in each of the selected geographic areas.

We intend to provide a more comprehensive list of health care providers included under the model if a proposed rulemaking moves forward.

For purposes of the potential IPI Model, beneficiaries would be included in the model if they are furnished any of the included drugs by a model participant in one of the selected geographic areas. More specifically, the following beneficiary eligibility criteria would be used based on the date that the included drug was furnished—

- The beneficiary is enrolled in Medicare Part B;
- The beneficiary is not enrolled in any group health plan or United Mine Workers of America health plan; [17] and
- Medicare FFS is the primary payer.

Medicare FFS beneficiaries who are not eligible for inclusion in the model would continue to receive drugs that were obtained by their health care provider using the buy and bill approach.

Under the IPI Model, model participants in the selected geographic areas would have to enroll with at least one model vendor and obtain included drugs from a model vendor for administration to included Medicare FFS beneficiaries. Model participants would have to follow model-specific billing instructions to submit informational drug claims and the model add-on payment. To reduce beneficiary impact, model participants would continue to collect beneficiary cost-sharing. We are considering ways to ensure the reconciling of beneficiary cost-sharing that model participants

[17] The United Mine Workers of America Health and Retirement Funds (''The Funds'') is a Medicare Health Care Prepayment Plan (HCPP) and is the Medicare payer for non-facility Part B services. As such, providers bill the Funds for Medicare Part B services. The Funds' payment to the provider includes the Medicare amount plus the Medicare coinsurance and deductible amount, making it unnecessary for the provider to submit claims to two payers.

would be collecting. An administrative approach that deducts the cost-sharing amounts from Medicare payments made for other services to the model participants could be feasible and would be less disruptive for beneficiaries.

2. Model Geographic Areas

The model would require the participation of physician practices and HOPDs (and potentially other providers and suppliers) in selected geographic areas across the U.S. and its territories, which would allow the Innovation Center to gain experience and insight into using an alternative payment methodology for drugs included in the model. We anticipate the selected geographic areas would include 50 percent of Medicare Part B spending on separately payable Part B drugs. The mandatory participation of physician practices and HOPDs (and potentially other health care providers that furnish included drugs) in the selected geographic areas would avoid having expected financial performance in the model influence the physician practice/HOPD's decision to participate or not. It also would ensure we capture the experiences of various types of physician practices and HOPDs in different geographic areas with varying characteristics and historic utilization patterns.

For the IPI Model, we are considering a randomized design with the randomization to intervention and comparison groups occurring at the geographic unit of analysis. There are two main factors that need to be considered when selecting geographies for the model: (1) The most appropriate geographic unit (ZIP code, county, core based statistical area, state, etc.) that reflects how care is delivered in markets, and (2) the geographic scope of the model, or the number of geographic units needed to generate statistically credible findings. Typically, the more geographic units available for random assignment to the model's intervention and comparison groups the better.

However, there is a tradeoff between the size of the geographic unit and the number of units available for assignment. We are considering using CBSAs (Core Based Statistical Areas) as the primary unit of analysis in the model. CMS is further considering whether it would be necessary to use larger geographic units such as aggregations of CBSAs (metropolitan statistical areas or combined statistical areas) to avoid the potential for routine shifts in the site of care to a practice location with a different assignment under the model. Geographic areas located outside CBSAs would not be included in the randomization to intervention or comparison groups. Health care providers outside of the randomized geographies could potentially have the opportunity to opt into the model. However, health care providers that are not part of the randomized treatment and control groups, but that opt into the model, would not be included in the evaluation sample.

3. Potential Drug Add-on Payment

Medicare Part B covers drugs administered by physicians in physician offices and hospital outpatient departments and certain drugs in other settings. In addition to payment for drug administration, Medicare Part B typically pays for separately payable Part B drugs at the average sales price (ASP) of a given drug, plus 6 percent of the ASP as an add-on (with sequestration, the actual payment allowance is ASP + 4.3 percent). This add-on payment can help to cover the costs of drug ordering, storage and handling borne by physicians and hospitals, payments to join group purchasing organizations (GPOs) or other entities with similar purchasing arrangements, as well as a portion of the drug costs themselves, in instances when the drug is acquired at a price more than ASP. However, the drug add-on payment may encourage increased utilization, particularly of higher-cost drugs, since doing so increases revenue for the physician or hospital when the add-on is higher than drug acquisition-related costs.

This section describes our thinking on alternative methods for making the drug add-on payment a set payment amount rather than as a percentage of ASP. We intend to structure the potential IPI model such that physicians and hospitals would be incentivized to seek out lower cost drugs for their beneficiaries, reduce inappropriate utilization, continue to pay for certain distribution costs, continue to bill Medicare for drug administration, albeit following model-specific instructions, and continue to collect beneficiary cost-sharing for included drugs. The goals for the model add-on payments would be to hold health care providers harmless to current revenue to the greatest extent possible; create an incentive to encourage appropriate drug utilization; remove the incentive to prescribe higher-cost drugs; and create incentives to prescribe lower-cost drugs in order to reduce beneficiary cost sharing. We have considered several different structures for the set payment amount.

a. Potential Alternative to the ASP Add-On

CMS would base payment calculations for the alternative compensation on six percent (+6 percent) of the included Part B drugs' ASP, which would represent an increase from the +4.3 percent add-on that currently is paid due to sequestration, and would support appropriate drug utilization under the model structure. That is, in total the alternative compensation for model participants would approximate the expected add-on amount for included drugs in the absence of the model, before sequestration. Because the alternative compensation would not be paid in a manner that is tied directly to the ASP of an administered drug, there would not be an incentive for use of higher cost drugs when an alternative is available. As described in section III.D. of this ANPRM, Medicare payment for the drugs themselves would be to the model vendors; model participants would no longer ''buy and bill'' Medicare for included Part B drugs administered to included beneficiaries. Payment for drug administration services, when applicable, would continue to be separately billed by model participants to Medicare; there would be no change in the payment for drug administration services under the model. Beneficiary cost-sharing would apply to the model-specific alternative compensation payments and for model payments for included drugs.

b. Description of Alternative Add-on Payment Amount

Model participants would be paid a set payment amount per encounter or per month (based on beneficiary panel size) for an administered drug, which would not vary based on the model payment for the drug itself. We are considering whether to set a unique payment amount for each class of drugs, physician specialty, or physician practice (or hospital). That is, there would be a set payment amount per administered drug that would be based on—(1) which class of drugs the administered drug belongs to; (2) the physician's specialty; or (3) the physician's practice. If used, specialties would likely be defined broadly rather than at a subspecialty level (for example, ophthalmology rather than neuro-ophthalmology) given the difficulty of doing this through claims data, although CMS may identify an alternative approach. We would calculate the final payment amount, by drug class, physician specialty, or physician practice, annually based on

the +6 percent of ASP revenue that model participants would have garnered without sequestration in the most recent year of claims data.

Total model payments to a model participant would vary based on utilization under an encounter-based model. To incentivize reduced utilization where appropriate, CMS is considering creating a bonus pool, where model participants would achieve bonus payments for prescribing lower-cost drugs or practicing evidence-based utilization. Importantly, as described in section III.F.3. of this ANPRM, we would monitor drug utilization carefully throughout the model to ensure beneficiary access to drugs is not compromised.

4. Requests for Feedback and Information

We welcome input from stakeholders on the potential approach for defining model participants, selecting geographic areas, and calculating an alternative to the ASP add-on for the IPI Model. Specifically, we would like to receive information on which alternative add-on option is preferable and how the specific payment methodology might be designed. For example:

- The exclusion of certain types of physician practices and/or HOPDs from the model. For example, should we consider excluding small physician practices/HOPDs (for example, those with 3 or fewer physicians) from the model or establish a low-volume threshold that would exclude those physician practices and HOPDs that fall below the threshold from participating in the model? How could CMS analyze an appropriate threshold?
- The inclusion of additional Part B providers and suppliers that furnish and bill for any of the model's included drugs as well as the inclusion of providers that are paid on a cost basis, such as PPS-exempt cancer hospitals, children's hospitals, or critical access hospitals.
- The potential approach to selecting geographic areas for the intervention and comparison groups in the model. Are there particular regions of the country that would need adjustments or exclusions from the model (for example, rural areas)?
- How should we operationalize the model for large provider networks that cover some regions that are included and some that are excluded?
- Should class of drugs, physician specialty, or physician practice determine the payment amount? Are there other characteristics that should determine the alternative add-on payment amount?
- How should a per month alternative add-on payment be determined? How and how often should a beneficiary panel size be determined?
- The potential inclusion of a bonus pool. Should a bonus pool be included in the model? If so, how should the model participant bonus pool be constructed to meet the goals of the model to incentivize the use of lower-cost drugs and clinically appropriate utilization? How could a bonus pool be constructed to best protect and enhance quality under the model? How should CMS handle variable low-volume estimates and missing data values when assessing performance for purposes of a bonus pool?
- The potential phase in of an alternate provider compensation. Should CMS phase in a change from percentage-based add-on payments to set payment amounts, or should set payment amounts be implemented in Year 1 of the potential IPI Model?
- How should CMS implement an administrative process to account for beneficiary cost-sharing for drugs that is collected by model participants?

*C. Included Drugs*

1. Background

The Part B drug benefit includes many types of drugs and encompasses a variety of care settings and payment methodologies. Of the approximately $28 billion per year of FFS Part B drug spending in 2016, about $23.6 billion or 84 percent, is for drugs administered incident to a physician's services. Among the ''incident to'' drugs, over 90 percent of spending is for single source drugs and biologicals (including biosimilars) as defined in section 1847A of the Act.[18] We plan to begin the model with these two broad groups of drugs both because they encompass most of the Part B spending, and as a result of their status as drugs with a single manufacturer, they allow for a more straightforward comparison to an international pricing metric. Examples of included drugs would be cancer drugs and adjunct therapy for cancer and related conditions, biologicals used for the treatment of rheumatoid arthritis and other immune mediated conditions, and drugs used to treat macular degeneration. For purposes of the model, we also would include HCPCS codes that contain only products with a single manufacturer, even if they are multiple source drugs as defined in section 1847A of the Act.

2. Potential Included Drugs

In Years 1 and 2 of the potential IPI Model, we would include single source drugs, biologicals, biosimilars, and multiple source drugs with a single manufacturer that we identify from what we believe are reliable sources of international pricing data, prior to direct data collection, as discussed in section III.D. of this ANPRM. In Years 3, 4 and 5, we would broaden the scope of included drugs to incorporate more of these single source drugs and biologicals as more sources of international pricing data become available, and we are considering further increasing the number of Part B drugs included in the model as discussed later in this section. We would begin with these two broad groups of drugs—single source drugs and biologicals—as they encompass most drugs used by most physician specialties that bill under Part B. At a minimum, we believe that we could begin the model by including most of the HCPCS codes that appear in the recent HHS report;[19] these drugs represent over 50 percent of Part B drug allowed charges in 2017. As we consider including more drugs over time, we would prioritize single source drugs and biologicals. We are also considering including HCPCS codes for drugs and biologicals that are clinically comparable, but not interchangeable, to those initially included in the model, particularly drugs and biologicals (including biosimilars) used incident to a physician's services, for example adding additional biologicals use to treat rheumatoid arthritis and other inflammatory diseases, including biosimilars if they are marketed.

The OPPS packages certain drugs with costs below a certain threshold and for policy reasons. This model would only include drugs that are separately paid under the OPPS, including drugs on pass-through payment status, and for which the drug's HCPCS code is assigned a distinct Ambulatory Payment Classification (APC) group for use when the drug is furnished in a HOPD. The model would include any separately payable drug or biological furnished in an HOPD, including any of the HOPD's off-campus provider-based departments (PBDs), regardless of whether those PBDs are excepted or nonexcepted under section 1833(t)(21)(B)(ii) of the

[18] Office of Enterprise Data and Analytics analysis of CMS, Chronic Conditions Data Warehouse, a database with 100 percent of Medicare enrollment and fee-for-service claims data, available at: *http://ccwdata.org/.*

[19] ''Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures'' accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-spending-medicare-part-b-drugs.*

Act, as added by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74).

For purposes of included drugs, we would remove any HCPCS codes that become inactive if they are not replaced by a successor code, and we would not include HCPCS codes for which a product becomes unavailable. If pricing data were available for other heavily utilized incident to drugs, we would consider adding them to the model. Over the course of the model, we seek to include HCPCS codes that encompass at least 75 percent of allowed charges in Part B. We note that HCPCS codes for products that are used across multiple settings, such as clotting factors or immunoglobulin G, would be included based on overall Part B use, but the model would only include those drugs when they are administered incident to a physician's service.

In addition, we are considering including multiple source drugs and drugs provided in other settings. Specifically, we are considering including multiple source drugs because we are concerned that price increases among generic drugs are also contributing to the rising payments for Part B drugs. Increasing the number of drugs included in the model over time could also be accomplished by setting; however, drug acquisition and billing within Part B settings outside of the physician office and outpatient hospital may not be conducive to a CAP vendor-like approach.

We are also considering the best ways to include newly approved and marketed drugs in the model. We anticipate that international pricing data for some but not all of these drugs would be available. We include a discussion of the potential alternatives for payments for new therapies in section III.D.5. of this ANPRM.

We anticipate that newly effective HCPCS codes could be added to the model on a quarterly or annual basis. Based on experiences with the CAP, we are concerned about issues such as the lag time resulting from the provider having to obtain drugs from regular channels before the drug is available from the vendor, the lead time for the development of vendors' acquisition arrangements, and the potential unavailability of pricing benchmarks for new drugs immediately after a drug is marketed.

Although we are not currently able to estimate exactly what the distribution of drugs over the course of the model may look like, Table 1 presents the percentage of the total allowed Part B charges for 2017 for Part B drugs. Table 1 lists the percentage of the total spending for the following two groups of HCPCS codes: The top 50 drugs by allowed charges in the office and hospital outpatient departments for 2017 and the top 100 such drugs. Spending for biologicals (including biosimilars), single source drugs, multiple source drugs and potentially excluded drugs within each of the three groups is also shown. We believe that this information is a reasonable preliminary estimate of the potential scope of this model and its possible incorporation of additional Part B drugs during the 5-year model duration.

TABLE 1—GROUPS OF DRUGS AS A PERCENTAGE OF TOTAL PART B SPENDING

| Number of drugs | Percentage of total allowed charges | Biologicals: percentage of total allowed charges | Single source drugs: [20] percentage of total allowed charges | Multiple source drugs: percentage of total allowed charges | Potential excluded drugs: percentage of total allowed charges |
|---|---|---|---|---|---|
| Top 50 Drugs | 81 | 65 | 12 | 0 – <1 | 4 |
| Top 100 Drugs | 94 | 73 | 15 | 1 | 6 |

The potential inclusion of a large subset of Part B drugs should not be interpreted to mean model participants would be required to obtain all products that are subject to inclusion from a specific model vendor. We would anticipate several model vendors to be available and that model participants could enroll with one or more model vendors.

3. Potential Excluded Drugs

We are considering excluding the following: drugs that are identified by the FDA to be in short supply (similar to the exclusion from the AMP price substitution policy for drugs in short supply (77 FR 69141)); and drugs paid under miscellaneous or ''not otherwise classified'' (NOC) codes, such as J3490, due to the operational complexity of identifying if drugs paid under the NOC codes are included model drugs. Thus, compounded drugs would be excluded from the model. We also plan to exclude radiopharmaceuticals and ESRD drugs paid under the authority in section 1881 of the Act. Finally, we also would exclude drugs that are packaged under the OPPS when they are furnished by a hospital outpatient department. If these drugs met other criteria, they would be included in the model when furnished by physician offices.

4. Requests for Feedback and Information

We are seeking information on the following:

- Whether the data that CMS uses to determine the inclusion of drugs and biologicals should be limited to claims from the physician's office and hospital outpatient department settings, or whether other settings should be included.
- The drugs to include in the model. Specifically, we are seeking information on how to incorporate multiple source drugs.
- Whether to include Part B drugs in all settings in which they are separately payable or only in certain settings.
- Whether quarterly updates for HCPCS codes included in the model are feasible. Feedback from the perspective of potential model participants and vendors are especially encouraged.
- The best way to include new drugs in the model as they become available.
- Whether to determine inclusion of drugs based on on-label (FDA approved) indications only, or whether CMS should consider on-label and off-label use (if supported by clinical guidelines and/or compendia).

We seek comment as to whether aspects of mandatory participation would require physicians and hospitals to have an agreement with a single vendor or would require physicians and hospitals to obtain all drugs included in the model via a single vendor.

*D. Model Payment Methodology for Vendor Supplied Drugs*

1. Calculating the Model's Medicare Part B Drug Payment

The Medicare payment for separately payable Part B drugs is typically based on ASP of a given Part B drug, plus 6 percent of the ASP as an add-on payment. For the potential IPI Model,

[20] Excluding biologicals.

CMS is considering testing an alternative payment for included drugs based on the international pricing, except where the ASP is lower. CMS would calculate the model payment to model vendors for included drugs through a multi-step process. Given current estimates of the differential between U.S. and international pricing, the model payment may be close to parity with international comparators. Additionally, Manufacturer sales through the IPI model would be included in current ASP reporting.

The potential calculation steps would include the following:

- CMS would calculate an average international price for each Part B drug included in the model based on a standard unit that is comparable to that in the drug HCPCS code.
- CMS would then calculate the ratio of Medicare spending using ASP prices for all Part B Drugs included in the model to estimated spending using international prices for the same number and set of drugs. In order to do this calculation, CMS would multiply Part B volumes by the ASP prices and then by the international prices. The resulting ratio of Medicare spending under ASP versus Medicare spending under the international prices holding volume and mix of drugs constant would represent the International Price Index (IPI).
- CMS would also establish the model Target Price for each drug by multiplying the IPI by a factor that achieves the model goal of more closely aligning Medicare payment with international prices, which would be about a 30 percent reduction in Medicare spending for included Part B drugs over time, and then multiplying that revised index (IPI adjusted for spending reduction) by the international price for each included drug. CMS would calibrate the revised index to account for any drugs with ASP below the Target Price. The percentage reduction between ASP and Target Price would vary for each drug. We would monitor price changes and recalibrate as needed.
- CMS would phase-in the Target Price over the 5 years of the model, as a blend of ASP and the Target Price. For each calculation, if ASP is lower than the Target Price for an included drug, the model would set the payment amount to ASP for that drug.

The potential phase-in would use the following blend of ASP and Target Price:

| Year | Percentage of ASP and target price |
|---|---|
| Year 1 ..... | 80 percent ASP and 20 percent Target Price. |
| Year 2 ..... | 60 percent ASP and 40 percent Target Price. |
| Year 3 ..... | 40 percent ASP and 60 percent Target Price. |
| Year 4 ..... | 20 percent ASP and 80 percent Target Price. |
| Year 5 ..... | 100 percent Target Price. |

- As with current Part B drug payments, we would plan to update the model payment amount for each drug periodically based on new ASP and international pricing data.

2. Data Sources on International Drug Sales

CMS is considering including collection of international drug sales data for purposes of the IPI Model. In the interim, before these data could be available, CMS is considering relying on existing data sources for calculating the model payment to model vendors for included drugs.

a. Existing Data Sources

CMS has evaluated several existing data sources to determine the availability of international drug price information. Based on our review, we believe there are appropriate sources that could be used for purposes of the potential IPI Model. These data sets include those provided by private companies or data obtained through review of publicly filed materials by manufacturers in other countries. Examples may include IQVIA's MIDAS dataset, the dataset used in the recent HHS analysis.[21] Alternatively, CMS can try to construct price comparisons from public sources from each country. One example of a public source is the UK's Drug Tariff, which lists the National Health Service (NHS) reimbursement rates for prescription drugs.[22] We believe that existing data sources may include all the information necessary to calculate the IPI and Target Prices. We are interested in better understanding the extent to which existing data sources for international sales completely capture drug information in every international market that we are considering for inclusion in our payment methodology and how private market drug sales are included in countries that provide drugs through public insurance.

b. CMS Data Collection

We are considering including a data collection system for manufacturers to report to CMS their international drug sales data to support the calculation of the IPI and the Target Price for each drug. We acknowledge that manufacturers have numerous and varying arrangements in other countries as well as in the U.S., so we are considering how we would determine the definition of manufacturer to ensure that U.S. manufacturers would robustly report this information to CMS. Under the Medicaid Drug Rebate Program in section 1927 of the Act, manufacturers are required to provide information to CMS on a quarterly basis to support the ASP calculations (as well as to support calculations for WAC and AMP[23]) for Part B drugs. Using the same framework, for the purposes of the potential IPI Model, we could require manufacturers to provide international drug sales data for prices and units sold.

We envision that we would require quarterly reporting on the international sales information and CMS would provide reporting instructions. The instructions would include information such as instructions for the unit level at which the manufacturer would report the sales information, which countries to include and how to account for the exchange rate, and use of reasonable assumptions. We anticipate that the units of measure for the international drug sales data would be the same as the units in a corresponding drug product's HCPCS code. For example, products reported in milligrams of drug in the U.S. would be reported in milligrams, and products reported in international units of biological activity would be reported in the same units of corresponding biological activity.

We acknowledge that this potential approach could create situations where very large numbers of units would be reported, and we seek information on alternative units of measure to consider. We recognize that it would take some time to establish the infrastructure and reporting instructions to collect and validate international sales information directly from manufacturers for purposes of a model. In light of this, we are considering whether existing data sources could be used to establish the IPI and Target Price in the short term and transition to using manufacturer reported data when available. We seek comment on the potential use of

[21] "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures" accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-spending-medicare-part-b-drugs.*

[22] See *https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff.*

[23] WAC means wholesaler acquisition cost and AMP means average manufacturer price.

existing data sources and new data sources to establish the IPI and the Target Price.

3. Frequency of Data and Model Payment Updates

We are considering examining the IPI and model payments on a quarterly basis, on the same schedule and using the same quarterly sales period duration as ASP data. We believe that we could use quarterly updates of existing data sources in the short term while we set up the infrastructure to collect and validate international drug sales information from the manufacturers on a quarterly basis (the data would be reported to CMS within 30 days of the close of the quarter). We seek comment on whether to examine the international pricing data, and recalculate the IPI and Target Prices on a quarterly, annual or other basis. We also seek feedback on the mechanism for reporting of international sales, and on any additional requirements that would be needed to ensure a feasible process to collect valid international sales information for the countries that would be included in the IPI, as discussed in the following section of this ANPRM. We also seek comment on ways to ensure confidentiality of reporting of international drug pricing to CMS.

4. Potential Included Countries

We are considering using pricing data from the following countries: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom.

We are considering including these countries as they are either economies comparable to the United States or they are included in Germany's market basket for reference pricing for their drug prices, and existing data sources contain pricing information for these countries. Some of the countries above have far lower per-capita incomes than the U.S. However, these countries were not consistently the lowest-priced countries according to the HHS analysis.[24] We seek comment on the countries included in our analysis to establish the IPI, Target Price, and model payment amounts.

5. Establishing Model Payments for New Drugs Entering the Market

For newly approved and marketed Part B drugs that would be included in the model, there could be some time lag or other issues associated with capturing international sales information. In the absence of international pricing data, CMS could still calculate a model payment amount by applying a standard factor. CMS could, for example, assume the same ratio for the new drug as the IPI, which would be the average volume-weighted payment amount across all Part B drugs included in the model. We seek comment on options for calculating the model payment for new drugs that may not yet have international sales.

6. Requests for Feedback and Information

We welcome input from stakeholders on the potential approach for establishing model payments for included drugs based on international pricing. For example:

- What sources of international pricing data capture drug information for the international markets that should be included in our payment methodology?
- Are there particular data sources to establish payment amounts based on international pricing that would best support this effort?
- How should private market drug sales included in countries that provide drugs through public insurance be included? How should CMS protect manufacturer reported international pricing information?
- What is the appropriate frequency for updating the international pricing information that we use in calculating the Part B payment under the model?
- How should manufacturers report international pricing information? Are there specific issues with data reporting processes that stakeholders would like the agency to consider, especially mechanisms that could reduce burden?
- How should we define manufacturer to ensure that all relevant entities that sell single source drug products, biologics, biosimilars and, if applicable, multiple source drugs report under the model?
- Are there areas of concern in data collection and reporting that could lead to inaccurate price calculations?
- Which countries should be included in our international price index calculations? Should the countries vary? What characteristics should CMS consider to analyze these countries?
- Are there specific considerations in the comparison of international and ASP prices that CMS should address?
- How should CMS standardize data collection and reporting? What should be the target reduction to ASP payment (that is, Target Price), and what should be the schedule for phasing down to the target savings amount?
- How would such a change in payment policy, as described in this section, affect incentives in the market? How could using international reference pricing affect innovation incentives in the biopharmaceutical market?

*E. Potential Foreign Market Considerations*

Using international sales data in the potential IPI Model could raise considerations for drug prices, drug availability, and sales data in foreign markets. For example, manufacturers may seek to raise prices or limit foreign sales. However, existing, multiyear pricing relationships in foreign markets may minimize this response. There are also potential model implications in considering manufacturers' responses in foreign markets. For example, there may be a decrease or lack of international sales to serve as inputs to the model's IPI calculation, if manufacturers withdraw or do not launch included drugs in foreign markets. Similarly, manufacturers may also adjust their product launch strategies within the U.S.

Requests for feedback and information:

- CMS welcomes input from stakeholders on the potential considerations related to foreign markets and the potential model payment approach that would rely on international sales data. For example the following:
- What foreign market considerations should CMS consider in developing the potential IPI Model?
- How should CMS monitor for changes in foreign markets that could impact the IPI Model?
- What are ways to address changes in foreign sales that could impact model payment calculations?

*F. Beneficiary Impact and Model Monitoring*

In addition to existing beneficiary protections, we would plan to actively monitor the IPI Model test to ensure it is operating effectively and meeting the needs of beneficiaries, health care providers, and the Medicare program.

1. Impact on Beneficiary Cost-Sharing

We would expect beneficiary cost-sharing for included drugs under the potential IPI Model would either be the same or lower than the non-model cost-sharing. Medicare payment policy for beneficiary cost-sharing would remain the same but since the IPI Model should reduce Medicare payment for some Part B drugs, the 20 percent beneficiary

[24] "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures" accessed via *https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-spending-medicare-part-b-drugs.*

coinsurance would be similarly proportionately reduced. For those beneficiaries dually eligible for Medicare and Medicaid, the coinsurance paid for by the beneficiary or state would similarly be reduced. If the Part B payment remains unchanged under the IPI Model, for example, for those drugs where Medicare payment is similar to international prices, cost-sharing would remain the same.

To minimize impact on beneficiaries, their health care provider would continue to collect cost-sharing for included drugs.

2. Medicare Ombudsman

We plan to coordinate with the Medicare Beneficiary Ombudsman to ensure that any Model-related beneficiary complaints, grievances, or requests for information submitted would be responded to in a timely manner.

3. Monitoring

Consistent with other Innovation Center Models, we would also implement a monitoring program for the IPI Model to ensure the model is meeting the needs of Medicare beneficiaries, health care providers and the Medicare program. These monitoring activities would enable CMS to access timely information about the effects of the Model on beneficiaries, providers, suppliers, and on the Medicare program and to facilitate real time identification and response to potential issues. We envision using Medicare claims and other available program data to analyze and monitor the Model's implementation, including actively looking at real-time data to identify potential impacts on beneficiaries, health care providers, model vendors, and the Medicare program. We would use these findings to inform Model oversight and the potential need for action to address findings.

As an example, CMS may conduct real-time analyses of claims and administrative data, such as monthly updates and historic comparisons of trends, including ensuring appropriate drug utilization and program spending, as well as changes in site-of-service delivery, mortality, hospital admissions, and other indicators present in claims and administrative data to identify any potential issues related to access and utilization. CMS would also consider how to best understand beneficiary experience in the model. We would consider surveys but would also be interested in other potential strategies to include beneficiary experience in our monitoring activities.

We are inviting public feedback on the appropriate beneficiary outcomes to monitor and how to monitor and measure such outcomes, as well as patient experience, in a way that minimizes burden on included health care providers and beneficiaries.

*G. Interaction With Other Models*

In designing each Innovation Center model, CMS considers potential overlap between a new model and other ongoing and potential models and programs. Based on the type of overlap, such as provider or beneficiary, operating rules are established for whether or not providers and beneficiaries can be part of both models as well as how to handle overlap when it is allowed to occur. These policies help to ensure that the evaluation of model impact is not compromised by issues of model overlap and that the calculation of Medicare savings is not overestimated due to double counting of beneficiaries and dollars across different models. In this vein, CMS has begun to review which models would have significant overlap with the potential IPI Model. One example is the Oncology Care Model (OCM) which runs through mid-2021. The OCM would require new policies that address model overlap due to the potential inclusion of some of OCM's initiating cancer therapies in the IPI Model and the probable overlap of some geographic areas with OCM practices included in the IPI Model. The IPI Model would potentially overlap with other Innovation Center models that operate in the same geographic areas and include Part B drug spending in the calculation of model payments, incentive payments or shared savings, and the Medicare Shared Savings Programs. We plan to carefully explore these potential overlaps and consider ways address overlap issues as we further develop the IPI Model.

H. Interaction With Other Federal Programs

With respect to single source or innovator multiple source drugs (which Medicaid recognizes to include biologicals and biosimilars), the term ''Medicaid Best Price'' is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity or governmental entity within the U.S. with certain exclusions. We seek comment on how to avoid unintended consequences on the interaction of the IPI Model with other federal programs.

1. Impact on ''Best Price''

Since the model payments to model vendors for drugs is a Medicare payment and it is not a ''price available from the manufacturer,'' the model payment amounts would not be included in the manufacturer's determination of best price. However, since the model payment amounts would drive manufacturer drug prices down, the model may impact a manufacturer's best price. In order for model vendors to purchase included drugs in the U.S. at prices that would not lead to financial loss, the prices available from the manufacturer would need to be competitive with the model payments. Therefore, such manufacturer sales to the model vendors could potentially lower best price and potentially increase Medicaid rebates. Medicaid programs could benefit.

Specifically, if the manufacturer lowers prices available to a model vendor at or below the model payment rate, such prices would be considered in the manufacturer's determination of best price and may reset the manufacturer's best price. This is particularly possible because the model payment amount includes the impact of sales outside of the U.S., which are typically lower than prices in the U.S., while a manufacturer's best price represents prices available only to purchasers in the U.S. We seek public comments on how manufacturers would respond to these factors as they relate to model vendors and Medicaid drug rebates.

2. Impact on Average Manufacturer Price (AMP)

Similarly, the model payment amounts to model vendors would not be part of the AMP determination. AMP is defined at section 1927(k)(1) of the Act. Generally, AMP is determined based on the average price paid to the manufacturer for a drug in the U.S. by wholesalers and retail community pharmacies with certain exclusions. The AMP for a Part B drug will likely be determined using the AMP computation for 5i drugs,[25] which would include sales that are not generally dispensed through retail community pharmacies (see 42 CFR 447.504(d)), such as sales to physicians, pharmacy benefit managers (PBMs) and hospitals. In this case, it is likely the manufacturer's sale to a model vendor (or price paid) that would be included in the AMP or 5i AMP and due to the downstream effects of the model payment approach, may lower AMP. If the AMP is lower, it may result in potentially lowering the Medicaid drug

[25] Inhalation, infusion, instilled, implanted or injectable drugs.

rebate paid to states (the rebate, in part, is based on a percentage of AMP), although the rebate would also be affected because ''best price'' may be lower as described above.

We continue to consider how the model may impact the Medicaid program. Authority for implementing innovative payment and quality models under 1115A of the Act does not completely include Title XIX waiver authority, and thus, such waiver authority does not extend to the Medicaid Drug Rebate Program, which is authorized under Title XIX at section 1927 of the Act. We welcome public feedback, including from State Medicaid programs, on this issue.

3. Interaction With 340B Program

The Health Resources and Services Administration (HRSA) administers the 340B Drug Pricing Program that allows certain hospitals and other health care providers (''covered entities'') to obtain discounted prices on ''covered outpatient drugs'' (as defined at 1927(k)(2) of the Act) from drug manufacturers. HRSA calculates a 340B ceiling price for each covered outpatient drug, which represents the maximum price a manufacturer can charge a covered entity for the drug. Several types of hospitals as well as clinics that receive certain federal grants from the HHS may enroll in the 340B program as covered entities. Such entities located in the selected model geographic areas would be included in the IPI Model and would be supplied included drugs for included beneficiaries through a model vendor.

4. Impact on 340B Ceiling Price

Covered entities that enroll in the 340B Program can purchase drugs at no more than a ''ceiling price'', which are calculated based on a drug's AMP net the Medicaid unit rebate amount. Since the Medicaid unit rebate amount is based partly on AMP minus best price, to the extent the potential model affects a drug's AMP and best price, the 340B prices would be affected.

*I. Quality Measures*

Congress created the Innovation Center for the purpose of testing innovative payment and service delivery models that are expected to reduce program expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. In the IPI Model, we are considering collecting quality measures to help us better understand the impact of this model on beneficiary access and quality of care. We intend to identify quality measures to be collected as part of this model that reflect national priorities for quality improvement and patient-centered care consistent with the measures described in section 1890(b)(7)(B) of the Act, to the extent feasible. To this end, we are interested in several categories of measures, specifically: patient experience measures, medication management measures, medication adherence, and measures related to access and utilization.

We are sensitive to concerns regarding adding administrative burden to model participants. Some models (for example, the Bundled Payments for Care Improvement Advanced Model) are currently structured to include quality measures that are calculated directly by CMS or collected during the evaluation and do not require the submission of additional data by providers and suppliers. We are considering following this approach, to the extent feasible, and to assess the quality of care for purposes of real-time monitoring of utilization, hospitalization, mortality, shifts in site-of-service and other important indicators of patient access and outcomes, without requiring providers or suppliers to report additional data.

We seek information on the categories and types of quality measures CMS can incorporate in the model that are targeted and judicious, while still capturing key indicators of patient experience, access, and medication management. We welcome recommendations for specific measures.

*J. Legal Considerations and Potential Waivers of Medicare Program Requirements for Purposes of Testing the Model*

We plan to test the potential IPI Model under the authority of section 1115A of the Act and to waive certain Medicare program requirements as necessary solely for purposes of testing the potential model. Under section 1115A(d)(1) of the Act, the Secretary of Health and Human Services may waive the requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 of the Act (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act.

We plan to waive requirements of the following provisions as may be necessary solely for purposes of testing the Model. The purpose of this flexibility would be to allow Medicare to test approaches described in the ''Model Payment Methodology'' section, with the goal of reducing Medicare expenditures while improving or maintaining the quality of beneficiaries' care as we implement and test this potential model.

- Section 1833(t) of the Act and 42 CFR 419.64 related to Medicare payment amounts for drugs and biologicals under the OPPS as necessary to permit testing of a modified payment amount for included drugs using the pricing approaches described in this section;
- Section 1847A of the Act and 42 CFR 414.904 and 414.802 related to use of ASP+6 percent and WAC as necessary to permit testing of a modified payment using the pricing approaches described in this paper.
- Section 1847B of the Act and 42 CFR 414.906 through 414.920 related to the Medicare Part B Drug Competitive Acquisition Program (CAP) requirements as necessary to permit testing using a CAP-like approach for the acquisition of included therapies through vendor-administered payment arrangements.
- Other requirements under title XVIII of the Act as may be necessary solely to test separate payment for included therapies furnished to included beneficiaries by participant health care providers not paid under the outpatient prospective payment system or section 1847A of the Act.

*K. Model Termination*

CMS may terminate the potential IPI Model for reasons including, but not limited to, the following: CMS determines that it no longer has the funds to support the Model; or CMS terminates the Model in accordance with section 1115A(b)(3)(B) of the Act.

*L. Model Evaluation*

Models operated under section 1115A of the Act are required to have an evaluation that must include an analysis of the quality of care furnished under the model and the changes in spending by reason of the model. The evaluation of the model would help inform the Secretary and policymakers whether this model, as designed, reduces program expenditures while maintaining or improving the quality of care furnished to Medicare beneficiaries.

Whenever feasible, a comparison group composed of entities similar to the model participants but not exposed to the model is used to determine the model impact. In this particular potential model, intervention and comparison groups would be determined through a random selection or assignment process. A randomized design helps minimize the impact of unmeasurable factors that may

contribute to providers' and suppliers' likelihood to participate in the model. Our inability to control for these unobserved differences could lead to biased or incorrect estimates in the evaluation of the model's impact on quality of care and spending. We note that to the extent that model sales affect the overall ASP calculation, we may experience evaluation challenges with the comparison group geographic areas not selected for the model.

We seek input on the evaluation approach to examine the IPI Model's impact on Medicare spending and quality of care including potential alternatives.

*M. Potential Impacts of Implementing the IPI Model*

1. Financial Impacts

This section outlines the potential financial impact of implementing the potential IPI Model on federal Medicare and Medicaid spending. There are many uncertainties around estimating the financial effects of this model. In addition to the various policy parameters that are either currently unspecified or subject to change throughout the policy development process, the expected change in beneficiary, provider, vendor, and manufacturer behavior would significantly affect the financial impact of the model. The current analysis of this model reflects many generalized assumptions that are likely to change pending further policy development and additional analysis. As such, the estimates shown below should be considered an approximate measure of the potential savings of the potential model, and subsequent analyses would likely be materially different from those shown below as additional information becomes available.

a. Medicare and Dual Medicare-Medicaid Impacts

The following table presents the potential financial impact of the model. For 2020–25, federal Medicare spending is estimated to be reduced by $16.3 billion and Medicaid spending for Medicare-Medicaid dual beneficiaries is expected to be reduced by $1.6 billion, of which $0.9 billion is reduced federal spending and $0.7 billion is reduced State spending.

**TABLE 2: ILLUSTRATION OF POTENTIAL FINANCIAL IMPACT (IN BILLIONS) [PHOTO]**

| | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2020-2025 |
|---|---|---|---|---|---|---|---|
| Part B Drug Baseline | 31.2 | 34.2 | 37.4 | 40.8 | 44.3 | 48.2 | |
| *Drug price* | | | | | | | |
| FFS impact | -0.3 | -0.9 | -1.9 | -3.1 | -5.3 | -2.3 | -13.8 |
| Gross impact (FFS+MA) | -0.6 | -1.5 | -3.2 | -5.3 | -9.2 | -4.1 | -23.9 |
| Net of premium offset | -0.4 | -1.1 | -2.4 | -4.0 | -6.9 | -3.1 | -17.9 |
| Medicaid impact | 0.0 | -0.1 | -0.2 | -0.4 | -0.7 | -0.3 | -1.8 |
| Federal | 0.0 | -0.1 | -0.1 | -0.2 | -0.4 | -0.2 | -1.0 |
| State | 0.0 | 0.0 | -0.1 | -0.2 | -0.3 | -0.1 | -0.8 |
| *Physician add-on payment* | | | | | | | |
| FFS impact | 0.1 | 0.2 | 0.2 | 0.3 | 0.3 | 0.1 | 1.3 |
| Gross impact (FFS+MA) | 0.2 | 0.3 | 0.4 | 0.5 | 0.6 | 0.2 | 2.2 |
| Net of premium offset | 0.2 | 0.2 | 0.3 | 0.4 | 0.4 | 0.1 | 1.6 |
| Medicaid impact | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 |
| Federal | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 |
| State | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 |
| *Total impact* | | | | | | | |
| FFS impact | -0.2 | -0.7 | -1.6 | -2.8 | -4.9 | -2.2 | -12.5 |
| Gross impact (FFS+MA) | -0.4 | -1.2 | -2.8 | -4.8 | -8.6 | -3.9 | -21.7 |
| Net of premium offset | -0.3 | -0.9 | -2.1 | -3.6 | -6.4 | -2.9 | -16.3 |
| Medicaid impact | 0.0 | -0.1 | -0.2 | -0.4 | -0.6 | -0.3 | -1.6 |
| Federal | 0.0 | -0.1 | -0.1 | -0.2 | -0.4 | -0.2 | -0.9 |
| State | 0.0 | 0.0 | -0.1 | -0.2 | -0.3 | -0.1 | -0.7 |

Notes: Amounts are presented by calendar year and are based on the date the service is incurred.
The model is assumed to run from April 1, 2020 through March 31, 2025.
The Part B baseline includes drugs provided by 340B hospitals

Note the following:

- No changes in utilization are assumed in this analysis.
- Medicare Advantage spending would be reduced proportionately to the reduction in FFS spending.
- Included drugs would represent 61 percent of Part B allowed drug spending in years 1 and 2, 81 percent of Part B allowed drug spending in years 3 and 4, and 94 percent of allowed drug spending in year 5.
- The Medicaid impact represents the portion of Medicare cost-sharing that is paid on behalf of dual beneficiaries. It is estimated based on the change in Medicare cost-sharing and current dual beneficiary enrollment. No assumptions are made for State price limitations that would limit the beneficiary cost-sharing paid for by Medicaid.
- Effects on private market cannot be estimated at this time and are not reflected in this analysis.

b. Medicaid Impacts

Based on a review of the Part B drugs that constituted the majority of Part B drug spending in 2017, as well as the top reported Medicaid drugs that were also covered by Part B, the affected drugs reimbursed by Medicaid spending totaled at least $4 billion in 2017, or an estimated 6 percent of gross Medicaid drug spending. The model may impact AMP, ASP, best price, and 340B pricing for these affected drugs, reducing both reimbursements as well as rebates. CMS would seek comment on whether we should exempt prices offered under the model from AMP and Best Price calculations.

2. Potential Impacts on Medicare Providers and Suppliers Participating in the Potential IPI Model

The potential IPI Model would affect a significant number of health care providers that would furnish included drugs to included Medicare beneficiaries. The effect of the model on individual hospitals, physicians, practitioners, and other providers and suppliers would depend on individual practice patterns and the drugs that would be selected for inclusion.

## IV. Collection of Information Requirements

This ANPRM is a general solicitation of comments on several options pertaining to the potential IPI Model and thereby not subject to OMB review as stated in the implementing regulations of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*) at 5 CFR 1320.3(h)(4). Should the outcome of the ANPRM result in any information collection requirements or burden that are not covered under the provisions in section 1115A(d)(3) of the Act [26] or otherwise covered under a PRA exemption, a detailed discussion of the requirements and burden will be submitted to OMB for approval. In accordance with the implementing regulations of the PRA at 5 CFR 1320.11, interested parties will also be provided an opportunity to comment on such information through subsequent proposed and final rulemaking documents.

## V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will review all comments we receive by the date and time specified in the **DATES** section of this preamble, as we continue to consider the model presented in this ANPRM.

In accordance with the provisions of Executive Order 12866, this ANPRM was reviewed by the Office of Management and Budget.

Dated: October 25, 2018.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: October 25, 2018.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2018–23688 Filed 10–25–18; 4:15 pm]

BILLING CODE 4120–01–P

[26] As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, U.S.C., shall not apply to the testing and evaluation of models under section 1115A of the Act

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## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

**[Docket No. FWS–R1–ES–2007–0024; FXES11130900000C6–189–FF09E42000]**

**RIN 1018–AU96**

## Endangered and Threatened Wildlife and Plants; Removing the Hawaiian Hawk From the Federal List of Endangered and Threatened Wildlife

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule; document availability and reopening of comment period.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the public comment period on the August 6, 2008, proposed rule to remove the Hawaiian hawk or io (*Buteo solitarius*) from the List of Endangered and Threatened Wildlife (List) under the Endangered Species Act of 1973, as amended (Act). Comments submitted during the 2008 comment period, 2009 reopened comment periods, and 2014 reopened comment period do not need to be resubmitted, and will be fully considered in preparation of our final rule. We are reopening the comment period once more to present information we have received since 2014 that is relevant to our consideration of the status of the Hawaiian hawk. We encourage those who may have commented previously to submit additional comments, if appropriate, in light of this new information. In addition, we are also seeking input on considerations for post-delisting monitoring of the Hawaiian hawk. Our goal is to respond to comments and come to a final determination on the status of the Hawaiian hawk in the form of a final rule by the end of 2018.

**DATES:** The comment period for the proposed rule published August 6, 2008, at 73 FR 45680 is reopened. To ensure that we are able to consider your comments and information, they must be received or postmarked no later than November 29, 2018. Please note that, if you are using the Federal eRulemaking Portal (see **ADDRESSES**, below), the deadline for submitting an electronic comment is 11:59 p.m. Eastern Time on this date. We may not be able to address or incorporate information that we receive after the above requested date.

**ADDRESSES:** You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov*. In the Search box, enter FWS–R1–ES–2007–0024, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment Now!'' Please ensure that you have found the correct rulemaking before submitting your comment.

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R1–ES–2007–0024, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3808.

We request that you send comments only by the methods described above. We will post all comments on *http://*

*www.regulations.gov*. This generally means that we will post any personal information you provide us (see Public Comments, below, for more information).

*Document availability:* The 2008 proposed delisting of the Hawaiian hawk, comments received during all the open comment periods, and the draft post-delisting monitoring plan (draft PDM plan) are available on *http://www.regulations.gov*. In addition, the supporting file for this proposed rule will be available for public inspection, by appointment, during normal business hours, at the Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard, Room 3–122, Honolulu, HI 96850; telephone 808–792–9400.

**FOR FURTHER INFORMATION CONTACT:** Mary Abrams, Field Supervisor, telephone: 808–792–9400. Direct all questions or requests for additional information to: U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard, Room 3–122, Honolulu, HI 96850. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

**SUPPLEMENTARY INFORMATION:**

## Species Information and Previous Federal Actions

On August 6, 2008, we published a proposed rule to delist the Hawaiian hawk (io) (73 FR 45680). Please refer to that proposed rule and the recovery plan (which can be found at: *http://ecos.fws.gov/docs/recovery_plan/840509.pdf*) for information about the Hawaiian hawk, its status, its threats, and a summary of factors affecting the species. Please refer to our February 12, 2014, notice to reopen the comment period for a summary of all previous Federal actions (79 FR 8413).

Since the 2008 proposed rule, we opened three additional comment periods. During these comment periods, we received new or updated information on projected urban growth rates and conversion of agriculture lands to unsuitable Hawaiian hawk habitat; and potential effects of climate change (*e.g.,* increased frequency or prolonged drought), rapid ohia death (ROD), and invasive plants (*e.g., Psidium cattleianum* (strawberry guava)) on Hawaiian hawk habitat. The majority of relevant information that has become available since our 2008 proposal to delist the Hawaiian hawk comes from over 173 public comments, 4 independent peer reviews, comments from the State of Hawaii and county agencies and the National Park Service, recent publications, and further evaluation of existing information. Information pertaining to the status of the species that has become available to us since the 2014 notice is provided below.

## New Information

Since the 2014 notice to reopen the comment period, we received updated information on trends in human population growth, urbanization, and land subdivision; biocontrol efforts for strawberry guava; impacts from ROD and climate change; and recent volcanic activity. We have also received some preliminary data from an in-house population viability assessment (PVA) (Vorsino and Nelson 2016, unpublished data). In addition, we are not aware of any changes in the status of the biofuel crop production or processing facility on the island since 2014 that would impact the status of the Hawaiian hawk.

Although trends in urban and exurban growth, and land subdivision show upward movement, the rate of growth has slowed. Population growth for Hawaii County between 2010 and 2017 was 1.1 percent annually, 0.5 percent lower than the 1.6 projection in 2012 (Hawaii Department of Business, Economic Development and Tourism (HDBEDT) 2018, in litt.). The number of new homes built per year has also decreased (County of Hawaii 2015, p. 146). Most urban and exurban growth is occurring in or adjacent to already developed areas (County of Hawaii 2015, p. 77, 150). We expect residential and exurban construction for Hawaii County to continue at a similar pace in the foreseeable future as indicated by expected human population growth for Hawaii County and home construction for the island of Hawaii for the last three decades (County of Hawaii 2010, tables 16.1–16.13; County of Hawaii 2015, pp. 144–146, 149–150; HDBEDT 2018, in litt.). Urban and exurban growth and subdivisions in Puna may slow even more due to the recent volcanic activity of Kilauea, which began in May 2018. The north Kona region has one of the highest urban and exurban growth rates on the island (County of Hawaii 2015, p. 11), as well as one of the highest densities of Hawaiian hawk (Gorresen *et al.* 2008, p. 42).

Since the successful deployment in 2012 of a biocontrol agent for strawberry guava (the Brazilian scale insect, *Tectococcus ovatus*) during field trials, the State of Hawaii and other partners have been working to establish *Tectococcus* on strawberry guava invaded forests throughout the islands (Chaney and Johnson in HCC 2013, p. 74; Chaney and Johnson 2018, in litt.; Kerr 2018, pers. comm.). Currently, the insect is established and reproducing on strawberry guava at multiple forest sites on five islands (Hawaii, Kauai, Lanai, Maui, and Oahu) (Chaney and Johnson 2018, in litt.). Under favorable conditions, *Tectococcus* populations have increased rapidly and spread 33 to 262 feet (10 to 80 meters) in a period of several months (Chaney and Johnson 2018, in litt.). The scale typically weakens the trees through its feeding, reducing the ability of the tree to fruit and set seed, thereby limiting its spread (U.S. Forest Service 2016, in litt.). The scale is not expected to kill already established trees (Hawaii Department of Agriculture 2011, in litt.). It is too early to know what effect this may have on guava tree vigor and rate of spread; however, infestations of *Tectococcus* are expected to spread gradually on the target plant, reaching damaging levels within a few years at each release site (Kerr 2018, pers. comm.). The Forest Service will continue to provide technical assistance and monitor the impacts of biocontrol. It is expected that a noticeable decrease in the spread of strawberry guava will be observed over a period of years (Kerr 2018, pers. comm.).

Hawaiian hawks frequently nest in native ohia (*Metrosideros polymorpha*), an evergreen tree in the myrtle family. In 2013, landowners in lower Puna District noticed an increased rate of what was thought to be ohia dieback (Friday and Friday 2013, entire), a phenomenon where trees affected show progressive dieback accompanied by browning of the leaves, reduction in leaf size, and death of all or part of the crown (Hodges *et al.* 1986, p. ii.). Although ohia dieback may have been the culprit of some of the observed dieback leading up to the 2013 report (Friday and Friday 2013, entire), we now believe that at least some of this dieback was actually caused by ROD. In addition to the other information we request in Public Comments, below, we request new information on ROD and its potential or actual impact on Hawaiian hawk.

Although new information shows negative habitat trends due to urbanization, nonnative plant species invasion, and ROD, efforts at habitat restoration that benefit the Hawaiian hawk are being implemented and are achieving success.

Both State and private foresters report an increase in forest areas on the island of Hawaii, particularly in native forest areas (Koch and Walter 2018, in litt.). Starting at the turn of the century, several large landowners (private, Federal, and State) have ended their

pastoral leases and are steadily promoting natural regeneration to take the place of old pastures (Koch and Walter 2018, in litt.). While we know this conversion is occurring, we do not have an exact number of acreage. Additionally, when economically feasible, many nonnative timber plantations in the State have begun planting native timber species, most often koa (*Acacia koa*), post-harvest (Koch and Walter 2018, in litt; Walter 2018, pers. comm.). We do not have an exact number regarding this conversion, but we know it is ongoing. The suitability of koa plantations for Hawaiian hawk foraging and nesting has not been studied, and hawk use of these areas may be variable, because koa plantations likely differ in their suitability as hawk habitat depending upon age of koa stands, stand density, and overstory characteristics related to harvest methods used. A new forest planting project between Waimea and Ahualoa will convert 565 acres (ac) (229 hectares (ha)) of grassland to koa and koa-ohia forests in the next 10 years (Koch and Walter 2018, in litt.).

There has also been a marked increase in protection of native forests-which combined with an increase in forest areas results in increased protection for the Hawaiian hawk by protecting potential nesting, breeding, and hunting habitat. Several large conservation efforts across the island are being implemented by Federal, State, and private landowners, often in collaborative efforts.

Fencing and ungulate removal at Puu Waawaa Forest Bird Sanctuary and parts of the State's Natural Area Reserve System contribute to Hawaiian hawk habitat restoration (Gorresen *et al.* 2008, p. 26) because it helps control the spread of invasive plants such as strawberry guava as well as contributes toward the natural regeneration of native or native exotic mixed habitat which in turn provides potential nesting, breeding, and foraging opportunities for the hawk. The Kohala Watershed Partnership, Mauna Kea Watershed Alliance, and TMA, which collectively encompass approximately 1,688,300 ac (675,137 ha) on Hawaii, have been fencing, outplanting native plants, and removing nonnative species since 2003, 2008, and 2009, respectively (*http://hawp.org/*). Currently, these entities conduct restoration actions on over 80,000 ac (32,374 ha) of forest area on Hawaii (TMA 2007, p. 41; Hawaii Department of Land and Natural Resources (DLNR) 2011, p. 16; State of Hawaii 2012, pp. 43–44; State of Hawaii 2017, pp. 1–6; Cole 2018, in litt.; Dwight 2018, in litt.; Perry 2018, in litt.; *http://hawp.org/*). This value is likely an underestimate as there are so many partners conducting restoration activities that it is difficult to know exactly how many acres are being managed by each entity. Additional activities implemented by the three watershed partnerships on the island of Hawaii include programs that implement fencing inspections and necessary replacements, native species surveys, greenhouse and plant propagation, prevention of the spread of ROD, and outreach (TMA 2007, p. 41; DLNR 2011, p. 16; State of Hawaii 2012, pp. 43–44; State of Hawaii 2017, pp. 1–6; Cole 2018, in litt.; Dwight 2018, in litt.; Perry 2018, in litt.; *http://hawp.org/*).

In 2016, the Governor of Hawaii initiated the Sustainable Hawaii Initiative (Initiative) in response to the 2016 World Conservation Congress Legacy Commitment to protect 30 percent (253,000 ac (102,385 ha)) of Hawaii's highest priority watershed forests by 2030 (*http://governor.hawaii.gov/sustainable-hawaii-initiative/*). Through this Initiative, the amount of priority watershed areas under high level of protection has increased from 10 to approximately 15 percent (*http://governor.hawaii.gov/sustainable-hawaii-initiative/;* State of Hawaii 2017, in litt.; *https://dashboard.hawaii.gov/en/stat/goals/5xhf-begg/4s33-f5iv/wtjm-96jt*). The Initiative has outplanted 20,000 native trees, and increased invasive plant control by 130,000 ac (52,609 ha) (State of Hawaii 2017, in litt). In addition, the Hawaii Department of Land and Natural Resources (DLNR), with funding from the Initiative, constructed 22 miles (35 kilometers) of fencing in the Kau watershed, and fenced 24,000 ac (9,712 ha) in the Manuka NAR, to protect these areas from the negative impacts of pigs and other ungulates (Smith 2013, in litt.; State of Hawaii 2014, p. 1). These measures benefit the Hawaiian hawk by securing potential nesting, breeding, and hunting habitat.

Over the past 6 years, the Hawaiian Legacy Reforestation Initiative (HLRI) has converted 1,000 ac (405 ha) of denuded pastureland into an intact ecosystem with over 300,000 endemic trees (*e.g.,* ohia, milo (*Thespesia populnea*), sandalwood (*Santalum* species), and koa), outplanted and a plans to outplant approximately 700,000 more endemic trees over the coming years (HLRI 2018, in litt.; *https://legacytrees.org/*).

Additional ongoing conservation efforts (*e.g.,* nonnative plant and animal removal, fencing, and outplanting native species) are implemented by, but not limited to, the Nahelehele Dryland Forest Restoration program (*http://www.drylandforest.org/*), partnerships working in the Puu Waawaa watershed (*e.g.,* the multi-agency Hawaii Experimental Tropical Forest (*http://www.hetf.us/page/home/*)), The Nature Conservancy's Kona Hema Preserve (*https://www.nature.org/ourinitiatives/regions/northamerica/unitedstates/hawaii/placesweprotect/kona-hema.xml*), Hawaii Volcano's National Park, Hakalau National Wildlife Refuge, and the Statewide Sustainable Hawaii Initiative (*https://governor.hawaii.gov/sustainable-hawaii-initiative/*). Additionally, there are many State Natural Area Reserves and Forest Reserves, and several wildlife sanctuaries that provide additional forest areas for Hawaiian hawks and other native species; however because hunting is allowed on many of the Natural Area Reserves and Forest Reserves, they are not maintained solely as protected areas for native species (*https://dlnr.hawaii.gov/recreation/hunting/*). As previously mentioned, forested areas, particularly native forest areas, are increasing on the island of Hawaii (Koch and Walter, 2018, in litt.); however we do not have an exact number to quantify this increase.

At the onset of the most recent Kilauea volcano eruption (May 2018), primarily private lands were impacted; however, more recently the ongoing eruption has impacted native forest areas. In June 2018, the 1,514 ac (613 ha) Malama Ki Forest Reserve (FR) and surrounding areas were either buried by acres of lava or scorched by fumes of sulphur dioxide (Bergfield 2018, in litt.; KHON2 2018, in litt.). This area previously provided habitat for endangered forest birds and plants, and other native species. We do not have an exact number of how much native forest has been, or will be, lost as the eruption is ongoing. The Kilauea eruption is so far concentrated to the East Rift Zone area (USGS 2018, in litt.).

The island of Hawaii, like the island chain, has fortunately evaded most hurricanes due to the surrounding cool water. An exception occurred in 2014 with Hurricane Iselle. Although Hurricane Iselle morphed into a tropical storm before making landfall on the island, it caused extensive canopy loss in some regions of the island (Federal Emergency Management Agency (FEMA) 2014, in litt.). Iselle was the strongest tropical storm to make landfall on the island of Hawaii in recorded history. In 2016, Hurricane Darby made landfall on the island of Hawaii but as a much weaker tropical storm. While

both of these hurricanes caused canopy loss in some regions of the island, no analysis has been done to determine impacts to Hawaiian hawk habitat. Recent data indicate that Hawaii may experience an increase in hurricane frequency and intensity due to increases of both ocean surface temperatures and El Niño events associated with a warming global climate system (Cai *et al.* 2015, pp. 1, 4–5; Herring *et al.* 2015, p. Sii; Knutson *et al.* 2015, p. 7222; Murakami *et al.* 2015, p. S118; Wing *et al.* 2015, pp. 8673–8676; Fletcher 2016, p. 14).

A preliminary female specific stochastic PVA model for the Hawaiian hawk was developed (Vorsino and Nelson 2016, unpublished data) using the mean and variance values of age-specific survival and fecundity (ability and willingness to produce offpring) in native, mixed native-exotic, and exotic habitat (Gorresen *et al.* 2008, p. 15; Klavitter *et al.* 2003, p. 170). Population viability was assessed for optimal and sub-optimal habitats, where population partitioning was based on Hawaiian hawk densities within the habitat types (optimal/sub-optimal) reported in Gorresen *et al.* (2008, p. 15). The effect of catastrophic weather events on the viability of Hawaiian hawk in these various habitat types was also projected and assessed. None of the projected PVAs showed a Hawaiian hawk population that declined to either zero, or below a quasi-extinction threshold of 50 individuals, when projected over 30 years across 500 model iterations.

Current analysis of biodiesel fuel development indicates that construction and testing of facilities on the island of Hawaii has plateaued at 2014 levels, with just one biodiesel facility on the island. In addition to the other information we request in Public Comments below, we request new information on the actual conversion of agricultural land to crops for biodiesel fuel production, including former and current crop type and acreage.

**Post-Delisting Monitoring Plan**

Section 4(g)(1) of the Act requires us, in cooperation with the States, to implement a monitoring program for not less than 5 years for all species that have been delisted due to recovery. The purpose of this requirement is to develop a program that detects the failure of any delisted species to sustain itself without the protective measures provided by the Act. If, at any time during the monitoring period, data indicate that protective status under the Act should be reinstated, we can initiate listing procedures, including, if appropriate, emergency listing.

The Service has developed a draft post-delisting monitoring (PDM) plan for Hawaiian hawk in cooperation with the State of Hawaii Department of Land and Natural Resources, Division of Forestry and Wildlife (DOFAW); the National Park Service (NPS); and the U.S. Geological Survey, Ecosystem Mission Area (formerly the Biological Resources Division). The draft PDM plan includes monitoring the Hawaiian hawk population every 5 years for 20 years and is designed to verify that the Hawaiian hawk remains secure from risk of extinction after its removal from the Federal List of Endangered and Threatened Wildlife. While not required, with this notice, we are again soliciting public comments and peer review on the draft PDM plan, which can be found on *http://www.regulations.gov* at docket number FWS–R1–ES–2007–0024. We are particularly interested in monitoring information pertaining to Hawaiian hawk habitat in light of ROD and strawberry guava. All comments on the draft PDM plan from the public and peer reviewers will be considered and incorporated into the final PDM plan as appropriate.

**Public Comments**

We intend that any final action resulting from the proposal will be based on the best scientific and commercial data available and will be as accurate and effective as possible. To ensure our determination is based on the best available scientific and commercial information, we request information on the Hawaiian hawk from governmental agencies, native Hawaiian groups, the scientific community, industry, and any other interested parties. We request comments or suggestions on our August 6, 2008 (73 FR 45680), proposal to delist the Hawaiian hawk; our draft PDM plan; new information presented in this **Federal Register** document; and any other information. Specifically, we seek information on:

(1) The species' biology, range, and population trends, including:

(a) Life history, ecology, and habitat use of the Hawaiian hawk, as well as the species' use of koa plantations and exurban areas;

(b) Range, distribution, population size, and population trends;

(c) Positive and negative effects of current and foreseeable land management practices on the Hawaiian hawk, including conservation efforts associated with watershed partnerships (*e.g.,* The Rain Follows the Forest initiative and the Governor's Sustainable Hawaii Initiative); patterns of land subdivision and development; effects on native forest of introduced plant species; conversion of land to biodiesel production, forestry, and diversified agriculture; and potential effects of biocontrol efforts on strawberry guava;

(d) Potential effects of temperature and rainfall change on fire frequency and intensity and forest type and distribution;

(e) Potential impacts of ROD and climate change (*e.g.,* increased frequency or prolonged drought); and

(f) Potential impacts of the recent Kilauea Volcano eruptions.

(2) The factors, as detailed in the August 6, 2008, proposed rule (73 FR 45680), that are the basis for making a listing/delisting/downlisting determination for a species under section 4(a) of the Act, which are:

(a) The present or threatened destruction, modification, or curtailment of its habitat or range;

(b) Overutilization for commercial, recreational, scientific, or educational purposes;

(c) Disease or predation;

(d) The inadequacy of existing regulatory mechanisms; or

(e) Other natural or manmade factors affecting its continued existence.

(3) Input or considerations for post-delisting monitoring of the Hawaiian hawk.

You may submit your information by one of the methods listed in **ADDRESSES**. If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If you submit a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this personal identifying information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Information and supporting documentation that we receive and use in preparing the proposal will be available for you to review at *http://www.regulations.gov,* or you may make an appointment during normal business hours at the Service's Pacific Islands Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

If you submitted comments or information previously on the August 6, 2008, proposed rule (73 FR 45680); the February 11, 2009, document that made available our draft PDM plan (74 FR 6853); the June 5, 2009, publication announcing public hearings and reopening the proposal's and draft PDM

plan's comment period (74 FR 27004); or the February 12, 2014, publication reopening the proposal's and draft PDM plan's comment period (79 FR 8413), please do not resubmit them. These comments have been incorporated into the public record and will be fully considered in the preparation of our final determination.

## References Cited

A complete list of references cited is available on the internet at *http://www.regulations.gov* and upon request from the Service's Pacific Islands Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

## Authors

The primary authors of this document are staff of the Service's Pacific Islands Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

## Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: August 14, 2018.

**James W. Kurth,**

*Deputy Director, U.S. Fish and Wildlife Service, Exercising the Authority of the Director, U.S. Fish and Wildlife Service.*

[FR Doc. 2018–23697 Filed 10–29–18; 8:45 am]

BILLING CODE 4333–15–P

# Notices

Federal Register
Vol. 83, No. 210
Tuesday, October 30, 2018

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.

## COMMISSION ON CIVIL RIGHTS

### Notice of Public Meetings of the New York Advisory Committee

**AGENCY:** Commission on Civil Rights.

**ACTION:** Announcement of meetings.

**SUMMARY:** Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a meeting of the New York Advisory Committee to the Commission will convene by conference call at 12:00 p.m. (EDT) on: Friday, November 9, 2018. The purpose of the meeting is to discuss topics of study.

**DATES:** Friday, November 9, 2018 at 12:00 p.m. EDT

*Public Call-In Information:* Conference call-in number: 1–877–260–1479 and conference ID# 6006921.

**FOR FURTHER INFORMATION CONTACT:** David Barreras, at *dbarreras@usccr.gov* or by phone at 312–353–8311.

**SUPPLEMENTARY INFORMATION:** Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 1–877–260–1479 and conference ID# 6006921. Please be advised that before placing them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free conference call-in number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–800–977–8339 and providing the operator with the toll-free conference call-in number: 1–877–260–1479 and conference ID# 6006921.

Members of the public are invited to make statements during the open comment period of the meetings or submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Midwest Regional Office, U.S. Commission on Civil Rights, 230 S Dearborn Street, Suite 2120, Chicago, IL 60604, faxed to (312) 353–8324, or emailed to David Barreras at *dbarreras@usccr.gov.* Persons who desire additional information may contact the Midwest Regional Office at (312) 353–8311.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://database.faca.gov/committee/meetings.aspx?cid=265;* click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Midwest Regional Office at the above phone numbers, email or street address.

**Agenda**

*Friday, November 9, 2018*

- Open—Roll Call
- Discussion of Study Topics
- Open Comment
- Adjourn

*Exceptional Circumstance:* Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstance of the rescheduling of a previously cancelled meeting.

Dated: October 24, 2018.

**David Mussatt,**

*Supervisory Chief, Regional Programs Unit.*

[FR Doc. 2018–23605 Filed 10–29–18; 8:45 am]

BILLING CODE P

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[S–134–2018]**

### Approval of Subzone Status; Digi-Key Corporation; Thief River Falls, Minnesota

On August 24, 2018, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Koochiching Economic Development Authority, grantee of FTZ 259, requesting subzone status subject to the existing activation limit of FTZ 259, on behalf of Digi-Key Corporation, in Thief River Falls, Minnesota.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (83 FR 44565–44566, August 31, 2018). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR Sec. 400.36(f)), the application to establish Subzone 259B was approved on October 25, 2018, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 259's 2,000-acre activation limit.

Dated: October 25, 2018.

**Andrew McGilvray,**

*Executive Secretary.*

[FR Doc. 2018–23662 Filed 10–29–18; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[C–570–980]**

### Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Amended Final Results of Countervailing Duty Administrative Review; 2015

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (Commerce) is amending the final results of the countervailing duty administrative review of crystalline silicon photovoltaic cells, whether or

not assembled into modules (solar cells), from the People's Republic of China (China) to correct a ministerial error.

**DATES:** Applicable October 30, 2018.

**FOR FURTHER INFORMATION CONTACT:** Gene H. Calvert, 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) 482–3586.

**SUPPLEMENTARY INFORMATION:**

## Background

In accordance with section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.221(b)(5), on July 23, 2018, Commerce published its final results in the administrative review of the countervailing duty order on solar cells from China for the period of review (POR) January 1, 2015, through December 31, 2015.[1] On August 2, 2018, Canadian Solar Inc. (Canadian Solar), a respondent in this administrative review, submitted timely ministerial error allegations concerning the *Final Results*.[2] On August 7, 2018, SolarWorld Americas, Inc. timely filed rebuttal comments to Canadian Solar's allegations.[3] No other parties submitted ministerial allegations or comments on Canadian Solar's allegations. Complaints were filed with the U.S. Court of International Trade (the Court, or CIT) challenging the *Final Results.* The United States sought leave from the Court to address these ministerial error allegations. The Court granted the United States' request and allowed until November 5, 2018, to issue any amended final results.

## Scope of the Order

The merchandise covered by this order is crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials. Merchandise covered by this order is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 8501.61.0000, 8507.20.80, 8541.40.6020, 8541.40.6030, and 8501.31.8000. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of this order is dispositive. A full description of the scope of the order is contained in the *Final Results* Decision Memorandum.[4]

## Ministerial Errors

Section 751(h) of the Act and 19 CFR 351.224(f) define a ''ministerial error'' as an error in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication, or the like, and any other similar type of unintentional error which the Secretary considers ministerial. Commerce finds that an error alleged by Canadian Solar regarding the calculation of the benchmark used to calculate benefits in the Aluminum Extrusions for Less Than Adequate Remuneration (LTAR) Program constitutes a ministerial error within the meaning of 19 CFR 351.224(f).[5]

In accordance with section 751(h) of the Act and 19 CFR 351.224(e), we are amending the *Final Results* to correct the ministerial error. Specifically, we are amending the net subsidy rates for the mandatory company respondents (*i.e.,* Canadian Solar and Changzhou Trina Solar Energy Co., Ltd.) and for the companies for which a review was requested that were not selected as mandatory company respondents (*i.e.,* the non-selected companies subject to this review).[6] The revised net subsidy rates are provided below.

## Amended Final Results

As a result of correcting the ministerial error, we determine the countervailable subsidy rates for the producers/exporters under review to be as follows:

| Producer/exporter | Subsidy rate (percent *ad valorem*) |
|---|---|
| Canadian Solar and its Cross-Owned Affiliates[7] | 11.59 |
| Trina Solar and its Cross-Owned Affiliates[8] | 9.12 |

Review-Specific Average Rate Applicable to the Non-Selected Companies Subject to this Review:

| Producer/exporter | Subsidy rate (percent *ad valorem*) |
|---|---|
| Baoding Jiasheng Photovoltaic Technology Co., Ltd. | 10.64 |
| Baoding Tianwei Yingli New Energy Resources Co., Ltd. | 10.64 |
| Beijing Tianneng Yingli New Energy Resources Co., Ltd. | 10.64 |
| Canadian Solar International, Ltd. | 10.64 |
| Chint Solar (Zhejiang) Co., Ltd. | 10.64 |
| Dongguan Sunworth Solar Energy Co., Ltd. | 10.64 |
| ERA Solar Co., Ltd. | 10.64 |
| ET Solar Energy Limited | 10.64 |
| ET Solar Industry Limited | 10.64 |
| Hainan Yingli New Energy Resources Co., Ltd. | 10.64 |
| Hangzhou Sunny Energy Science and Technology Co., Ltd. | 10.64 |
| Hangzhou Zhejiang University Sunny Energy Science and Technology Co., Ltd. | 10.64 |
| Hengdian Group DMEGC Magnetics Co., Ltd. | 10.64 |
| Hengshui Yingli New Energy Resources Co., Ltd. | 10.64 |
| JA Solar Technology Yangzhou Co., Ltd. | 10.64 |

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Final Results of Countervailing Duty Administrative Review; 2015,* 83 FR 34828 (July 23, 2018) (*Final Results*) and accompanying Issues and Decision Memorandum (Decision Memorandum).

[2] *See* Letter from Canadian Solar, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from the People's Republic of China: Ministerial Error Comments,'' dated August 2, 2018; *see also* Memorandum, ''Administrative Review of the Countervailing Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Extension of Deadline for Ministerial Error Comments,'' dated July 30, 2018.

[3] *See* Letter from the petitioner, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Rebuttal to Canadian Solar's Ministerial Error Comments,'' dated August 7, 2018.

[4] *See Final Results* Decision Memorandum at 3–4.

[5] *See* Memorandum, ''Administrative Review of the Countervailing Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China, 2015; Response to Ministerial Error Allegations in the Final Results,'' dated concurrently with this notice (Response to Ministerial Error Allegations).

[6] Consistent with the *Final Results,* for the non-selected companies, we calculated an amended rate by weight-averaging the amended subsidy rates of the two mandatory respondents using their publicly-ranged sales data for exports of subject merchandise to the United States during the POR.

[7] Cross-owned affiliates are: Canadian Solar Inc.; Canadian Solar Manufacturing (Luoyang) Inc.; Canadian Solar Manufacturing (Changshu) Inc.; CSI Cells Co., Ltd.; CSI Solar Power (China) Inc.; CSI Solartronics (Changshu) Co., Ltd.; CSI Solar Technologies Inc.; CSI Solar Manufacture Inc. (name was changed to CSI New Energy Holding Co., Ltd. in July 2015); CSI–GCL Solar Manufacturing (Yancheng) Co., Ltd.; Changshu Tegu New Materials Technology Co., Ltd.; Changshu Tlian Co., Ltd.; and Suzhou Sanysolar Materials Technology Co., Ltd. *See* Preliminary Decision Memorandum.

[8] Cross-owned affiliates are: Changzhou Trina Solar Energy Co., Ltd.; Trina Solar (Changzhou) Science and Technology Co., Ltd.; Yancheng Trina Solar Energy Technology Co., Ltd.; Changzhou Trina Solar Yabang Energy Co., Ltd.; Hubei Trina Solar Energy Co., Ltd.; Turpan Trina Solar Energy Co., Ltd.; and Changzhou Trina PV Ribbon Materials Co., Ltd.

| Producer/exporter | Subsidy rate (percent *ad valorem*) |
|---|---|
| Jiangsu High Hope Int'l Group | 10.64 |
| Jiawei Solarchina Co., Ltd. | 10.64 |
| Jiawei Solarchina (Shenzhen) Co., Ltd. | 10.64 |
| JingAo Solar Co., Ltd. | 10.64 |
| Jinko Solar Co., Ltd. | 10.64 |
| Jinko Solar Import and Export Co., Ltd. | 10.64 |
| Jinko Solar International Limited | 10.64 |
| Jinko Solar (U.S.) Inc. | 10.64 |
| Lightway Green New Energy Co., Ltd. | 10.64 |
| Lixian Yingli New Energy Resources Co., Ltd. | 10.64 |
| Luoyang Suntech Power Co., Ltd. | 10.64 |
| Ningbo Qixin Solar Electrical Appliance Co., Ltd. | 10.64 |
| Risen Energy Co., Ltd. | 10.64 |
| Shanghai JA Solar Technology Co., Ltd. | 10.64 |
| Shenzhen Glory Industries Co., Ltd. | 10.64 |
| Shenzhen Topray Solar Co., Ltd. | 10.64 |
| Sumec Hardware & Tools Co. Ltd. | 10.64 |
| Systemes Versilis, Inc. | 10.64 |
| Taizhou BD Trade Co., Ltd. | 10.64 |
| tenKsolar (Shanghai) Co., Ltd. | 10.64 |
| Tianjin Yingli New Energy Resources Co., Ltd. | 10.64 |
| Toenergy Technology Hangzhou Co., Ltd. | 10.64 |
| Wuxi Suntech Power Co., Ltd. | 10.64 |
| Yingli Energy (China) Co., Ltd. | 10.64 |
| Zhejiang Era Solar Technology Co., Ltd. | 10.64 |
| Zhejiang Jinko Solar Co., Ltd. | 10.64 |
| Zhejiang Sunflower Light Energy Science & Technology Limited Liability Company | 10.64 |

## Assessment Rates/Cash Deposits

Normally, Commerce would issue appropriate assessment instructions to U.S. Customs and Border Protection (CBP) 15 days after the date of publication of these amended final results of review, to liquidate shipments of subject merchandise produced and/or exported by the companies listed above entered, or withdrawn from warehouse, for consumption on or after January 1, 2015, through December 31, 2015. However, on August 31, 2018, and on September 20 and 24, 2018, the CIT enjoined liquidation of certain entries that are subject to the *Final Results*.[9] Accordingly, Commerce will not instruct CBP to assess countervailing duties on those enjoined entries pending resolution of the associated litigation.

Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties, in the amounts shown above for the companies listed above, on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after July 23, 2018, which is the date of publication of the *Final Results.* For all non-reviewed firms, we will instruct CBP to collect cash deposits at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

## Administrative Protective Order

This notice also serves as a reminder to parties that are 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), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the 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.

## Disclosure

We intend to disclose the calculations performed for these amended final results to interested parties within five business days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

We are issuing and publishing these results in accordance with section 751(h) and 777(i)(1) of the Act, and 19 CFR 351.224(e).

Dated: October 25, 2018.

**Gary Taverman,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

[FR Doc. 2018–23667 Filed 10–29–18; 8:45 am]

BILLING CODE 3510–DS–P

[9] The CIT issued the statutory injunctions in case numbers 18–00184, 18–00185, and 18–00186.

# DEPARTMENT OF COMMERCE

## International Trade Administration

**[A–570–082]**

## Certain Steel Wheels From the People's Republic of China: Preliminary Determination of Sales at Less-Than-Fair-Value

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (Commerce) preliminarily determines that steel wheels from the People's Republic of China (China) are being, or are likely to be, sold in the United States at less-than-fair-value (LTFV) for the period of investigation (POI) July 1, 2017, through December 31, 2017. Interested parties are invited to comment on this preliminary determination.

**DATES:** Applicable October 30, 2018.

**FOR FURTHER INFORMATION CONTACT:** Lingjun Wang, 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) 482–2316.

**SUPPLEMENTARY INFORMATION:**

## Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on April 24, 2018.[1] On August 20, 2018, Commerce postponed the preliminary determination of this investigation and the revised deadline is now October 23, 2018.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty

[1] *See Certain Steel Wheels from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 83 FR 17798 (April 24, 2018) (*Initiation Notice*).

[2] *See Steel Wheels from the People's Republic of China: Postponement of Preliminary Determination in the Less-Than-Fair-Value Investigation,* 83 FR 42110 (August 20, 2018).

[3] *See* Memorandum re: Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Certain Steel Wheels from the People's Republic of China, dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and it is available to all parties in the Central Records Unit, room B8024 of the main building of Commerce. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

**Scope of the Investigation**

The products covered by this investigation are steel wheels from China. For a complete description of the scope of this investigation, *see* Appendix I.

**Scope Comments**

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice.* Commerce is not modifying the scope language as it appeared in the *Initiation Notice. See* the scope in Appendix I.

**Methodology**

Commerce is conducting this investigation in accordance with section 731 of the Act. Pursuant to section 776(a) and (b) of the Act, we have preliminarily relied upon facts otherwise available, with adverse inferences, for the China-wide entity because it did not respond to our requests for information. Specifically, two mandatory respondents withdrew their participation, and no other companies have demonstrated their eligibility for a separate rate; thus, all companies are preliminarily found to be part of the China-wide entity. Furthermore, we find that the China-wide entity's lack of participation, including the failure of certain parts of the China-wide entity to respond to Commerce's questionnaires, constitute circumstances under which it is reasonable to conclude that the China-wide entity as a whole failed to cooperate to the best of its ability to comply with Commerce's requests for information. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

**Preliminary Determination**

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

| Producer | Exporter | Estimated weighted-average dumping margin (percent) |
|---|---|---|
| China-Wide Entity | China-Wide Entity | 231.70 |

**Suspension of Liquidation**

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as discussed below. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the amount by which normal value exceeds U.S. price, adjusted, as appropriate, for export subsidies, as indicated in the chart above.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion CVD proceeding when CVD provisional measures are in effect. Accordingly, where Commerce has made a preliminary affirmative determination for domestic subsidy pass-through or export subsidies, Commerce has offset the calculated estimated weighted-average dumping margin by the appropriate rate(s). As discussed in the Preliminary Decision Memorandum, we have made no adjustment for domestic subsidy pass-through. As further explained in the Preliminary Decision Memorandum, as an extension of our AFA finding for the China-wide entity, the appropriate export subsidy adjustment is the lowest amount of export subsidies found for any respondent in the companion CVD investigation, which is zero.

These suspension of liquidation instructions will remain in effect until further notice.

**Disclosure**

Normally, Commerce discloses to interested parties the calculations performed in connection with a preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied total AFA to companies in this investigation in accordance with section 776 of the Act, and the applied AFA rate is based solely on the petition, there are no calculations to disclose.

**Verification**

Because the mandatory respondents withdrew their participation, Commerce preliminarily determines each of the mandatory respondents to have been uncooperative, and verification of Sunrise and Jingu will not be conducted.

**Public Comment**

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 45 days after the date of publication of the preliminary determination, unless the Secretary alters the time limit. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[6] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

[6] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

### Final Determination

Section 735(a)(1) of the Act and 19 CFR 351.210(b)(1) provide that Commerce will issue the final determination within 75 days after the date of its preliminary determination. However, on August 15, 2018, pursuant to section 735(a)(2) of the Act, Sunrise requested that Commerce postpone the final determination and extend provisional measures from four months to six months.[7] In accordance with 19 CFR 351.210(e)(2), we are still considering this request. Should we determine to postpone the final determination and extend provisional measures, we will publish a notification in the **Federal Register**.[8]

### International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination of sales at LTFV. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of the subject merchandise are materially injuring, or threaten material injury to, the U.S. industry.

### Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

[7] *See* Sunrise's August 15, 2018 Request to Postpone Final Determination.

[8] *See* 19 CFR 351.210(g).

Dated: October 23, 2018.

**Gary Taverman,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

## Appendix I

### Scope of the Investigation

The merchandise subject to the investigation is certain on-the-road steel wheels, discs, and rims for tubeless tires, with a nominal rim diameter of 22.5 inches and 24.5 inches, regardless of width. Certain on-the-road steel wheels with a nominal wheel diameter of 22.5 inches and 24.5 inches are generally for Class 6, 7, and 8 commercial vehicles (as classified by the Federal Highway Administration Gross Vehicle Weight Rating system), including tractors, semi-trailers, dump trucks, garbage trucks, concrete mixers, and buses, and are the current standard wheel diameters for such applications. The standard widths of certain on-the-road steel wheels are 7.5 inches, 8.25 inches, and 9.0 inches, but all certain on-the-road steel wheels, regardless of width, are covered by the scope. While 22.5 inches and 24.5 inches are standard wheel sizes used by Class 6, 7, and 8 commercial vehicles, the scope covers sizes that may be adopted in the future for Class 6, 7, and 8 commercial vehicles.

The scope includes certain on-the-road steel wheels with either a ''hub-piloted'' or ''stud-piloted'' mounting configuration, and includes rims and discs for such wheels, whether imported as an assembly or separately. The scope includes certain on-the-road steel wheels, discs, and rims, of carbon and/or alloy steel composition, whether cladded or not cladded, whether finished or not finished, and whether coated or uncoated. All on-the-road wheels sold in the United States are subject to the requirements of the National Highway Traffic Safety Administration and bear markings, such as the ''DOT'' symbol, indicating compliance with applicable motor vehicle standards. *See* 49 CFR 571.120. The scope includes certain on-the-road steel wheels imported with or without the required markings. Certain on-the-road steel wheels imported as an assembly with a tire mounted on the wheel and/or with a valve stem attached are included. However, if the certain on-the-road steel wheel is imported as an assembly with a tire mounted on the wheel and/or with a valve stem attached, the certain on-the-road steel wheel is covered by the scope, but the tire and/or valve stem is not covered by the scope.

Excluded from the scope are:

(1) Steel wheels for tube-type tires that require a removable side ring;

(2) aluminum wheels;

(3) wheels where steel represents less than fifty percent of the product by weight; and

(4) steel wheels that do not meet National Highway Traffic Safety Administration requirements, other than the rim marking requirements found in 49 CFR 571.120S5.2.

Imports of the subject merchandise are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 8708.70.4530, 8708.70.4560, 8708.70.6030, 8708.70.6060, 8716.90.5045, and 8716.90.5059. Merchandise meeting the scope description may also enter under the following HTSUS subheadings: 4011.20.1015, 4011.20.5020, and 8708.99.4850. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the subject merchandise is dispositive.

## Appendix II

### List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Scope Of the Investigation
V. Discussion of the Methodology
  A. Non-Market Economy Country
  B. Separate Rate Status
  C. The China-wide Entity
  D. Application of Facts Available and Adverse Inferences
VI. Adjustments Under Section 777(A)(F) of the Act
VII. Adjustments Under Section 772(C) of the Act
VIII. Conclusion

[FR Doc. 2018–23661 Filed 10–29–18; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

**RIN 0648–XG371**

## Marine Mammals; File No. 22095

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

**ACTION:** Notice; receipt of application.

**SUMMARY:** Notice is hereby given that SeaWorld, LLC., 9205 Southpark Center Loop, Suite 400, Orlando, FL 32819 (Responsible Party: Christopher Dold, DVM), has applied in due form for a scientific research and enhancement permit for one non-releasable beluga whale (*Delphinapterus leucas*) from the Cook Inlet distinct population segment (DPS).

**DATES:** Written, telefaxed, or email comments must be received on or before November 29, 2018.

**ADDRESSES:** The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 22095 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 22095 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

**FOR FURTHER INFORMATION CONTACT:** Amy Sloan, Jennifer Skidmore, or Courtney Smith, (301) 427–8401.

**SUPPLEMENTARY INFORMATION:** The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The applicant proposes to conduct research on and provide long-term care for one male beluga whale calf from the Cook Inlet DPS. The calf stranded alone as a neonate when he was less than a month old, and was rescued and rehabilitated by the Alaska marine mammal stranding network under the authority of the NMFS Marine Mammal Health and Stranding Response Program's (MMHSRP) scientific research and enhancement permit. Based on his young age, health conditions, and need for socialization with other beluga whales, NMFS determined him to be non-releasable and unable to survive in the wild, and chose SeaWorld of Texas to accept Tyonek into their beluga population, which was best suited for his needs. NMFS followed the standard placement process for non-releasable marine mammals as outlined in the NMFS Placement Process for Non-releasable Marine Mammals, No. 02–308–02, which is available at: *http://www.nmfs.noaa.gov/op/pds/documents/02/308/02-308-02.pdf.* The calf is currently held at SeaWorld of Texas under the authority of the MMHSRP permit (No. 18786–03). SeaWorld is now applying for their own scientific research and enhancement permit for the long-term care of this non-releasable animal and to conduct research to benefit the endangered wild population of Cook Inlet beluga whales.

SeaWorld's proposed research activities for this beluga whale include investigations of vocalizations (passive recordings) and hearing development (auditory evoked potential measurements). The proposed enhancement would include educational presentations on topics including the endangered status and current threats to the Cook Inlet DPS; continued daily husbandry care (feeding, training, and monitoring growth (measurements, weight, ultrasound)); veterinary care (exams and biological sampling including but not limited to blood, exhalate, swabs, urine, feces; and treatments as warranted); and behavioral observations and enrichment. This animal would be placed on public display incidental to the proposed activities but would not be used in interactive programs with the public or trained for performance. Presentations to educate the public may include demonstrations of trained husbandry and enrichment behaviors as well as natural behaviors. The permit is requested for a 5-year period, the maximum duration of a permit.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

NMFS has forwarded the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: October 24, 2018.

**Julia M. Harrison,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2018–23652 Filed 10–29–18; 8:45 am]

BILLING CODE 3510–22–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XG558**

### Marine Mammals; Issuance of Permits

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

**ACTION:** Notice; issuance of permits.

**SUMMARY:** Notice is hereby given that individuals and institutions have been issued Letters of Confirmation for activities conducted under the General Authorization for Scientific Research on marine mammals. See **SUPPLEMENTARY INFORMATION** for a list of names and address of recipients.

**ADDRESSES:** The Letters of Confirmation and related documents are available for review upon written request or by appointment in the following office:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

**FOR FURTHER INFORMATION CONTACT:** Office of Protected Resources, Permits and Conservation Division, (301) 427–8401.

**SUPPLEMENTARY INFORMATION:** The requested Letters of Confirmation have been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216). The General Authorization allows for *bona fide* scientific research that may result only in taking by Level B harassment of marine mammals. The following Letters of Confirmation (LOC) were issued in Fiscal Year 2018 (October 1, 2017—September 30, 2018).

*File No. 19826–01:* Issued to Tara Moll, Naval Undersea Warfare Center, Division Newport, 1176 Howell Street, Newport, RI, 02841 on November 6, 2017, to conduct ground and vessel surveys, photo-identification, and behavioral observations of gray (*Halichoerus grypus*), harbor (*Phoca vitulina*), and harp (*Pagophilus groenlandicus*) seals in lower Chesapeake Bay, VA and Narragansett Bay, RI. The amended LOC expands the location of research activities in Virginia to include the eastern Atlantic shore of Virginia, rather than just coastlines within the Chesapeake Bay. The LOC expires on January 31, 2021.

*File No. 21363:* Issued to David Johnston, Ph.D., Assistant Professor of the Practice, Duke University, Marine Science and Conservation, 135 Duke Marine Lab Rd., Beaufort, NC, 28516 on November 9, 2017, to use unmanned aircraft systems to count and photograph 11 pinniped species. Images will be used for photogrammetry, health assessments and habitat descriptions. Research may occur in three different areas: (1) Along the U.S. east coast from Maine to South Carolina; (2) along the U.S. West Coast from Alaska to

California; and (3) along the Western Antarctic Peninsula. The objectives are to determine the density and distribution of non-listed pinnipeds using risk adverse and low impact technology. The LOC expires on November 15, 2022.

*File No. 19826–02:* Issued to Deanna Rees, Naval Undersea Warfare Center, Division Newport, 1176 Howell Street, Newport, RI 02841 on November 28, 2017, to conduct ground and vessel surveys, photo-identification, and behavioral observations of gray, harbor, and harp seals in Virginia and Narragansett Bay, RI. The amended LOC changes the Principal Investigator. The objectives do not change from those authorized under LOC No. 19826–01. The LOC expires on January 31, 2021.

*File No. 19613:* Issued to Eric Zolman, NOAA National Ocean Service, Hollings Marine Laboratory, 331 Ft. Johnson, Charleston, SC, 29412–9110 on December 21, 2017, to conduct research on bottlenose dolphins (*Tursiops truncatus*) within coastal waters of the southeastern United States (including the western North Atlantic and northern Gulf of Mexico). Dolphins may be closely approached during vessel surveys for the purposes of photo-identification and behavioral observations to address the following objectives: (1) To estimate abundance of specific inshore bottlenose dolphin stocks; (2) to better define stock boundaries in targeted regions; and (3) to assess the status and health of targeted dolphin populations. The LOC expires on January 1, 2023.

*File No. 18101–03:* Issued to Jens Currie, Pacific Whale Foundation, 300 Ma'alaea Rd., Suite 211, Wailuku, HI 96793 on March 23, 2018. The amended Letter of Confirmation changes the Principal Investigator and applicant, and extends the LOC by one year for vessel-based research activities on cetaceans within the Maui-4 islands area. The objectives do not change from those authorized under LOC No. 18101–02. The LOC expires on June 21, 2019.

*File No. 21932:* Issued to Jessica Taylor, Outer Banks Center for Dolphin Research, 310 West Eden St., Kill Devil Hills, NC 27948 on April 4, 2018, to conduct vessel surveys of bottlenose dolphins in the waters of northern North Carolina. Animals may be approached for photo-identification, behavioral observations, and focal follows. The objective of the research is to continue to monitor the presence, identity, ecology, and behavior of bottlenose dolphins in the area. The LOC expires on April 30, 2023.

*File No. 21889:* Issued to Lesley Thorne, Ph.D., School of Marine and Atmospheric Sciences, Stony Brook University, Stony Brook, NY, 11794 on April 23, 2018, to conduct vessel and unmanned aircraft system (UAS) surveys of 18 cetacean species. Animals may be approached for photo-identification, photogrammetry, behavioral observations, and abundance estimates. Research may occur in the New York Bight up to 120 nm offshore. The objective of the research is to provide detailed species-level information on the abundance, distribution, movements and body condition of cetaceans within the study area to the New York State Department of Environmental Conservation as part of an offshore monitoring program. The LOC expires on July 30, 2023.

*File No. 21556:* Issued to Stephen McCulloch, Dolphins Plus, 31 Corrine Place, Key Largo, FL 33037 on May 14, 2018 to conduct vessel surveys targeting bottlenose dolphins to include close approach for counts, photo-identification, video recording, and behavioral observations in the Upper Florida Keys, between North Key Largo to Islamorada, FL. The objectives of the research are to provide a contemporary account of common bottlenose dolphins utilizing the Upper Florida Keys. The LOC expires on May 15, 2023.

*File No. 22198:* Issued to Samuel Wasser, Ph.D., Center for Conservation Biology, University of Washington, Seattle, WA 98195 on May 22, 2018, to conduct boat-based vessel surveys targeting killer whales (*Orcinus orca,* West Coast Transient stock) within the inland waters of Washington State. Whales may be approached during focal follows for photo-identification, behavioral observations, and fecal sample collection. The objective of the research is to, through analysis of feces, address the physiologic measures of nutritional stress with variation in prey abundance, toxicant levels and boat traffic to endpoint measures such as successful birth outcomes and annual mortality. The LOC expires on July 15, 2019.

*File No. 20519–01:* Issued to Peggy Stap, Marine Life Studies, P.O. Box 884, Monterey, CA 93942–0884 on June 27, 2018. The amended LOC allows for the use of small UAS to determine the number of marine mammals in a group and for photogrammetry of Transient and Offshore killer whales. The objectives do not change from those authorized under LOC 20519. The LOC expires on December 31, 2021.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: October 24, 2018.

**Julia Harrison,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2018–23653 Filed 10–29–18; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### Public Meeting for Recommending a National Estuarine Research Reserve Site in Connecticut's Lower Connecticut River and Eastern Long Island Sound

**AGENCY:** Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

**ACTION:** Public meeting notice.

**SUMMARY:** Notice is hereby given that a public meeting will be held for the purpose of providing information and receiving comments on the preliminary recommendation by the State of Connecticut that portions of the Lower Connecticut River and Eastern Long Island Sound be proposed to NOAA for designation as a National Estuarine Research Reserve.

The public meeting will be held at 6 p.m. on November 13, 2018 in the Academic Building Auditorium at the University of Connecticut's Avery Point campus, located at 1084 Shennecossett Rd, Groton, CT 06340.

*The state agencies holding the meeting:* The Connecticut Department of Energy and Environmental Protection's Coastal Management Program; the University of Connecticut; and Connecticut Sea Grant. NOAA's Office for Coastal Management will assist with the meeting.

The proposed research reserve site is comprised of the following state-owned properties: Lord Cove Wildlife Management Area; Great Island Wildlife Management Area; Bluff Point State Park and Coastal Reserve and Natural Area Preserve; Haley Farm State Park; and the public trust portions of waterbodies defined by:

(a) Long Island Sound ranging approximately west to east from the mouth of the Connecticut River to Mason's Island and north to south waterward of the mean high water

shoreline to just shy of the Connecticut state boundary in Long Island Sound;

(b) the area waterward of the mean high shoreline of the lower Thames River from approximately the Gold Star Bridge south to the area described in (a);

(c) the area waterward of the mean high shoreline of the lower Connecticut River from approximately Lord Cove south to the area described in (a).

The views of interested persons and organizations regarding the proposed site recommendation are solicited. This information may be expressed orally and in written statements. A presentation about the proposed site and the National Estuarine Research Reserve System will be provided. Written comments may be also be sent to: Kevin O'Brien, Connecticut Department of Energy and Environmental Protection—Land & Water Resources Division, 79 Elm Street, Hartford, CT 06106–5127 or to: *kevin.obrien@ct.gov.* All written comments must be received no later than seven calendar days following the public meeting. All comments received will be considered by the State in formally nominating a site to NOAA.

The research reserve system is a federal and state partnership program administered by the federal government, specifically the National Oceanic and Atmospheric Administration (NOAA). The research reserve system currently has 29 sites and protects more than 1.3 million acres of estuarine and Great Lakes habitat for long-term research, monitoring, education, and stewardship. Established by the Coastal Zone Management Act of 1972, each reserve is managed by a lead state agency or university, with input from local partners. NOAA provides partial funding and national programmatic guidance.

This particular site selection effort is a culmination of several years of local, grassroots-support for a research reserve site in Connecticut. The preliminary site recommendation follows a comprehensive evaluation process that sought the views of the public, affected landowners, and other interested parties. State and local agency representatives, as well as estuarine experts, served as committee members and evaluated site proposals. The committee is recommending the Lower Connecticut River and Eastern Long Island Sound as the preferred site for the state to nominate to NOAA.

**FOR FURTHER INFORMATION CONTACT:** Ms. Erica Seiden, Office for Coastal Management, National Ocean Service, NOAA, 1305 East West Highway, N/OCM, Silver Spring, MD 20910 or Email: *erica.seiden@noaa.gov.*

Persons with disabilities please contact Michelle MarcAurele at the University of Connecticut Avery Point campus by November 6, 2018 to make arrangements. Phone: 860–405–9115, Email: *michelle.marcaurele@uconn.edu.*

(Federal Domestic Assistance Catalog Number 11.420 (Coastal Zone Management) Research Reserves)

Dated: October 22, 2018.

**Paul M. Scholz,**

*Associate Assistant Administrator for Management and CFO/CAO, Ocean Services and Coastal Zone Management.*

[FR Doc. 2018–23607 Filed 10–29–18; 8:45 am]

**BILLING CODE 3510–22–P**

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

*Agency:* National Oceanic and Atmospheric Administration (NOAA).

*Title:* Pacific Islands Region Coral Reef Ecosystems Logbook and Reporting.

*OMB Control Number:* 0648–0462.

*Form Number(s):* None.

*Type of Request:* Regular (extension of a currently approved information collection).

*Number of Respondents:* 5.

*Average Hours per Response:* Pre-trip and pre-landing notifications, 3 minutes; logbook reports, 30 minutes; transshipment reports, 15 minutes.

*Burden Hours:* 18.

*Needs and Uses:* This request is for extension of a current information collection.

The National Marine Fisheries Service (NMFS) requires any U.S. citizen issued a Special Coral Reef Ecosystem Fishing Permit to complete logbooks and submit them to NMFS (50 CFR 665). The Special Coral Reef Ecosystem Fishing Permit is authorized under the Fishery Ecosystem Plans for American Samoa Archipelago, Hawaiian Archipelago, Mariana Archipelago, and Pacific Remote Island Areas. The information in the logbooks is used to obtain fish catch/fishing effort data on coral reef fishes and invertebrates harvested in designated low-use marine protected areas and on those listed in the regulations as potentially-harvested coral reef taxa in waters of the U.S. exclusive economic zone in the western Pacific region. These data are needed to determine the condition of the stocks, whether the current management measures are having the intended effects, and to evaluate the benefits and costs of changes in management measures. The logbook information includes interactions with protected species, including sea turtles, monk seals, and other marine mammals, which are used to monitor and respond to incidental takes of endangered and threatened marine species.

*Affected Public:* Business or other for-profit organizations; individuals or households.

*Frequency:* On occasion.

*Respondent's Obligation:* Mandatory.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: October 25, 2018.

**Sarah Brabson,**

*NOAA PRA Clearance Officer.*

[FR Doc. 2018–23640 Filed 10–29–18; 8:45 am]

**BILLING CODE 3510–22–P**

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XG567**

### Nominations for the 2019–2022 General Advisory Committee and the Scientific Advisory Subcommittee to the United States Delegation to the Inter-American Tropical Tuna Commission

**AGENCY:** National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

**ACTION:** Notice; request for nominations.

**SUMMARY:** National Marine Fisheries Service, on behalf of the Secretary of Commerce, is seeking nominations for the General Advisory Committee to the U.S. delegation to the Inter-American Tropical Tuna Commission, as well as to a Scientific Advisory Subcommittee of the General Advisory Committee. The purpose of the General Advisory Committee and its Scientific Advisory Subcommittee is to provide public input

and advice to the U.S. delegation in the formulation of policy and positions at meetings of the Inter-American Tropical Tuna Commission and its subsidiary bodies. The Scientific Advisory Subcommittee shall also function as the National Scientific Advisory Committee provided for in the Agreement on the International Dolphin Conservation Program.

**DATES:** Nominations must be received no later than November 29, 2018.

**ADDRESSES:** Nominations should be directed to Barry Thom, Regional Administrator, NMFS West Coast Region, and may be submitted by any of the following means:

- *Email: RegionalAdministrator.WCRHMS@noaa.gov* with the subject line: ''General Advisory Committee and Scientific Advisory Subcommittee nominations''
- *Mail:* Taylor Debevec, NMFS West Coast Region Long Beach Office, 501 W. Ocean Blvd., Suite 4200, Long Beach, CA 90802.

**FOR FURTHER INFORMATION CONTACT:** Taylor Debevec, NMFS West Coast Region; email: *taylor.debevec@noaa.gov;* telephone: 562–980–4066.

**SUPPLEMENTARY INFORMATION:**

## General Advisory Committee

The Tuna Conventions Act (16 U.S.C. 951 *et seq.*) (TCA) provides that the Secretary of Commerce, in consultation with the Secretary of State, shall appoint a ''General Advisory Committee'' (GAC) to advise the U.S. delegation to the Inter-American Tropical Tuna Commission (IATTC or Commission). The GAC shall be composed of no more than 25 individuals who shall be representative of the various groups concerned with the fisheries covered by the IATTC, including non-governmental conservation organizations, providing an equitable balance among such groups to the maximum extent practicable. Members of the GAC shall be invited to attend all non-executive meetings of the U.S. delegation to the IATTC and at such meetings shall be given the opportunity to examine and be heard on all proposed programs of investigation, reports, recommendations, and regulations of the Commission.

The Chair of the Pacific Fishery Management Council's (Pacific Council) Advisory Subpanel for Highly Migratory Fisheries and the Chair of the Western Pacific Fishery Management Council's (Western Pacific Council's) Advisory Committee shall be ex-officio members of the GAC by virtue of their positions advising those Councils. GAC members will be eligible to participate as members of the U.S. delegation to the Commission and its working groups to the extent that the Commission rules and space for delegations allow.

Meetings of the GAC, except when in executive session, shall be open to the public, and prior notice of meetings shall be made public in timely fashion. In accordance with Public Law 114–81, the GAC shall not be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

Individuals appointed to serve as a member of the GAC shall serve without pay. While away from their homes or regular places of business to attend meetings of the GAC, they shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently by the Federal Government are allowed expenses under 5 U.S.C. 5703. In addition, individuals appointed to serve as a member of the GAC shall not be considered Federal employees except for the purposes of injury compensation or tort.

## Scientific Advisory Subcommittee

The TCA also provides that the Secretary of Commerce, in consultation with the Secretary of State, shall appoint persons to serve on the subcommittee of the GAC, referred to here as the ''Scientific Advisory Subcommittee'' (SAS). The SAS shall be composed of no fewer than 5 and no more than 15 qualified scientists with balanced representation from the public and private sectors, including non-governmental conservation organizations. In determining whether a person is a qualified scientist the Secretary may consider, among other things, advanced degrees and/or publications in fields such as fisheries or marine science.

## National Scientific Advisory Committee

The SAS shall also function as the National Scientific Advisory Committee which is required to be established pursuant to Article XI of the Agreement on the International Dolphin Conservation Program (AIDCP). In this regard, the SAS shall perform the functions of the National Scientific Advisory Committee as specified in Annex VI of the AIDCP. These functions include, but are not limited to: (1) Receiving and reviewing relevant data, including data provided to NMFS by IATTC staff; (2) advising and recommending measures and actions to the U.S. Government that should be undertaken to conserve and manage stocks of living marine resources in the eastern Pacific Ocean; (3) making recommendations to the U.S. Government regarding research needs related to the eastern Pacific Ocean tuna purse seine fishery; (4) promoting the regular and timely full exchange of data among the AIDCP Parties on a variety of matters related to the implementation of the AIDCP; and (5) consulting with other experts, as necessary, in order to achieve the objectives of the AIDCP.

Members of the SAS/National Scientific Advisory Committee shall receive no compensation for their service.

## General Provisions

Each member of the GAC shall be appointed for a term of 3 years and may be reappointed. The Secretary of Commerce and the Secretary of State shall provide the GAC with relevant information concerning fisheries and international fishery agreements. The Secretary of Commerce shall provide to the GAC such administrative and technical support services that are necessary for its effective functioning in a timely manner.

## Procedures for Submitting Applications

Applications for the GAC and the SAS/National Scientific Advisory Committee should be submitted to NMFS West Coast Region (see **ADDRESSES**). This request for applications is for first time nominees, current members whose appointments will end in April 2019, and previous members. Self-nomination applications are acceptable. Applications should include all of the following information:

(1) Full name, address (home and business, if different), telephone, and email address of nominee;

(2) Specification about whether the application is for the GAC or the SAS/National Scientific Advisory Committee or both;

(3) Nominee's organization(s) or professional affiliation(s) serving as the basis for the nomination;

(4) Background statement describing the nominee's qualifications and experience, especially as related to fisheries for tuna and tuna-like species in the eastern Pacific Ocean or other factors relevant to the implementation of the Convention Establishing the IATTC or the AIDCP. Applications to the SAS should highlight advanced degrees and academic publications; and

(5) A written statement from the nominee of intent to participate actively and in good faith in the meetings and activities of either the GAC or the SAS/National Scientific Advisory Committee, or both.

Applicants who submitted material in response to the **Federal Register** Notice

published by NMFS on January 20, 2016 (81 FR 3118), or prior, should resubmit their applications pursuant to this notice.

**Authority:** 16 U.S.C. 951 *et seq.*

Dated: October 24, 2018.

**Karen H. Abrams,**

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

[FR Doc. 2018–23634 Filed 10–29–18; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### Department of the Army

**[Docket ID: USA–2018–HQ–0024]**

### Proposed Collection; Comment Request

**AGENCY:** U.S. Army Corps of Engineers, DoD.

**ACTION:** Information collection notice.

**SUMMARY:** In compliance with the *Paperwork Reduction Act of 1995,* the U.S. Army Corps of Engineers announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

**DATES:** Consideration will be given to all comments received by December 31, 2018.

**ADDRESSES:** You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24 Suite 08D09, Alexandria, VA 22350–1700.

*Instructions:* All submissions received must include the agency name, docket number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

**FOR FURTHER INFORMATION CONTACT:** To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the U.S. Army Corps of Engineers Omaha District, ATTN: Kelly Baxter, 1616 Capitol Ave., Ste. 9000, Omaha, NE 68102; call at 402–995–2447; or email at *Kelly.D.Baxter@usace.army.mil.*

**SUPPLEMENTARY INFORMATION:** For a secondary source to request more information on this proposed information collection, please write to the U.S. Army Corps of Engineers Walla Walla District, ATTN: Karen Zelch, 201 N 3rd Ave, Walla Walla, WA 99362; call at 509–527–7251; or email at *Karen.S.Zelch@usace.army.mil.*

*OMB Number:* Pacific Northwest Households Recreation Use Surveys, OMB Control Number 0710–XXXX.

*Needs and Uses:* The U.S. Army Corps of Engineers, Bonneville Power Administration (BPA), and Bureau of Reclamation (BOR), are jointly developing an environmental impact statement (EIS), referred to as the Columbia River System Operations (CRSO) EIS. As part of the EIS, the Corps is tasked with evaluating changes in the economic value provided by water-based recreation.

The purpose of this survey effort is to gather information that will support development of a water-based recreational demand model for the Columbia River Basin in Washington, Oregon, Idaho, and western Montana. The proposed design involves a mail survey for preliminary screening to identify eligible recreators, followed by a telephone survey of eligible recreators to collect data on recreational trips and activities within the region. The model will be used to evaluate recreational impacts associated with alternatives identified within the CRSO EIS.

**Mail Screener**

*Affected Public:* Individuals or households.
*Annual Burden Hours:* 1,150.
*Number of Respondents:* 11,500.
*Responses per Respondent:* 1.
*Annual Responses:* 11,500.
*Average Burden per Response:* 6 minutes.
*Frequency:* One-time.

**Follow-up Telephone Survey**

*Affected Public:* Individuals or households.
*Annual Burden Hours:* 414.
*Number of Respondents:* 1,242.
*Responses per Respondent:* 1.
*Annual Responses:* 1,242.
*Average Burden per Response:* 20 minutes.
*Frequency:* One-time.

**Average Totals**

*Annual Burden Hours:* 1,564.
*Number of Respondents:* 11,500.
*Responses per Respondent:* 1.
*Annual Responses:* 11,500.
*Average Burden per Response:* 8.16 minutes.
*Frequency:* One-time.

We anticipate that approximately 11,500 households will complete the mail screener. Based on the results of a small pretest, we expect that it will take approximately 1 minute to read the screener letter and approximately 5 minutes to complete the screener questionnaire (total of 6 minutes per respondent). Approximately 1,242 eligible adults within those households will complete the follow-up telephone survey. Also based on the results of a small pretest, we expect that it will take approximately 20 minutes to complete the follow-up telephone survey. Based on that data, the burden for 10,258 households will be 6 minutes. The burden for 1,242 eligible adults will be a total of 26 minutes. This yields a total respondent burden estimate of 1,564 hours.

Dated: October 25, 2018.

**Morgan E. Park,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2018–23675 Filed 10–29–18; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Transmittal No. 18–34]**

### Arms Sales Notification

**AGENCY:** Defense Security Cooperation Agency, Department of Defense.

**ACTION:** Arms sales notice.

**SUMMARY:** The Department of Defense is publishing the unclassified text of an arms sales notification.

**FOR FURTHER INFORMATION CONTACT:** DSCA at *dsca.ncr.lmo.mbx.info@mail.mil* or (703) 697–9709.

**SUPPLEMENTARY INFORMATION:** This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 18–34 with attached Policy Justification and Sensitivity of Technology.

Dated: October 24, 2018.

**Aaron T. Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

SEP 1 3 2018

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 18-34, concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Republic of Korea for defense articles and services estimated to cost $2.1 billion. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

Transmittal No. 18–34

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Republic of Korea

| | |
|---|---|
| Major Defense Equipment * | $1.54 billion |
| Other | $ .56 billion |
| TOTAL | $2.10 billion |

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

*Major Defense Equipment (MDE):*

Six (6) P–8A Patrol Aircraft, which includes:

Nine (9) Multifunctional Information Distribution System Joint Tactical Radio System 5 (MIDS JTRS) (one (1) for each aircraft, one (1) for the Tactical Operations Center, and two (2) spares)

Forty-two (42) AN/AAR–54 Missile Warning Sensors (six (6) for each aircraft and six (6) spares)

Fourteen (14) LN–251 with Embedded Global Positioning Systems (GPS)/Inertial Navigations Systems (EGIs) (two (2) for each aircraft and two (2) spares)

*Non-MDE includes:*

Commercial engines; Tactical Open Mission Software (TOMS); Electro-Optical (E.O.) and Infrared (IR) MX–20HD; AN/AAQ–2(V)1 Acoustic System; AN/APY–10 Radar; ALQ–240 Electronic Support Measures; AN/ALE–47 Counter Measures Dispensing System; support equipment; operation support systems; maintenance trainer/classrooms; publications; software, engineering, and logistics technical assistance; foreign Liaison officer support, contractor engineering technical services; repair and return; transportation; aircraft ferry; and other associated training, logistics, support equipment and services.

(iv) *Military Department:* Navy (KS–P–SEJ)

(v) *Prior Related Cases, if any:* N/A

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Annex Attached

(viii)*Date Report Delivered to Congress:* September 13, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

*POLICY JUSTIFICATION*

*Korea—P–8A Aircraft and Associated Support*

The Republic of Korea (ROK) has requested to buy six (6) P–8A Patrol Aircraft, which includes: nine (9) Multifunctional Information Distribution System Joint Tactical Radio Systems 5 (MIDS JTRS 5) (one (1) for each aircraft, one (1) for the Tactical Operations Center (TOC) and two (2) as spares); fourteen (14) LN–251 with Embedded Global Positioning Systems (GPS)/Inertial Navigations Systems (EGIs) (two (2) for each aircraft and two (2) as spares); and forty-two (42) AN/AAR–54 Missile Warning Sensors (six (6) for each aircraft and six (6) as spares). Also included are commercial engines; Tactical Open Mission Software (TOMS); Electro-Optical (E.O.) and Infrared (IO) MX–20HD; AN/AAQ–2(V)1 Acoustic System; AN/APY–10 Radar; ALQ–240 Electronic Support Measures; AN/ALE–47 Counter Measures Dispensing System; support equipment; operation support systems; maintenance trainer/classrooms; publications; software, engineering, and logistics technical assistance; foreign liaison officer support; contractor engineering technical services; repair and return; transportation; aircraft ferry; and other associated training, logistics, support equipment and services. The total estimated program cost is $2.1 billion.

The ROK is one of the closest allies in the INDOPACOM Theater. The proposed sale will support U.S. foreign policy and national security objectives by enhancing Korea's naval capabilities to provide national defense and significantly contribute to coalition operations.

The ROK procured and has operated U.S.-produced P–3 Maritime Surveillance Aircraft (MSA) for over 25 years, providing interoperability and critical capabilities to coalition maritime operations. The ROK has maintained a close MSA acquisition and sustainment relationship with the U.S. Navy over that period. The proposed sale will allow the ROK to modernize and sustain its MSA capability for the next 30 years. As a long-time P–3 operator, the ROK will have no difficulty transitioning its MSA force to P–8A.

The proposed sale of this equipment and support does not alter the basic military balance in the region.

The prime contractor will be The Boeing Company, Seattle, WA. Additional contractors include: ASEC; Air Cruisers Co LLC; Arnprior Aerospace, Canada; AVOX Zodiac Aerospace; BAE; Canadian Commercial Corporation (CCC)/EMS; Compass; David Clark; DLS or ViaSat, Carlsbad, CA; DRS; Exelis, McLean, VA; GC Micro, Petaluma, CA; General Dynamics; General Electric, UK; Harris; Joint Electronics; Lockheed Martin; Martin Baker; Northrop Grumman Corp, Falls Church, VA; Pole Zero, Cincinnati, OH; Raytheon, Waltham, MA; Raytheon, UK; Rockwell Collins, Cedar Rapids, IA; Spirit Aero, Wichita, KS; Symmetries Telephonics, Farmingdale, NY; Terma, Arlington, VA; Viking; and WESCAM.

The purchaser typically requests offsets. There are no known offset agreements proposed in connection with this potential sale. Any offset agreement will be defined in negotiations between the Purchaser and the prime contractor.

Implementation of this proposed sale will require approximately three (3) U.S. government personnel and ten (10) contractor personnel to support the program in country.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 18–34

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The P–8A aircraft is a militarized version of the Boeing 737–800 Next Generation (NG) commercial aircraft. The P–8A is replacing the P–3C as the Navy's long-range Anti-Submarine Warfare (ASW), Anti-Surface Warfare (ASuW), Intelligence, Surveillance and Reconnaissance (ISR) aircraft. The overall highest classification of the P–8A weapon system is SECRET. The P–8A mission systems hardware is largely UNCLASSIFIED, while individual software elements (mission systems, acoustics, ESM, EWSP, etc.) are classified up to SECRET.

2. P–8A mission systems include:

a. Tactical Open Mission Software (TOMS). TOMS functions include environment planning, tactical aids, weapons planning aids, and data correlation. TOMS includes an algorithm for track fusion which automatically correlates tracks produced by on board and off board sensors.

b. Electro-Optical (E.O.) and Infrared (IR) MX–20HD. The E.O./IR system processes visible E.O. and IR spectrum to detect and image objects.

c. AN/AAQ–2(V)1 Acoustic System. The Acoustic sensor system is integrated within the mission system as the primary sensor or the aircraft ASW missions. The system has multi-static active coherent (MAC) 64 sonobuoy processing capability and acoustic sensor prediction tools.

d. AN/APY–10 Radar. The aircraft radar is a direct derivative of the legacy AN/APS–137(V) installed in the P–3C. The radar capabilities include GPS Selective Availability Anti-Spoofing Module (SAASM), SAR and ISAR imagery resolutions, and periscope detection mode.

e. ALQ–240 Electronic Support Measures (ESM). This system provides real time capability for the automatic detection, location, measurement, and analysis of RF-signals and modes. Real time results are compared with a library of known emitters to perform emitter classification.

f. Electronic Warfare Self Protection (EWSP). The P–8A aircraft EWSP consists of the ALQ–213 Electronic Warfare Management System (EWMS), AN/AAR–54 Missile Warning Sensors and AN/ALE–47 Countermeasures Dispensing System (CMDS). The EWSP includes threat information. Technical data and documentation to be provided are UNCLASSIFIED.

g. Multifunctional Information Distribution System-Joint Tactical Radio System 5 (MIDS JTRS 5) is an advanced Link-16 Command, Control, Communications, and Intelligence (C3I) system incorporating high-capacity, jam-resistant, digital communication links for exchange of near real-time tactical information, including both data and vice, among air, ground, and sea elements. The MIDS JTRS 5 terminal hardware, publications, performance specifications, operational capability, parameters, vulnerabilities to countermeasures, and software documentation are classified CONFIDENTIAL. The classified information to be provided consists of that which is necessary for the operation, maintenance, and repair (through intermediate level) of the data link terminal, installed systems, and related software.

h. The Embedded Global Positioning System (EGI)-Inertial Navigation System (INS)/LN–251 is a sensor that combines Global Positioning System (GPS) and inertial sensor inputs to provide accurate location information for navigation and targeting. The EGI–INS/LN–251 is UNCLASSIFIED. The GPS cryptovariable keys needed for highest GPS accuracy are classified up to SECRET.

3. If a technologically advanced adversary were to obtain access of the P–8A specific hardware and software elements, systems could be reverse engineering to discover USN capabilities and tactics. The consequences of the loss of this technology, to a technologically advanced or competent adversary, could result in the development of countermeasures or equivalent systems, which could reduce system effectiveness or be used in the development of a system with similar advanced capabilities.

4. A determination has been made that the recipient government can provide substantially the same degree of protection for the technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to the Republic of Korea.

[FR Doc. 2018–23612 Filed 10–29–18; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF EDUCATION

**[Docket No. ED–2018–ICCD–0089]**

## Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Health Education Assistance Loan (HEAL) Program: Forms

**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 November 29, 2018.

**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–2018–ICCD–0089. 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. *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:* Health Education Assistance Loan (HEAL) Program: Forms.

*OMB Control Number:* 1845–0128.

*Type of Review:* An extension of an existing information collection.

*Respondents/Affected Public:* Private Sector; Individuals or Households.

*Total Estimated Number of Annual Responses:* 69.

*Total Estimated Number of Annual Burden Hours:* 11.

*Abstract:* The HEAL forms are required for lenders to make application to the HEAL insurance program, to report accurately and timely on loan actions, including transfer of loans to a secondary agent, and to establish the repayment status of borrowers who qualify for deferment of payments using form 508. The reports assist in the diligent administration of the HEAL program, protecting the financial interest of the federal government.

Dated: October 25, 2018.

**Kate Mullan,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2018–23664 Filed 10–29–18; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

**[Docket No.: ED–2018–ICCD–0091]**

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Student Assistance General Provisions—Subpart K—Cash Management

**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 November 29, 2018.

**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–2018–ICCD–0091. 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. *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:* Student Assistance General Provisions—Subpart K—Cash Management.

*OMB Control Number:* 1845–0106.

*Type of Review:* An extension of an existing information collection.

*Respondents/Affected Public:* Private Sector; State, Local, and Tribal Governments; Individuals or Households.

*Total Estimated Number of Annual Responses:* 3,037,182.

*Total Estimated Number of Annual Burden Hours:* 916,357.

*Abstract:* The Department of Education (the Department) is requesting an extension of the information collection for the requirements that are contained in the regulations § 668.164—Disbursing funds. The regulations require that an institution that makes direct payments to a student or parent by electronic funds transfer (EFT) and that chooses to enter into an arrangement described in 668.164(e) or (f), including an institution that uses a third-party servicer to make those payments, must establish a selection process under which the student chooses one of several options for receiving those Title IV, HEA fund payments. The Department amended the Student Assistance General Provisions regulations issued under the Higher Education Act of 1965, as amended (HEA), to implement the changes made to the Student Assistance General Provisions regulations—Subpart K—Cash Management § 668.164—Disbursing funds. These regulations are intended to ensure students and parents have convenient access to their Title IV, HEA program funds, do not incur unreasonable and uncommon financial account fees on these title IV funds and are not led to believe that they must open a particular financial account to receive their Federal student aid.

Dated: October 25, 2018

**Kate Mullan,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2018–23666 Filed 10–29–18; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

**[Docket No.: ED–2018–ICCD–0090]**

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Income Based Repayment—Notifications

**AGENCY:** Federal Student Aid (FSA), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

**DATES:** Interested persons are invited to submit comments on or before November 29, 2018.

**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–2018–ICCD–0090. 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. *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:* Income Based Repayment—Notifications.

*OMB Control Number:* 1845–0114.

*Type of Review:* An extension of an existing information collection.

*Respondents/Affected Public:* State, Local, and Tribal Governments; Private Sector.

*Total Estimated Number of Annual Responses:* 958,240.

*Total Estimated Number of Annual Burden Hours:* 76,665.

*Abstract:* The Higher Education Act of 1965, as amended (HEA), established the Federal Family Education Loan (FFEL) Program under Title IV, Part B. Section 493C [20 U.S.C. 1098e] of the HEA authorizes income based repayment for Part B borrowers who have a partial financial hardship. The regulations in 34 CFR 682.215(e)(2) require notifications to borrowers from the loan holders once a borrower establishes a partial financial hardship and is placed in an income based repayment (IBR) plan by the loan holder. The regulations identify information the loan holder must provide to the borrower to continue to participate in an IBR plan. This is a request for extension of the current information collection 1845–0114.

Dated: October 25, 2018.

**Kate Mullan,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2018–23665 Filed 10–29–18; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

**[Docket No. ED–2018–ICCD–0114]**

### Agency Information Collection Activities; Comment Request; FY 2018 Child Care Access Means Parents in School Annual Performance Report Package 84.335A

**AGENCY:** Office of Postsecondary Education (OPE), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, ED is proposing a reinstatement of a previously approved information collection.

**DATES:** Interested persons are invited to submit comments on or before December 31, 2018.

**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–2018–ICCD–0114. 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. *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 Harold Wells, 202–453–6131.

**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:* FY 2018 Child Care Access Means Parents in School Annual Performance Report Package 84.335A.

*OMB Control Number:* 1840–0763.

*Type of Review:* A reinstatement of a previously approved information collection.

*Respondents/Affected Public:* Private Sector.

*Total Estimated Number of Annual Responses:* 350.

*Total Estimated Number of Annual Burden Hours:* 9,800.

*Abstract:* The Child Care Access Means Parents In School (CCAMPIS) annual performance reports are used to collect programmatic data for purposes of annual reporting; budget submissions to OMB; Congressional hearings and testimonials; Congressional inquiries; and responding to inquiries from higher education interest groups and the general public.

Dated: October 25, 2018.

**Kate Mullan,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2018–23663 Filed 10–29–18; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF ENERGY

### Agency Information Collection Extension

**AGENCY:** U.S. Department of Energy.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years, an information collection request with the Office of Management and Budget (OMB).

**DATES:** Comments regarding this proposed information collection must be received on or before December 31, 2018. If you anticipate difficulty in submitting comments within that period, contact the person listed below as soon as possible.

**ADDRESSES:** Written comments may be sent to Eric Mulch at 1000 Independence Ave. SW, Washington, DC 20585 or by email at *eric.mulch@hq.doe.gov.*

**FOR FURTHER INFORMATION CONTACT:** Eric F. Mulch, Attorney-Adviser, at (202) 287–5746, or via email at *eric.mulch@hq.doe.gov.*

**SUPPLEMENTARY INFORMATION:** Comments are invited on: (a) Whether the extended collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. This information collection request contains: (1) *OMB No.* 1910–5115; (2) *Information Collection Request Title:* Contractor Legal Management Requirements; (3) *Type of Review:* Extension; (4) *Purpose:* The information collection to be extended has been and will be used to form the basis for DOE actions on requests from the contractors for reimbursement of litigation and other legal expenses. The information collected related to annual legal budget, staffing and resource plans, and initiation or settlement of defensive or offensive litigation is and will be similarly used; (5) *Annual Estimated Number of Respondents:* 45; (6) *Annual Estimated Number of Total Responses:* 154; (7) *Annual Estimated Number of Burden Hours:* 1,150; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* 0.

**Statutory Authority:** Section 161 of the Atomic Energy Act of 1954, 42 U.S.C. 2201, the Department of Energy Organization Act, 42 U.S.C 7101, *et seq.,* and the National Nuclear Security Administration Act, 50 U.S.C. 2401, *et seq.*

Signed in Washington, DC on October 23, 2018.

**Theodore J. Garrish,**

*Acting General Counsel, United States Department of Energy.*

[FR Doc. 2018–23668 Filed 10–29–18; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF ENERGY

**[Case Number 2017–007; EERE–2017–BT–WAV–0041]**

## Energy Conservation Program: Decision and Order Granting a Waiver to AHT Cooling Systems GmbH and AHT Cooling Systems USA Inc. From the Department of Energy Commercial Refrigerator, Freezer, and Refrigerator-Freezer Test Procedure

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

**ACTION:** Notice of decision and order.

**SUMMARY:** The U.S. Department of Energy (''DOE'') gives notice of a Decision and Order (Case Number 2017–007) that grants AHT Cooling Systems GmbH and AHT Cooling Systems USA Inc. (''AHT'') a waiver from specified portions of the DOE test procedure for determining the energy consumption of specified commercial refrigerators, freezers, and refrigerator-freezers (collectively ''commercial refrigeration equipment'') basic models. Under the Decision and Order, AHT is required to test and rate the specified basic models of its commercial refrigeration equipment in accordance with the alternate test procedure specified in the Decision and Order.

**DATES:** The Decision and Order is effective on October 30, 2018. The Decision and Order will terminate upon the compliance date of any future amendment to the test procedure for commercial refrigeration equipment located at 10 CFR part 431, subpart C, appendix B that addresses the issues presented in this waiver. At such time, AHT must use the relevant test procedure for this equipment for any testing to demonstrate compliance with standards, and any other representations of energy use.

**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. Telephone: (202) 287–1604. Email: *AS_Waiver_Requests@ee.doe.gov.*

Mr. Pete Cochran, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (202) 586–9496. Email: *peter.cochran@hq.doe.gov.*

**SUPPLEMENTARY INFORMATION:** In accordance with Title 10 of the Code of Federal Regulations (10 CFR 431.401(f)(2)), DOE gives notice of the issuance of its Decision and Order as set forth below. The Decision and Order grants AHT a waiver from the applicable test procedure in 10 CFR part 431, subpart C, appendix B (''Appendix B'') for specified basic models of commercial refrigeration equipment, provided that AHT tests and rates such equipment using the alternate test procedure specified in the Decision and Order. AHT's representations concerning the energy consumption of the specified basic models must be based on testing according to the provisions and restrictions in the alternate test procedure set forth in the Decision and Order, and the representations must fairly disclose the test results. Distributors, retailers, and private labelers are held to the same requirements when making representations regarding the energy consumption of this equipment. (42 U.S.C. 6314(d))

Consistent with 10 CFR 431.401(j), not later than December 31, 2018, any manufacturer currently distributing in commerce in the United States equipment employing a technology or characteristic that results in the same need for a waiver from the applicable test procedure must submit a petition for waiver. Manufacturers not currently distributing such equipment in commerce in the United States must petition for and be granted a waiver prior to the distribution in commerce of that equipment in the United States. Manufacturers may also submit a request for interim waiver pursuant to the requirements of 10 CFR 431.401.

Signed in Washington, DC, on October 16, 2018.

**Kathleen B. Hogan,**

*Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.*

### Case #2017–007

*Decision and Order*

### I. Background and Authority

The Energy Policy and Conservation Act of 1975 (''EPCA''),[1] Public Law 94–

[1] All references to EPCA in this document refer to the statute as amended through the EPS Improvement Act of 2017, Public Law 115–115 (January 12, 2018).

163 (42 U.S.C. 6291–6317, as codified), among other things, authorizes the U.S. Department of Energy (''DOE'') to regulate the energy efficiency of a number of consumer products and industrial equipment. Title III, Part C [2] of EPCA established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve energy efficiency for certain types of industrial equipment. This equipment includes commercial refrigerators, freezers, and refrigerator-freezers (collectively ''commercial refrigeration equipment''), the focus of this document. (42 U.S.C. 6311(1)(E)) EPCA also requires the Secretary of Energy to prescribe test procedures that are reasonably designed to produce results that measure energy efficiency, energy use, or estimated operating costs during a representative average-use cycle, and that are not unduly burdensome to conduct. (42 U.S.C. 6314(a)(2)) The test procedure for commercial refrigeration equipment is contained in 10 CFR part 431, subpart C, appendix B.

DOE's regulations set forth at 10 CFR 431.401 contain provisions that allow an interested person to seek a waiver from the test procedure requirements for a particular basic model when the petitioner's basic model for which the petition for waiver was submitted contains one or more design characteristics that either (1) prevent testing according to the prescribed test procedure, or (2) cause the prescribed test procedures to evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 431.401(a)(1). A petitioner must include in its petition any alternate test procedures known to the petitioner to evaluate the basic model in a manner representative of its energy consumption characteristics. 10 CFR 431.401(b)(1)(iii).

DOE may grant a waiver subject to conditions, including adherence to alternate test procedures. 10 CFR 431.401(f)(2). As soon as practicable after the granting of any waiver, DOE will publish in the **Federal Register** a notice of proposed rulemaking to amend its regulations so as to eliminate any need for the continuation of such waiver. 10 CFR 431.401(l). As soon thereafter as practicable, DOE will publish in the **Federal Register** a final rule. *Id.*

The wavier process also provides that DOE may grant an interim waiver if it appears likely that the petition for waiver will be granted and/or if DOE determines that it would be desirable for public policy reasons to grant immediate relief pending a determination on the underlying petition for waiver. 10 CFR 431.401(e)(2). Within one year of issuance of an interim waiver, DOE will either: (i) Publish in the **Federal Register** a determination on the petition for waiver; or (ii) publish in the **Federal Register** a new or amended test procedure that addresses the issues presented in the waiver. 10 CFR 431.401(h)(1). When DOE amends the test procedure to address the issues presented in a waiver, the waiver will automatically terminate on the date on which use of that test procedure is required to demonstrate compliance. 10 CFR 431.401(h)(2).

## II. AHT's Petition for Waiver: Assertions and Determinations

By letter dated May 16, 2017, AHT submitted a petition for waiver and an application for interim waiver for specified basic models of commercial refrigeration equipment that are required to be tested using the commercial refrigeration equipment test procedure at 10 CFR part 431, subpart C, appendix B.[3] AHT stated that the basic models listed in the petition do not have a defrost cycle when operated in freezer mode, and therefore cannot be tested under Appendix B, which references defrosts for the start of the test period and door-opening period.

On June 4, 2018, DOE published a notice that announced its receipt of the petition for waiver and granted AHT an interim waiver. 83 FR 25658. (''Notice of Petition for Waiver''). In the Notice of Petition for Waiver, DOE presented AHT's claim that its specified basic models cannot be tested according to Appendix B due to their lack of defrost when operated in freezer mode. AHT requested an alternate test procedure, which would test the specified commercial freezer basic models according to appendix B, but with the test period starting after the unit achieves steady state conditions and the door-opening period starting 3 hours after the start of the test period.

As explained in the Notice of Petition for Waiver, DOE evaluated the alternate test procedure requested by AHT, as well as the operating manual for the commercial freezer basic models. DOE's test procedure requires beginning the test period at the start of a defrost cycle and recording data for 24 hours, and initiating a door-opening period 3 hours after the start of a defrost cycle. As such, for the specified basic models, which do not defrost, there is no defined start to either the test period or the door-opening period under DOE's test procedure. Based on review of the application for an interim waiver, DOE determined that the alternate test procedure that AHT suggested appropriately reflects the energy consumption of and is appropriate for the commercial freezer basic models identified in AHT's petition for waiver.

In the Notice of Petition for Waiver, DOE also solicited comments from interested parties on all aspects of the petition and the specified alternate test procedure, which was consistent with AHT's requested alternate approach. DOE received no comments in response to the Notice of Petition for Waiver.

For the reasons explained here and in the Notice of Petition for Waiver, DOE understands that absent a waiver, the commercial freezer basic models identified by AHT in its petition contain a design characteristic—lack of a defrost cycle when operated in freezer mode—that prevents testing and rating such models on a basis representative of their true energy consumption characteristics. DOE has reviewed the recommended procedure suggested by AHT and concludes that it will allow for the accurate measurement of the energy use of the equipment, while alleviating the testing problems associated with AHT's implementation of DOE's applicable commercial refrigeration equipment test procedure for the specified basic models. Thus, DOE is requiring that AHT test and rate the commercial freezer basic models for which it has requested a waiver according to the alternate test procedure specified in this Decision and Order, which is identical to the procedure provided in the interim waiver.

This Decision and Order is applicable only to the basic models listed within it and does not extend to any other basic models. DOE evaluates and grants waivers for only those basic models specifically set out in the petition, not future models that may be manufactured by the petitioner. AHT may request that the scope of this waiver be extended to include additional basic models that employ the same technology as those listed in this waiver. 10 CFR 431.401(g). AHT may also submit another petition for waiver from the test procedure for additional basic models that employ a different technology and meet the

[2] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated as Part A–1.

[3] AHT's petition for waiver and petition for interim waiver can be found in the regulatory docket at *https://www.regulations.gov/docket?D=EERE-2017-BT-WAV-0041.*

criteria for test procedure waivers. 10 CFR 431.401(a)(1).

DOE notes that it may modify or rescind the waiver at any time upon DOE's determination that the factual basis underlying the petition for waiver is incorrect, or upon a determination that the results from the alternate test procedure are unrepresentative of the basic models' true energy consumption characteristics. 10 CFR 431.401(k)(1). Likewise, AHT may request that DOE rescind or modify the waiver if the company discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other appropriate reasons. 10 CFR 431.401(k)(2).

## III. Order

After careful consideration of all the material that was submitted by AHT in this matter, it is *ordered* that:

(1) AHT must, as of the date of publication of this Order in the **Federal Register**, test and rate the following AHT brand commercial freezer basic models (which do not have defrost cycle capability when operated in freezer mode) with the alternate test procedure as set forth in paragraph (2):

| Brand name | Basic model |
|---|---|
| AHT | IBIZA 100 NAM F |
| AHT | IBIZA 145 NAM F |
| AHT | IBIZA 210 NAM F |
| AHT | MALTA 145 NAM F |
| AHT | MALTA 185 NAM F |
| AHT | MANHATTAN 175 NAM F |
| AHT | MANHATTAN 210 NAM F |
| AHT | MIAMI 145 NAM F |
| AHT | MIAMI 185 NAM F |
| AHT | MIAMI 210 NAM F |
| AHT | MIAMI 250 NAM F |
| AHT | PARIS 145 NAM F |
| AHT | PARIS 185 NAM F |
| AHT | PARIS 210 NAM F |
| AHT | PARIS 250 NAM F |
| AHT | SYDNEY 175 NAM F |
| AHT | SYDNEY 210 NAM F |
| AHT | SYDNEY 213 NAM F |
| AHT | SYDNEY 223 NAM F |
| AHT | SYDNEY 230 NAM F |
| AHT | SYDNEY 250 NAM F |
| AHT | SYDNEY XL175 NAM F |
| AHT | SYDNEY XL210 NAM F |
| AHT | SYDNEY XL250 NAM F |

(2) The alternate test procedure for the AHT basic models listed in paragraph (1) of this Order is the test procedure for commercial refrigeration equipment prescribed by DOE at 10 CFR part 431, subpart C, appendix B, except that the test period shall be selected as detailed below. All other requirements of Appendix B and DOE's regulations remain applicable.

The test shall begin when steady state conditions occur (per ASHRAE Standard 72–2005, Section 3, definitions, which defines steady state as ''the condition where the average temperature of all test simulators changes less than 0.2 °C (0.4 °F) from one 24-hour period or refrigeration cycle to the next'' ASHRAE 72–2005, Section 3, definitions). Additionally, the door-opening requirements shall be as defined in ASHRAE 72–2005 Section 7.2, with the exception that the eight-hour period of door openings shall begin three hours after the start of the test. Ambient temperature, test simulator temperatures, and all other data shall be recorded at three-minute intervals beginning at the start of the test and throughout the 24-hour testing period.

(3) *Representations.* AHT may not make representations about the energy use of the basic models identified in paragraph (1) of this Order for compliance, marketing, or other purposes unless the basic model has been tested in accordance with the provisions set forth above and such representations fairly disclose the results of such testing in accordance with 10 CFR part 431, subpart C, appendix B and 10 CFR 429.42, as specified in this Order.

(4) This waiver shall remain in effect according to the provisions of 10 CFR 431.401.

(5) This waiver is issued on the condition that the statements, representations, and documentation provided by AHT are valid. If AHT makes any modifications to the controls or capabilities (*e.g.,* adding automatic defrost to freezer mode) of these basic models, the waiver will no longer be valid and AHT will either be required to use the current Federal test method or submit a new application for a test procedure waiver. DOE may revoke or modify this waiver at any time if it determines the factual basis underlying the petition for waiver is incorrect, or the results from the alternate test procedure are unrepresentative of the basic models' true energy consumption characteristics. 10 CFR 431.401(k)(1). Likewise, AHT may request that DOE rescind or modify the waiver if AHT discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other appropriate reasons. 10 CFR 431.401(k)(2).

(6) Granting of this waiver does not release AHT from the certification requirements set forth at 10 CFR part 429.

Signed in Washington, DC, on October 16, 2018.

Kathleen B. Hogan,

*Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy*

[FR Doc. 2018–23669 Filed 10–29–18; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF ENERGY

### Environmental Management Site-Specific Advisory Board, Oak Ridge

**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), Oak Ridge. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

**DATES:** Wednesday, November 14, 2018 6:00 p.m.

**ADDRESSES:** DOE Information Center, Office of Science and Technical Information, 1 Science.gov Way, Oak Ridge, Tennessee 37831.

**FOR FURTHER INFORMATION CONTACT:** Melyssa P. Noe, Alternate Deputy Designated Federal Officer, U.S. Department of Energy, Oak Ridge Office of Environmental Management (OREM), P.O. Box 2001, EM–942, Oak Ridge, TN 37831. Phone (865) 241–3315; Fax (865) 241–6932; Email: *Melyssa.Noe@orem.doe.gov.* Or visit the website at *https://energy.gov/orem/services/community-engagement/oak-ridge-site-specific-advisory-board.*

**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:*

- Welcome and Announcements
- Comments from the Deputy Designated Federal Officer (DDFO)
- Comments from the DOE, Tennessee Department of Environment and Conservation, and Environmental Protection Agency Liaisons
- Public Comment Period
- Presentation: Overview of Ongoing Efforts to Assure Sufficient Waste Disposal Capacity
- Motions/Approval of October 10, 2018 Meeting Minutes
- Status of Outstanding Recommendations
- Alternate DDFO Report
- Committee Reports
- Adjourn

*Public Participation:* The EM SSAB, Oak Ridge, 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 Melyssa P. Noe at least seven days in advance of the meeting at the phone 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 the agenda item should contact Melyssa P. Noe 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 Melyssa P. Noe at the address and phone number listed above. Minutes will also be available at the following website: *https://energy.gov/orem/listings/oak-ridge-site-specific-advisory-board-meetings.*

Signed in Washington, DC on October 23, 2018.

**LaTanya Butler,**

*Deputy Committee Management Officer.*

[FR Doc. 2018–23642 Filed 10–29–18; 8:45 am]

**BILLING CODE 6450–01–P**

## DEPARTMENT OF ENERGY

### Environmental Management Site-Specific Advisory Board, Paducah

**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), Paducah. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

**DATES:** Thursday, November 15, 2018 6:00 p.m.

**ADDRESSES:** West Kentucky Community and Technical College, Emerging Technology Center, 5100 Alben Barkley Drive, Paducah, Kentucky 42001.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Woodard, Deputy Designated Federal Officer, Department of Energy Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001, (270) 441–6825.

**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, Introductions, Review of Agenda
- Administrative Issues
- Public Comments (15 minutes)
- Adjourn

Breaks Taken As Appropriate.

*Public Participation:* The EM SSAB, Paducah, 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 Jennifer Woodard as soon as possible 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 Jennifer Woodard at the telephone number listed above. Requests must be received as soon as possible 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. The EM SSAB, Paducah, will hear public comments pertaining to its scope (clean-up standards and environmental restoration; waste management and disposition; stabilization and disposition of non-stockpile nuclear materials; excess facilities; future land use and long-term stewardship; risk assessment and management; and clean-up science and technology activities). Comments outside of the scope may be submitted via written statement as directed above.

*Minutes:* Minutes will be available by writing or calling Jennifer Woodard at the address and phone number listed above. Minutes will also be available at the following website: *https://www.energy.gov/pppo/pgdp-cab/listings/meeting-materials.*

Signed in Washington, DC on October 24, 2018.

**LaTanya Butler,**

*Deputy Committee Management Officer.*

[FR Doc. 2018–23643 Filed 10–29–18; 8:45 am]

**BILLING CODE 6450–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. EL16–120–000]**

### New England Power Generators, Inc. v. ISO New England Inc.; Notice of Filing

Take notice that on October 19, 2018, ISO New England Inc. submitted tariff filing per: Refund Report to be effective N/A, pursuant to the order issued by the Federal Energy Regulatory Commission (Commission) on September 20, 2018.[1]

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

*Comment Date:* 5:00 p.m. Eastern Time on November 9, 2018.

Dated: October 22, 2018.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2018–23604 Filed 10–29–18; 8:45 am]

**BILLING CODE 6717–01–P**

[1] *New England Power Generators, Inc.* v. *ISO New England Inc.,* 164 FERC ¶ 61,190 (2018).

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. CP19–4–000]**

### National Fuel Gas Supply Corporation; Notice of Request Under Blanket Authorization

Take notice that on October 11, 2018, National Fuel Gas Supply Corporation (National Fuel), 6363 Main Street, Williamsville, New York 14221, filed in Docket No. CP19–4–000, a Prior Notice Request pursuant to sections 157.205 and 157.216 of the Commission's regulations under the Natural Gas Act (NGA), and National Fuel's blanket certificate issued in Docket No. CP83–4–000, requesting authorization to plug and abandon one injection/withdrawal (I/W) well (Zoar Well 804–I) and abandon in place approximately 212 feet of 4-inch-diameter associated well line (AW 804) in the Zoar Storage Field located in Eerie County, New York. National Fuel states elevated levels of corrosion were found in the production casing of Zoar Well 804–I during evaluations and rehabilitation would be cost prohibitive due to the well's configuration and historically low volume deliverability, all as more fully described in the application which is on file with the Commission and open to public inspection. The filing 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 document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this prior notice should be directed to Alice A. Curtiss, Deputy General Counsel, National Fuel Gas Supply Corporation, 6363 Main Street, Williamsville, New York 14221, by telephone at (716) 857–7075, by fax at (716) 857–7206, or by email at *curtissa@natfuel.com* or Matthew J. Luzi, Regulatory Analyst II, National Fuel Gas Supply Corporation, 6363 Main Street, Williamsville, New York 14221, by telephone (716) 857–7813, by fax (716) 857–7206, or by email at *luzim@natfuel.com.*

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

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 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 for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's EA.

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 and will be notified of any 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 and will not have the right to seek court review of the Commission's final order.

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 an original and 3 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

Dated: October 22, 2018.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2018–23600 Filed 10–29–18; 8:45 am]

BILLING CODE 6717–01–P

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. AD19–4–000]**

### Panel Member List for Hydropower Licensing Study Dispute Resolution; Notice Requesting Applications for Panel Members for Hydropower Licensing Study Dispute Resolution

This notice requests applications from those interested in being listed as potential panel members to assist in the Federal Energy Regulatory Commission's (Commission) study dispute resolution process for the integrated licensing process (ILP) of hydropower projects.

**Background**

The Commission's ILP regulations pertaining to hydroelectric licensing under the Federal Power Act encourages informal resolution of study disagreements. In cases where this is not successful, a formal study dispute resolution process is available for state and federal agencies or Indian tribes with mandatory conditioning authority.[1]

The ILP provides that the disputed study must be submitted to a dispute resolution panel consisting of a person from Commission staff, a person from the agency or Indian tribe referring the dispute to the Commission, and a third person selected by the other two panelists from a pre-established list of persons with expertise in the disputed resource area.[2] The third panel member (TPM) will serve without compensation, except for certain allowable travel expenses to be borne by the Commission (41 CFR part 301).

The role of the panel members is to make a finding, with respect to each disputed study request, on the extent to which each study criteria set forth in the regulations is or is not met,[3] and why. The panel will then make a recommendation to the Director of the Office of Energy Projects based on the panel's findings.

[1] *See* 5.14 of the final rule at *https://www.ferc.gov/industries/hydropower/indus-act/order-2002.asp.*

[2] These persons must not be otherwise involved with the proceeding.

[3] *See* 5.9 of the final rule.

TPMs can only be selected from a list of qualified persons (TPM list) that is developed and maintained by the Commission. This notice seeks additional members for the TPM list, which was originally compiled in 2004, 2010, and 2015. Current members of the TPM list do not need to reapply, but are encouraged to update their qualifications and contact information, if not current. Each qualified panel member will be listed by area(s) and sub-area(s) of technical expertise, for example Aquatic Resources—instream flows. The TPM list and qualifications will be available to the public on the Commission's website. All individuals submitting their applications to the Commission for consideration must meet the Commission's qualifications.

**Application Contents**

The applicant should describe in detail his/her qualifications in items 1–4 listed below.

1. Technical expertise, including education and experience in each resource area and sub-area for which the applicant wishes to be considered:

- Aquatic Resources
  - water quality
  - instream flows
  - fish passage
  - macroinvertebrates
  - threatened and endangered species
- Terrestrial Resources
  - wildlife biology
  - botany
  - wetlands ecology
  - threatened and endangered species
- Cultural Resources
- Recreational Resources
  - recreational flows
- Land use and Aesthetics
  - shoreline management
- Geology & Soils
  - geomorphology
  - erosion
- Socio-economics
- Engineering
  - civil engineering
  - hydraulic engineering
  - environmental engineering

2. Knowledge of the effects of construction and operation of hydroelectric projects.

3. Working knowledge of laws relevant to the expertise, such as: The Fish and Wildlife Coordination Act, the Endangered Species Act, the Clean Water Act, the Coastal Zone Management Act, the Wild and Scenic Rivers Act, the Federal Power Act, or other applicable laws.

4. Ability to promote constructive communication about a disputed study.

**How To Submit Applications**

Applicants must submit their applications along with the names and contact information of three references. Applications will be evaluated as they are received, and each applicant will be individually notified of the Commission's decision.

*Date:* Applications are requested by January 31, 2019. However, the application period will remain open indefinitely to maintain a current listing of potential applicants.

*Address:* Applications must be filed electronically. See the instructions on the Commission's website (*https://www.ferc.gov/docs-filing/efiling.asp*). Applications should reference ''Docket No. AD19–4–000, Notice Requesting Applications for Panel Member List for Hydropower Licensing Study Dispute Resolution''.

*Other Information:* Complete individual contact information must be provided. However, contact information for the applicant and their references may be filed as ''privileged''. See the instructions on the Commission's website at *https://www.ferc.gov/docs-filing/efiling.asp.*

**FOR FURTHER INFORMATION CONTACT:** Kim Nguyen, Federal Energy Regulatory Commission, Office of Energy Projects, 888 First Street NE, Room 61–01, Washington, DC 20426, (202) 502–6105, *Kim.Nguyen@ferc.gov*.

Dated: October 22, 2018.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2018–23602 Filed 10–29–18; 8:45 am]

BILLING CODE 6717–01–P

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket Nos. CP15–550–000; CP15–551–000; CP15–551–001]**

### Venture Global Calcasieu Pass, LLC; TransCameron Pipeline, LLC; Notice of Availability of the Final Environmental Impact Statement for the Proposed Calcasieu Pass Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a final environmental impact statement (EIS) for the Calcasieu Pass Project, proposed by Venture Global Calcasieu Pass, LLC (Venture Global Calcasieu Pass) and TransCameron Pipeline, LLC (TransCameron Pipeline) in the above-referenced dockets. Venture Global Calcasieu Pass requests authorization to site, construct, and operate a natural gas liquefaction and storage facility, and marine export terminal in Cameron Parish, Louisiana. TransCameron Pipeline requests authorization to construct, install, and operate certain natural gas pipeline facilities also in Cameron Parish, Louisiana. The new liquefaction facilities would have a peak production capacity of 12 million metric tons of liquefied natural gas (LNG) per annum.

The final EIS assesses the potential environmental effects of construction and operation of the Calcasieu Pass Project in accordance with the requirements of the National Environmental Policy Act. The FERC staff concludes that approval of the proposed project, with the mitigation measures recommended in the EIS, would have some adverse environmental impact; however, all of these impacts would be reduced to less-than-significant levels.

The U.S. Army Corps of Engineers, U.S. Coast Guard, U.S. Department of Energy, U.S. Environmental Protection Agency, and U.S. Department of Transportation participated as cooperating agencies in the preparation of the EIS. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by a proposal and participate in the National Environmental Policy Act analysis. Although the cooperating agencies provided input on the conclusions and recommendations presented in the final EIS, the agencies will present their own conclusions and recommendations in their respective Records of Decision for the project.

The final EIS addresses the potential environmental effects of the construction and operation of the following project facilities:

- Nine integrated pre-cooled single mixed refrigerant (SMR) blocks;
- two full-containment aboveground LNG storage tanks, each with a usable capacity of approximately 200,000 cubic meters;
- a 1,500-foot by 3,000-foot turning basin adjacent to the Calcasieu River Ship Channel;
- two LNG berthing docks, each designed to handle carriers of 120,000 to 210,000 cubic meter cargo capacity;
- a 720 megawatt natural gas-fired combined cycle gas turbine electric generation facility;
- approximately 23.4 miles of 42-inch-diameter pipeline to bring feed gas from interconnections with ANR Pipeline Company, Texas Eastern Transmission, LP, and Bridgeline Holdings, LP to the terminal site;
- one meter station;
- three mainline valves; and
- one pig launcher at the meter station and one pig receiver at the gas gate station on the terminal site.

The Commission staff mailed a copy of the *Notice of Availability* to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; and libraries in the project area. The final EIS is only available in electronic format. It may be viewed and downloaded from the FERC's website (*www.ferc.gov*), on the Environmental Documents page (*https://www.ferc.gov/industries/gas/enviro/eis.asp*). In addition, the final EIS may be accessed by using the eLibrary link on the FERC's website. Click on the eLibrary link (*https://www.ferc.gov/docs-filing/elibrary.asp*), click on General Search, and enter the docket number in the ''Docket Number'' field, excluding the last three digits (*i.e.* CP15–550 or CP15–551). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: October 22, 2018.

**Kimberly D. Bose,**

*Secretary.*

[FR Doc. 2018–23603 Filed 10–29–18; 8:45 am]

**BILLING CODE 6717–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[Docket ID No. EPA–R08–OAR–2018–0389; FRL–9985–60–Region 8]**

## North Dakota Pollutant Discharge Elimination System; Transfer

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of availability; request for comment.

**SUMMARY:** The Environmental Protection Agency (EPA) is providing notice of a proposed program revision to transfer the authority to implement and enforce the North Dakota Pollutant Discharge Elimination System (NDPDES) program from the North Dakota Department of Health (NDDOH) to the newly established North Dakota Department of Environmental Quality (NDDEQ). If approved, the NDDEQ will administer the approved NDPDES program regulating discharges of pollutants into waters of the United States under its jurisdiction as described in the state's program application. The EPA will retain the authority to issue NPDES permits for facilities located in Indian country and/or discharging to waters in Indian country.

**DATES:** Written comments and/or requests for a public hearing must be received on or before November 29, 2018.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R08–OAR–2018–0389, to the Federal Rulemaking Portal: *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *www.regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

*Docket:* All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Wastewater Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. The EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding federal holidays.

**FOR FURTHER INFORMATION CONTACT:** VelRey Lozano, U.S. Environmental Protection Agency, Region 8, (8WP–CWW), 1595 Wynkoop Street, Denver, Colorado 80202–1129, 303–312–6128, email *lozano.velrey@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Background Information

On April 7, 2017, the Governor of North Dakota signed a bill into law mandating the creation of a new North Dakota Department of Environmental Quality. NDDEQ will be a cabinet-level agency that will implement all of the federally authorized or delegated environmental programs currently run by the Environmental Health Section of NDDOH. The law gives NDDOH until July 1, 2019, to obtain the necessary program authorizations and approvals from EPA to allow NDDEQ to implement the State's delegated and/or authorized environmental programs.

A state may revise its NPDES program. 40 CFR 123.62(a). In doing so, the State must submit a modified program description, Attorney General's statement, Memorandum of Agreement or other such documentation as EPA determines to be necessary under the circumstances. 40 CFR 123.62(b). States with approved programs are required to notify EPA whenever they propose to transfer all or part of the approved State agency to any other State agency and to identify any new division of responsibilities amongst the agencies involved. 40 CFR 123.62(c). Organizational charts required in the State's original authorization package must be revised and resubmitted. *Id.* The new agency is not authorized to administer the program until approved by the Regional Administrator.

On July 30, 2018, the EPA received a complete program revision package from the state of North Dakota. The EPA has determined the program revision package contains all the required elements. The full program revision package is available for inspection and copying at the addresses appearing in the **ADDRESSES** section of this notice.

**General Information**

*A. Does this action apply to me?*

Entities potentially affected by this action are: The EPA; and the regulated community and residents within the state of North Dakota (see Table 1). This table is not intended to be exhaustive; rather, it provides a guide for readers regarding entities that this action is likely to affect.

TABLE 1—ENTITIES POTENTIALLY AFFECTED BY THIS PROPOSED APPROVAL

| Category | Examples of potentially affected entities |
|---|---|
| State and Indian Tribal Governments, and Federal Agencies. | States and Indian tribes that provide certification under section 401 of the CWA; States, Indian Tribes, and federal agencies that own or operate treatment works outside of Indian country that require an NDPDES permit. |
| Municipalities | POTWs required to apply for or seek coverage under an NDPDES individual or general permit and to perform routine monitoring as a condition of an NDPDES permit. |
| Industry | Facilities required to apply for or seek coverage under an NDPDES individual or general permit and to perform routine monitoring as a condition of an NDPDES permit. |
| NDPDES Stakeholders | Any party that may review and provide comments on NDPDES permits. |
| Residents of the state of North Dakota | Any party that may review and provide comments on NDPDES permits. |

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What action is EPA taking?*

With this action, the EPA is providing notice of a proposed program revision to the State of North Dakota's approved NPDES program to transfer authority to administer the NDPDES program from the NDDOH to the NDDEQ. This action is not changing the current scope of North Dakota's NDPDES program and is transferring authority to another agency to implement the state's current NPDES program as part of the larger effort to move all federally authorized or delegated environmental programs from the NDDOH to the NDDEQ. If the proposed program revision is approved, EPA will retain the authority to issue permits for facilities located in Indian country [1] and/or discharging to waters in Indian country.

*C. What is EPA's authority for taking this action?*

This action is taken under the authority of section 402 of the Clean Water Act as amended, 33 U.S.C. 1342. Under 40 CFR 123.62(b)(2), the EPA is required to determine whether proposed program revisions are substantial and, if so, issue public notice and provide an opportunity to comment for a period of at least 30 days. The EPA considers this transfer of state authority to be substantial.

Dated: October 24, 2018.

**Darcy O'Connor,**

*Assistant Regional Administrator, Office of Water Protection, EPA, Region 8.*

[FR Doc. 2018–23632 Filed 10–29–18; 8:45 am]

**BILLING CODE 6560–50–P**

[1] EPA's approval of North Dakota's request to transfer its NPDES authority from the North Dakota Department of Health to the North Dakota Department of Environmental Quality does not extend to Indian country. As defined in 18 U.S.C. Section 1151, Indian country generally includes lands within the exterior boundaries of the following Indian reservations located within North Dakota: The Fort Berthold Indian Reservation, the Spirit Lake Reservation, the Standing Rock Sioux Reservation, and the Turtle Mountain Reservation; any land held in trust by the United States for an Indian tribe; and any other areas that are ''Indian country'' within the meaning of 18 U.S.C. Section 1151. EPA, or eligible Indian tribes, as appropriate, will retain responsibilities under the Clean Water Act NPDES program for wastewater discharges in Indian country.

## ENVIRONMENTAL PROTECTION AGENCY

**[EPA–HQ–OECA–2014–0061; FRL–9985–59–OEI]**

## Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mill (Renewal)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mill (EPA ICR Number 1805.10, OMB Control Number 2060–0377), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a request for approval of a new collection. Public comments were previously requested via the **Federal Register** on June 29, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

**DATES:** Additional comments may be submitted on or before November 29, 2018.

**ADDRESSES:** Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0061, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

The EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

**FOR FURTHER INFORMATION CONTACT:** Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

**SUPPLEMENTARY INFORMATION:** Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket

can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about the EPA's public docket, visit: *http://www.epa.gov/dockets.*

*Abstract:* The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills apply to new and existing chemical recovery combustion sources at kraft, soda, sulfite, and stand-alone semichemical pulp mills, for which the chemical recovery combustion sources emit greater than or equal to 10 tons per year (tpy) of any one hazardous air pollutant (HAP) or greater than or equal to 25 tpy of any combination of HAPs. In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of any failures to meet applicable standards, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to 40 CFR part 63, subpart MM.

*Form Numbers:* None.

*Respondents/affected entities:* Chemical recovery combustion sources at kraft, soda, sulfite, and stand-alone semichemical pulp mills.

*Respondent's obligation to respond:* Mandatory (40 CFR part 63, subpart MM).

*Estimated number of respondents:* 107 (total).

*Frequency of response:* Initially, occasionally, and semiannually.

*Total estimated burden:* 122,000 hours (per year). Burden is defined at 5 CFR 1320.3(b).

*Total estimated cost:* $14,700,000 (per year), which includes $831,000 in annualized capital/startup and/or operation & maintenance costs.

*Changes in the Estimates:* There is decrease in the total estimated respondent burden compared with the ICR currently approved by OMB. This ICR includes a more accurate estimate of the number of new respondents based on EPA's recent consultations with industry trade groups, which indicated that one new facility will start up in the third year of this information collection, in addition to the one new respondent per year that is an existing facility constructing new process units. This ICR also updates the burden associated with the October 11, 2017 RTR amendments, including removing first-year costs associated with the amendments, and accounting for the remaining one-time burden for facilities that applies through October 2020.

**Courtney Kerwin,**

*Director, Regulatory Support Division.*

[FR Doc. 2018–23648 Filed 10–29–18; 8:45 am]

**BILLING CODE 6560–50–P**

## FEDERAL DEPOSIT INSURANCE CORPORATION

**[OMB No. 3064–0121; 3064–0135]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Notice and request for comment.

**SUMMARY:** The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collections described below (3064–0121 and 3064–0135). On August 20, 2018, the FDIC requested comment for 60 days on a proposal to renew the information collections described below. No comments were received. The FDIC hereby gives notice of its plan to submit to OMB a request to approve the renewal of these information collections, and again invites comment on these renewals.

**DATES:** Comments must be submitted on or before November 29, 2018.

**ADDRESSES:** Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *https://www.FDIC.gov/regulations/laws/federal.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202–898–3767), Counsel, MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Manny Cabeza, Counsel, 202–898–3767, *mcabeza@fdic.gov,* MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

**SUPPLEMENTARY INFORMATION:** On August 20, 2018, the FDIC requested comment for 60 days on a proposal to renew the information collections described below. No comments were received. The FDIC hereby gives notice of its plan to submit to OMB a request to approve the renewal of these collections, and again invites comment on these renewals.

*Proposal to renew the following currently approved collections of information:*

1. *Title:* Certification of Compliance with Mandatory Bars to Employment.

*OMB Number:* 3064–00121.

*Form Number:* 2120/16.

*Affected Public:* Individuals seeking employment from the FDIC.

*Burden Estimate:*

SUMMARY OF ANNUAL BURDEN

| | Type of burden | Estimated number of respondents | Estimated time per response | Frequency of response | Total annual estimated burden hours |
|---|---|---|---|---|---|
| Form 2120/16 | Reporting | 500 | 10 minutes | On Occasion | 83 |

*General Description of Collection:* There has been no change in the method or substance of this information collection. The change in estimates annual burden is due to a decrease in estimated number of new hires from an annual average of 600 in 2015 to an annual average of 500 currently. This information collection arises from the reporting requirements contained in 12 CFR part 336, subpart B of the FDIC Rules and Regulations entitled

''Minimum Standards of Fitness for Employment with the Federal Deposit Insurance Corporation''. This rule implements Section 19 of the Resolution Trust Corporation Completion Act (''Completion Act''), Public Law 103–204, by (among other things) prescribing a certification, with attachments in some cases, relating to job applicants' fitness and integrity. More specifically, the statute provides that the FDIC shall issue regulations implementing provisions that prohibit any person from becoming employed by FDIC, who has been convicted of any felony; has been removed from, or prohibited from participating in the affairs of, any insured depository institution pursuant to any final enforcement action by any appropriate federal banking agency; has demonstrated a pattern or practice of defalcation regarding obligations to insured depository institutions; or has caused a substantial loss to federal deposit insurance funds. This collection of information implements these mandatory bars to employment through a certification, signed by job applicants prior to an offer of employment using form 2120/16.

2. *Title:* Purchaser Eligibility Certification.

*OMB Number:* 3064–0135.

*Form Number:* 7300–06.

*Affected Public:* Individuals and entities wishing to purchase receivership assets from the FDIC.

*Burden Estimate:* There has been no change in the method or substance of this information collection. The Subject Matter Experts (SMEs) from the FDIC's Division of Resolutions and Receiverships have estimated that this information collection will affect 600 respondents annually for the next three years. This estimate is unchanged from 2015. The SMEs reached this estimate by calculating the average number of Purchaser Eligibility Certifications (PECs) completed in the past three years and rounding up.

| Year | Number of PECs [1] |
|---|---|
| 2015 | 952 |
| 2016 | 468 |
| 2017 | 369 |
| Total | 1,789 |
| Three-Year Average | 596.33 |

[1] SMEs within the FDIC's Division of Resolutions and Receiverships (DRR) compiled this information by the contacting the managers that handle each asset sales category (structured transactions, cash loan sales, other real estate sales, and securities sales).

The number of PECs completed each year has been declining since 2009. If this trend were to continue, the number of respondents would be expected to continue to decrease from 369 over the next three years, which would imply that the estimated number of respondents should be lower for this collection compared to the one in 2015. The SMEs have acknowledged that 600 respondents may be a conservative estimate, but also believe that it is reasonable. This rationale stems from the fact that the current rate of bank failures is very low. The SMEs also point out that the PECs are collected from prospective purchasers and not just the winning bidders. As a result, the annual number of PECs could increase if there is an increase in the demand for the assets the FDIC sells even if the number of assets for sale decreases in line with the current trend of diminishing bank failures.

The estimated hourly burden for this information collection is 30 minutes per PEC form. The SMEs have arrived at this estimate through their personal observations of individuals completing these forms at open-outcry auction events. The table below contains estimates for the total estimated reporting burden for this information collection.

SUMMARY OF ANNUAL BURDEN

| | Type of burden | Estimated number of respondents | Estimated frequency of responses | Estimated time per response (hrs) | Total estimated annual burden (hrs) |
|---|---|---|---|---|---|
| Purchaser Eligibility Certification | Reporting | 600 | 1 | 0.50 | 300.00 |

**Request for Comment**

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2018–23597 Filed 10–29–18; 8:45 am]

BILLING CODE 6714–01–P

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications

must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 27, 2018.

*A. Federal Reserve Bank of New York* (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001. Comments can also be sent electronically to *Comments.applications@ny.frb.org:*

1. *The Adirondack Trust Company Employee Stock Ownership Trust, Saratoga Springs, New York;* to acquire fifty additional shares of 473 Broadway Holding Corporation and two thousand additional shares of The Adirondack Trust Company, both of Saratoga Springs, New York.

*B. Federal Reserve Bank of Kansas City* (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Foote Financial Services, LLC, Hoxie, Kansas;* to become a bank holding company by acquiring voting shares of Peoples State Bank, Manhattan, Kansas.

Board of Governors of the Federal Reserve System, October 25, 2018.

**Yao-Chin Chao,**

*Assistant Secretary of the Board.*

[FR Doc. 2018–23682 Filed 10–29–18; 8:45 am]

BILLING CODE P

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association and nonbanking companies owned by the savings and loan holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the HOLA (12 U.S.C. 1467a(e)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 10(c)(4)(B) of the HOLA (12 U.S.C. 1467a(c)(4)(B)). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 27, 2018.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *Comments.applications@phil.frb.org:*

1. *WSFS Financial Corporation, Wilmington, Delaware;* to merge with Beneficial Bancorp, Inc., Philadelphia, Pennsylvania, and therefore indirectly acquire shares of Beneficial Bank, Philadelphia, Pennsylvania. WSFS Financial Corporation has applied to become a savings and loan holding company with respect to Beneficial Bank's conversion to a stock federal savings association.

Board of Governors of the Federal Reserve System, October 25, 2018.

**Yao-Chin Chao,**

*Assistant Secretary of the Board.*

[FR Doc. 2018–23683 Filed 10–29–18; 8:45 am]

BILLING CODE P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

### Performance Review Board Membership

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice of Performance Review Board Membership.

**FOR FURTHER INFORMATION CONTACT:** Kathy Vaughn, 410–786–1050 or *katherine.vaughn@cms.hhs.gov.*

**SUMMARY:** 5 U.S.C. 4314(c)(1) through (5) requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more Senior Executive Service (SES) Performance Review Boards.

The PRB shall review and evaluate the initial summary rating of a senior executive's performance, the executive's response, and the higher-level official's comments on the initial summary rating. In addition, the PRB will review and recommend executive performance bonuses and pay increases.

5 U.S.C. 4314(c)(4) requires the appointment of board members to be published in the **Federal Register**. The following persons comprise a standing roster to serve as members of the SES PRB for the Centers for Medicare & Medicaid Services:

Elisabeth Handley, Director, Office of Human Capital (serves as the Chair)
Demetrious Kouzoukas, Principal Deputy Administrator for Medicare
Karen Jackson, Deputy Chief Operating Officer
Jeffrey Wu, Deputy Director for Operations, Center for Consumer Information and Insurance Oversight
Jean Moody-Williams, Deputy Center Director, Center for Clinical Standards and Quality
Nancy O'Connor, Philadelphia Regional Administrator

Dated: October 16, 2018.

**Elisabeth Handley,**

*Director, Office of Human Capital.*

[FR Doc. 2018–23814 Filed 10–29–18; 8:45 am]

BILLING CODE 4120–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–3369–PN]**

### Medicare and Medicaid Programs: Application From the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) for Continued CMS-Approval of Its Outpatient Physical Therapy and Speech Language Pathology Services Accreditation Program

**AGENCY:** Centers for Medicare and Medicaid Services (CMS), HHS.

**ACTION:** Notice with request for comment.

**SUMMARY:** This proposed notice acknowledges the receipt of an application from the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) for continued recognition as a national accrediting organization (AO) for clinics, rehabilitation agencies, or public health agencies that furnish outpatient physical therapy and speech language pathology services that wish to participate in the Medicare or Medicaid programs.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 29, 2018.

**ADDRESSES:** In commenting, please refer to file code CMS–3369–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3369–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3369–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Erin McCoy, (410) 786–2337, Monda Shaver, (410) 786–3410, or Renee Henry, (410) 786–7828.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

## I. Background

Under section 1861(p) of the Medicare statute, eligible beneficiaries may receive outpatient physical therapy and speech language pathology (OPT) services from a provider of services, a clinic, rehabilitation agency, a public health agency, or others, provided certain requirements are met. Section 1832(a)(2)(C) of the Social Security Act (the Act) permits payment for OPT services. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 485 subpart H specify the conditions that a clinic, rehabilitation agency or public health agency (''OPT providers'') must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for OPT providers.

Generally, to enter into an agreement, an OPT provider must first be certified by a State survey agency as complying with the conditions of participation set forth in part 485, subpart H of our Medicare regulations. Thereafter, the OPT provider is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we may deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. An AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at § 488.5.

AAAASF's current term of approval for its OPT provider accreditation program expires April 4, 2019.

## II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of an AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of AAAASF's request for continued CMS approval of its OPT provider accreditation program. This proposed notice also solicits public comment on whether AAAASF's requirements meet or exceed the Medicare conditions of participation (CoPs) for OPT providers.

## III. Evaluation of an AO's Accreditation Program

AAAASF submitted all the necessary materials to enable us to make a determination concerning its request for continued CMS-approval of its OPT provider accreditation program. This application was determined to be complete on September 6, 2018. Under Section 1865(a)(2) of the Act and our regulations at § 488.5, our review and evaluation of AAAASF will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of AAAASF's standards for OPT providers as compared with Medicare's CoPs for OPT providers.
- AAAASF's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of AAAASF's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ AAAASF's processes and procedures for monitoring an OPT provider found out of compliance with AAAASF's program requirements. These monitoring procedures are used only when AAAASF identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c)(1).

++ AAAASF's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ AAAASF's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of AAAASF's staff and other resources, and its financial viability.

++ AAAASF's capacity to adequately fund required surveys.

++ AAAASF's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ AAAASF's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

## IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

## V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this proposed notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

Dated: October 19, 2018.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2018–23611 Filed 10–29–18; 8:45 am]

BILLING CODE 4120–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–3689]**

## 21st Century Cures: Announcing the Establishment of a Surrogate Endpoint Table; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the establishment of a public docket to receive suggestions and comments from interested parties (including academic institutions, regulated industry, and patient groups) on the Agency's publication of the surrogate endpoint table (SE table). FDA has developed a web page, available at *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm613636.htm* that displays the SE table, describes the purpose of the table, and provides additional background information. Comments received on the SE table will help FDA determine its utility and may assist FDA in developing future iterations of the SE table and identifying best methods for conveying information about SEs on the FDA's website.

**DATES:** Submit either electronic or written comments on this notice by December 31, 2018.

**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 December 31, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 31, 2018. 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–3689 for ''21st Century Cures: Announcing the Establishment of a Surrogate Endpoint Table.'' 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:** Christopher Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6461, Silver Spring, MD 20993–0002, 301–796–0017, *Christopher.Leptak@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 3011 of the 21st Century Cures Act established section 507 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 357), which mandates that FDA publish a list of surrogate endpoints used as a basis to approve or license a drug or biological product under both accelerated and traditional approval provisions. The SE table fulfills this legislative requirement and is intended to provide valuable information for drug developers on endpoints that may be considered and discussed with FDA for individual development programs. FDA refers the public to the following web page for additional background information as well as the SE table: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm606684.htm.*

Section 507(e)(9) of the FD&C Act defines the term ''surrogate endpoint'' to mean a marker, *e.g.,* a laboratory measurement, radiographic image, physical sign, or other measure, that does not directly measure clinical benefit but (1) is known to predict clinical benefit and can potentially be used to support traditional approval of a drug or biological product or (2) is reasonably likely to predict clinical benefit and could be used to support accelerated approval in accordance with section 506(c) of the FD&C Act (21 U.S.C. 356(c)).

This SE table includes SEs that sponsors have used as primary efficacy clinical trial endpoints for approval of new drug applications (NDAs) or biologics license applications (BLAs). The table also includes SEs that may be appropriate for use as a primary efficacy clinical trial endpoint for drug or biologic approval, although the SEs have not necessarily been used to support an approved NDA or BLA. FDA believes that this table should facilitate discussions of potential SEs by sponsors when developers are designing their drug development programs.

## II. Additional Issues for Consideration

To help FDA determine the utility of the SE table, develop future iterations of the SE table, and identify best methods for conveying this information on FDA's website, FDA is soliciting public suggestions and comments on the SE table listed on the following web page: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm606684.htm.*

Specifically, FDA welcomes comments concerning: (1) The utility of the SE table; (2) suggestions on SEs that may not be reflected on the current SE table but that have been used for drug or biologic approvals; (3) the best approach for developing future iterations of the table, and (4) SE table questions you would like FDA to address in future communications. As required by section 507(c)(1) of the FD&C Act, FDA will update this table on the website every 6 months. The Agency will consider comments submitted to the docket as it revises the SE table.

Dated: October 25, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–23641 Filed 10–29–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–3809]**

### Sesame as an Allergen in Foods

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or we) invites data and other information on the prevalence and severity of sesame allergies in the United States and the prevalence of sesame-containing foods sold in the United States that are not required to disclose sesame as an ingredient. We are taking this action to inform possible regulatory action on sesame to protect and promote the public health.

**DATES:** Submit either electronic or written comments on this document by December 31, 2018.

**ADDRESSES:** You may submit comments as follows. Electronic comments must be submitted on or before December 31, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 31, 2018. 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–3809 for ''Sesame as an Allergen in Foods.''

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.'' We will review this copy, including the claimed confidential information, in our 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:**

Carol D'Lima, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2033.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Food allergies occur when the body's immune system reacts to certain food proteins (Ref. 1). Allergic reactions to food due to immunoglobulin E (IgE) antibodies cause the body to release inflammatory chemicals and can be particularly severe, leading to symptoms such as hives, facial swelling, vomiting, wheezing, shock, and even death. Because there is no cure for food allergies, allergic consumers must use avoidance to prevent allergic reactions. Successful avoidance requires, among other things, that allergic consumers and their caregivers can read and understand the relevant information on packaged food labels and can identify food allergens in other settings, such as at retail or food service establishments.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that a food (other than a raw agricultural commodity) that bears or contains a ''major food allergen'' declare the allergen using its ''common or usual name.'' A food is misbranded if it contains a major food allergen and fails to declare that major food allergen on its label using the major food allergen's common or usual name (section 403(w) of the FD&C Act). The FD&C Act defines a ''major food allergen,'' in part, as any of the following:

• Milk,
• Eggs,
• Fish (*e.g.,* bass, flounder, or cod),
• Crustacean shellfish (*e.g.,* crab, lobster, or shrimp),
• Tree nuts (*e.g.,* almonds, pecans, or walnuts),
• Wheat,
• Peanuts, and
• Soybeans.

See section 201(qq)(1) of the FD&C Act (21 U.S.C. 321(qq)(1)). When Congress amended the FD&C Act regarding food allergens in 2004, these eight foods and food groups, out of more than 160 identified food allergens, accounted for 90 percent of serious food allergic reactions. We issued guidance in 2006 to help the public understand our implementation of the amendments, including what foods and manufacturers are subject to the amendments and labeling requirements (Ref. 2). We issued another guidance in 2014 to clarify the information we need when considering whether to exempt certain ingredients derived from major food allergens from the allergen labeling requirements (Ref. 3). These statutory requirements with respect to a label or labeling for major food allergens do not alter the authority of the Secretary of Health and Human Services under the FD&C Act to require a label or labeling for other food allergens (21 U.S.C. 343 note).

A common or usual name must accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients and can either be the name established by common use or the name required by a regulation (21 CFR 102.5). In addition to the specific requirement for allergen labeling, any food is misbranded unless its label uses: (1) The common or usual name of the food, if it has one, and (2) the common or usual name of each ingredient, if the food is made from two or more ingredients (section 403(i) of the FD&C Act). Thus, the FD&C Act includes other authorities that assist consumers with a food allergy or other reason for avoiding an ingredient. For example, the label of a food made with sugar must declare this ingredient by its common or usual name—''sugar''—rather than the chemical name ''sucrose'' (see section 403(i) of the FD&C Act (21 U.S.C. 343(i))).

In addition, section 403(x) of the FD&C Act gives us the authority to issue regulations requiring the disclosure of spices, flavorings, colorings, and incidental additives that are, or contain, allergens other than the eight major food allergens. We relied on this authority, in part, to require the labeling of carmine and cochineal in foods (see 74 FR 207).

In 2014, the Center for Science in the Public Interest, several medical professionals, and two consumer advocacy groups submitted a citizen petition (Ref. 4) requesting, in part, that we issue a rule to require that sesame seeds and sesame products be regulated in a manner similar to the manner in which major food allergens are regulated under the FD&C Act, and specifically to require sesame's disclosure by the common or usual name ''sesame'' in food labeling. The petition noted, among other things, that the European Union, Canada, Australia, and New Zealand require labeling of

sesame and provided scientific information to support the petitioners' argument that sesame is an allergen of public health concern. The petition also requested that we add sesame to our list of allergens in our Compliance Policy Guide, which includes discussion of adulteration due to insufficient controls to prevent potential allergen cross-contact (the unintentional incorporation of allergens into foods that are not intended to include those allergens) (Ref. 5). Since the citizen petition was posted, more than 750 comments have been submitted to the docket.

We are interested in learning more about the prevalence and severity of sesame allergies in the United States, and the prevalence of sesame-containing foods sold in the United States that are not required to disclose sesame as an ingredient. We will consider the data and other information submitted, along with previously submitted information, to inform possible steps on sesame as an allergen in food to protect and promote the public health.

## II. Additional Issues for Consideration; Request for Data and Information

We invite comment, particularly scientific data and other evidence, about the following topics:

### *A. Prevalence of Allergies and Allergic Reactions Due to Sesame in the United States*

1. What is the prevalence of IgE-mediated sesame food allergies in the United States? Please provide any studies or data that support your conclusion, and provide your unit of measure (*e.g.,* ''1 in 10,000 adults''). What is the nature of the allergic response(s) to sesame in food and what are the impacts on consumers?

2. How does the prevalence of IgE-mediated sesame food allergies in the United States compare to the prevalence of IgE-mediated allergies to the major food allergens? Please provide any studies or data that support your conclusion.

3. What proportion of allergic reactions in the United States may be attributed specifically to exposure to undeclared sesame? Please provide any studies or data that support your conclusion.

4. What proportion of allergic reactions to undeclared sesame occur in response to sesame found in packaged food products versus sesame found in foods served at retail or food service establishments (*e.g.,* restaurants, grocery stores, supermarkets, hospitals, nursing homes, childcare centers, and temporary food establishments)?

5. In packaged food products, what proportion of allergic reactions to sesame is due to:

a. Sesame in generically listed spices, flavorings, colorings, or incidental additives;

b. Sesame used as an ingredient and listed by some other name (*e.g.,* ''tahini'' rather than ''sesame''); or

c. Cross-contact?

### *B. Prevalence and Amounts of Undeclared Sesame in Foods*

1. What are examples of products or product categories that contain sesame as a spice, flavor, color, or incidental additive and that do not list ''sesame'' on the product labeling?

2. What amount or concentration of sesame is in products or product categories that contain sesame as a spice, flavor, color, or incidental additive and that do not list ''sesame'' on the product labeling? Please provide a unit of measure (*e.g.,* ''5 grams of sesame per kilogram of packaged food product'' or ''50 milligrams of sesame protein per serving'').

3. What are examples of products or product categories other than ''spices'' that contain sesame in one of the listed ingredients, but the common or usual name of that ingredient does not list ''sesame,'' specifically, on the product labeling? Please provide a copy of the labeling, if available.

4. What amount or concentration of sesame is in products or product categories that contain sesame in one of the listed ingredients, but the common or usual name of that ingredient does not list ''sesame,'' specifically, on the product labeling? Please provide a unit of measure (*e.g.,* ''5 grams of sesame per kilogram of packaged food product'' or ''50 milligrams of sesame protein per serving'').

5. What are examples of food products or product categories in which sesame has been found in a product because of cross-contact?

6. What amount or concentration of sesame has been found in products or product categories that contain sesame because of cross-contact? Please provide a unit of measure (*e.g.,* ''5 grams of sesame per kilogram of packaged food product'' or ''50 milligrams of sesame protein per serving'').

### *C. Possible Costs of Any Future Regulatory Action FDA Might Take Regarding Sesame*

1. What would the costs be if we established disclosure requirements for sesame? We are interested in any costs, specifically those to manufacturers for labeling changes to reflect sesame as an ingredient, spice, flavor, color, or incidental additive.

2. What would the costs be to manufacturers to control allergen cross-contact from sesame and what would the costs be of educating food managers at retail or food establishments to control for sesame as an allergen?

3. What steps have manufacturers taken to eliminate or reduce cross-contact from sesame and/or sesame-containing ingredients?

## III. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* 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. ''Food Allergies: What You Need to Know.'' March 2017. Available at *https://www.fda.gov/downloads/Food/ResourcesForYou/Consumers/UCM220117.pdf.*
2. ''Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004'' (Edition 4). October 2006. Available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm059116.htm.*
3. ''Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications.'' May 2014. Available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm395494.htm.*
4. Docket No. FDA–2014–P–2035, available at *https://www.regulations.gov/docket?D=FDA-2014-P-2035.*
5. ''Compliance Policy Guide Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens.'' August 2000. Available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-ice/documents/webcontent/ucm074552.pdf.*

Dated: October 24, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–23635 Filed 10–29–18; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–D–3759]**

### Considerations for the Development of Dried Plasma Products Intended for Transfusion; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled ''Considerations for the Development of Dried Plasma Products Intended for Transfusion; Draft Guidance for Industry.'' This guidance is intended to assist manufacturers, sponsors, and applicants developing dried plasma products intended for transfusion in order to facilitate the availability of safe and effective dried plasma products in the United States. The draft guidance document provides considerations for the successful development and licensing of dried plasma products and for the approval of devices used to manufacture dried plasma. The guidance includes recommendations on optimal sources of input plasma; manufacturing and product quality, including product characterization; packaging and reconstitution; clinical studies; and device submissions.

**DATES:** Submit either electronic or written comments on the draft guidance by January 28, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2018–D–3759 for ''Considerations for the Development of Dried Plasma Intended for Transfusion; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft document entitled ''Considerations for the Development of Dried Plasma Products Intended for Transfusion; Draft Guidance for Industry.'' Plasma is a critical component of early transfusion therapy in the management of traumatic hemorrhage. Plasma can replenish various coagulation proteins that are consumed during the coagulopathy that can accompany traumatic injury. Because plasma products intended for transfusion such as fresh frozen plasma (FFP), plasma frozen within 24 hours after phlebotomy (PF24), and plasma frozen within 24 hours after phlebotomy held at room temperature up to 24 hours after phlebotomy (PF24, RT24) are stored frozen, these products need to be thawed prior to transfusion. This limits

or prevents the use of plasma in settings where freezers and other support equipment are unavailable (*e.g.* battlefields, remote locations, and other austere settings) and may lead to delayed administration. Dried plasma (such as freeze-dried or spray-dried plasma) offers the potential to address these challenges by providing a product that is stable at ambient temperatures and can be rapidly reconstituted and transfused.

Recent clinical studies have demonstrated promising efficacy and safety of dried plasma, particularly in military applications, and dried plasma products are available for limited use in Germany, South Africa, and France. This guidance is intended to assist manufacturers, sponsors, and applicants developing dried plasma products intended for transfusion in order to facilitate the availability of safe and effective dried plasma products in the United States.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on considerations for the development of dried plasma products intended for transfusion. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

## II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 610 have been approved under OMB control numbers 0910–0116, 0910–0139, and 0910–0338; the collections of information in 21 CFR part 630 have been approved under OMB control number 0910–0116; the collections of information in 21 CFR part 640 have been approved under OMB control number 0910–0116; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: October 25, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–23637 Filed 10–29–18; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–0188]**

### Denial of Hearing Request Regarding Proposal To Refuse To Approve a New Drug Application for Oxycodone Hydrochloride Immediate-Release Abuse-Deterrent Formulation, Oral Capsules, 5 Milligrams, 15 Milligrams, and 30 Milligrams; Order Refusing Approval

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Chief Scientist is denying a request for a hearing regarding the proposal by the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA or Agency) to refuse to approve a new drug application submitted by Pharmaceutical Manufacturing Research Services, Inc. (PMRS) for oxycodone hydrochloride (HCl) immediate-release (IR) capsules, 5 milligrams (mg), 15 mg, and 30 mg in its present form. The Chief Scientist denies approval.

**DATES:** The order is applicable October 30, 2018.

**FOR FURTHER INFORMATION CONTACT:** Nathan R. Sabel, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 301–796–8588.

**SUPPLEMENTARY INFORMATION:**

## I. Procedural Background

PMRS submitted new drug application (NDA) 209155 for oxycodone HCl IR capsules, 5 mg, 15 mg, and 30 mg, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)(2)), relying in part on the Agency's previous findings of safety and effectiveness for ROXICODONE (oxycodone HCl IR tablets (NDA 021011)) (Ref. 1).

PMRS's product contains excipients, including a dye blend, that have solubility in common solvents, including water and ethanol, similar to the solubility of the active pharmaceutical ingredient (API). PMRS contends that a solution prepared from its product for subcutaneous or intravenous injection will look relatively ''impure'' compared to a solution prepared from Roxicodone and will have a dark, opaque, ''contaminated-looking'' appearance, providing both a ''visual deterrent'' and a ''chemical deterrent'' to abuse by injection (Refs. 2 and 3).[1] PMRS provided in vitro data intended to show that a solution prepared for injection would have these qualities but provided no data or literature supporting the conclusion that people who inject opioids would, in fact, be deterred from injecting such a solution (Ref. 2).

PMRS also provided in vitro data intended to demonstrate that its product would be more difficult to grind into particle sizes suitable for snorting compared to ROXICODONE but provided no data from studies in human subjects to evaluate the pharmacokinetic or pharmacodynamic properties of the product following abuse via the nasal route (Ref. 1).[2] Nonetheless, PMRS proposed labeling for its product representing that it has abuse-deterrent properties (Ref. 4).

On November 16, 2017, CDER issued a complete response letter to PMRS under § 314.110(a) (21 CFR 314.110(a)) stating that the NDA could not be

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[1] With respect to the purported ''chemical deterrent'' aspect of its product, we note that PMRS's claims that its product resists physical and chemical ''extraction'' appear to rest on a misunderstanding of how that term is used in the context of abuse-deterrent opioids. PMRS appears to be using the term ''extraction'' to mean that it is difficult to separate the API from the excipients in solution, not that it is difficult to prepare a solution that contains the API. In fact, PMRS's data show that the oxycodone in its formulation can be readily extracted in commonly available solvents into a solution physically suitable for injection. These data show that more of the API could be extracted from oxycodone HCl IR capsules (approximately 98 percent of the API) than from ROXICODONE (approximately 90–91 percent) in both small and medium volume extraction and at ambient and high temperatures (Refs. 1 and 2).

[2] While PMRS initially intended for the product to confer resistance to grinding to particle sizes suitable for snorting (Ref. 7), PMRS has conceded, based on the results of its testing, that the formulation should not be considered to have this property. See Ref. 2 at 12–13 (''Because of the decrease in particle size distribution after grinding as the drug product ages, resistance to grinding cannot be considered as one of the characteristics of [PMRS' product]'').

approved in its present form, describing the specific deficiencies, and, where possible, recommending ways PMRS might remedy these deficiencies (Ref. 5). The deficiencies cited include the following:

(1) The application in its present form is not approvable with the proposed labeling describing abuse-deterrent properties, for multiple reasons. In particular, (a) the oxycodone in the formulation can be readily extracted in commonly available solvents into a solution suitable for injection; (b) there were insufficient data showing the presence of excipients (including dye) in the formulation can be expected to deter abuse by injection; (c) the data submitted were insufficient to show the product was meaningfully resistant to manipulation for misuse or abuse; and (d) there were not data submitted, including data from pharmacokinetic and human abuse liability studies, fully characterizing the product's abuse potential by all relevant routes of abuse. Also, the data submitted were not sufficient to rule out the possibility that the proposed formulation could result in a greater proportion of abuse by injection of PMRS's product compared to a conventional oxycodone IR formulation. Abuse by injection carries greater risk of overdose and transmission of infectious disease than abuse by other routes.

(2) The safety and purity of the excipients intended (but not shown) to confer abuse-deterrent properties were not adequately characterized, either by the intended oral route of use or by expected routes of abuse, including injection.

(3) An overall evaluation of elemental impurities in the final formulation and a risk assessment for each heavy metal (taking into consideration the maximum daily dose) were not provided.

(4) The application did not fully comply with the patent certification requirements applicable to applications submitted under section 505(b)(2) of the FD&C Act.

The complete response letter describes additional deficiencies relating to the chemistry, manufacturing, and controls (CMCs) and current good manufacturing practice requirements that CDER determined precluded approval of the application in its present form (Ref. 5). The complete response letter also noted that satisfactory resolution of objectionable inspection observations was required before the application could be approved (Ref. 5).

In response to the complete response letter, on November 17, 2017, PMRS submitted a request for an opportunity for hearing under § 314.110(b)(3) on whether there are grounds under section 505(d) of the FD&C Act for denying approval of the NDA.

On February 13, 2018, FDA published a notice of opportunity for a hearing (NOOH) setting forth CDER's proposal to refuse to approve PMRS's NDA for oxycodone HCl IR capsules in 5-mg, 15-mg, and 30-mg strengths (83 FR 6196). The NOOH stated that, for the reasons described above and others described in the complete response letter, notice is given to PMRS and to all other interested persons that FDA proposes to issue an order refusing to approve the NDA because the application fails to meet the criteria for approval under section 505(d) of the FD&C Act, including that: (1) PMRS has not provided sufficient data to show that the product would be safe (section 505(d)(1)); (2) PMRS has not shown that the methods used in, and the facilities and controls used for, the manufacture, processing, or packing of the product are adequate to preserve its identity, strength, quality, and purity (section 505(d)(3)); and (3) the labeling PMRS proposed for the product is false or misleading (section 505(d)(7)).

PMRS submitted a request for a hearing on February 15, 2018. PMRS also submitted data, information, and analysis in support of its hearing request on April 13, 2018 (April Submission).[3] CDER submitted a proposed order on June 13, 2018, and PMRS submitted a Response to CDER's Proposed Order on August 9, 2018 (August Submission), consistent with regulations at § 314.200(g)(3) (21 CFR 314.200(g)(3)), affording the hearing requestor 60 days to respond to a proposed order.

## II. Statutory and Regulatory Framework Regarding 21 CFR Part 12 Hearings

Under § 12.24(a)(2) (21 CFR 12.24(a)(2)), the Agency reviews a hearing request to determine whether a hearing has been justified. FDA has the authority to deny a hearing when it appears from the hearing request that there are no material disputes of fact. See *Costle* v. *Pacific Legal Found.,* 445 U.S. 198, 214 (1980) (a party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing''), *reh'g denied,* 446 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 620–21 (1973); *Pineapple Growers Ass'n* v. *FDA,* 673 F.2d 1083, 1085–86 (9th Cir. 1982) (holding that no hearing is necessary unless ''material issues of fact'' have been raised).

In determining whether there are material issues of fact suitable for a hearing, FDA considers the specific criteria set out in § 12.24(b) and grants a hearing only if the material submitted in support of the request shows the following: (1) There is a genuine and substantial factual issue for resolution at a hearing; a hearing will not be granted on issues of policy or law;[4] (2) the factual issue can be resolved by available and specifically identified reliable evidence; a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requestor; a hearing will be denied if the Agency concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate;[5] (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested (*e.g.,* if the Agency concludes that the action would be the same even if the factual issue were resolved in the way sought);[6] (5) the action requested is

[3] Although timely filed, PMRS did not submit the data, information, and factual analysis in the required format (*e.g.,* the submission lacks a statement signed by the person responsible for such submission that it includes in full all studies and information as required) (§ 314.200(d)(3)). The Chief Scientist has nevertheless reviewed PMRS's April Submission in its entirety.

[4] See also *Georgia Pacific Corp.* v. *U.S. EPA,* 671 F.2d 1235, 1241 (9th Cir. 1982) (finding that a party's argument that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' is not sufficient to justify a hearing); *Citizens for Allegan County, Inc.* v. *FPC,* 414 F.2d 1125, 1128 (D.C. Cir. 1969) (finding that ''no evidentiary hearing is required where there is no dispute on the facts and the agency proceeding involves only a question of law.''); and *Sun Oil Co.* v. *FPC,* 256 F.2d 233, 240 (5th Cir. 1958), *cert. denied,* 358 U.S. 872 (1958).

[5] See also *John D. Copanos & Sons, Inc. and Kanasco, Ltd.* v. *FDA,* 854 F.2d 510, 522 (D.C. Cir. 1988) (''The mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact . . . Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted.'') (emphasis in original), quoting *Anderson* v. *Liberty Lobby, Inc.,* 477 U.S. 242, 247–248 (1986) and *Hynson,* 412 U.S. at 620.

[6] See also *Hynson,* 412 U.S. at 621 (1973) and *Dyestuffs & Chemicals, Inc.* v. *Flemming,* 271 F.2d 281, 286 (8th Cir. 1959) (''Where the objections stated and the issues raised thereby are, even if true, legally insufficient, their effect is a nullity and no objections have been stated. Congress did not intend the governmental agencies created by it to

Continued

not inconsistent with any provision in the FD&C Act or any FDA regulation; and (6) the requirements in other applicable regulations, *e.g.,* 21 CFR 10.20, 12.21, 12.22, and 314.200, and in the NOOH are met. Similarly, § 314.200(g) provides that a person requesting a hearing ''may not rely upon allegations or denials but is required to set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing with respect to a particular drug product specified in the request for hearing.''

## III. Analysis

Following review of the administrative record related to this proceeding, the Chief Scientist [7] finds that PMRS has not raised a genuine and substantial issue of fact justifying a hearing regarding CDER's proposal to refuse to approve the NDA in its present form.[8] As further explained below, the Chief Scientist finds that a hearing would not otherwise be in the public interest. Accordingly, the Chief Scientist denies PMRS's hearing request under §§ 12.24(b) and 314.200(g) and orders approval denied under section 505(d) of the FD&C Act for PMRS's NDA in its present form.

### *A. PMRS's Request for a Hearing Is Denied Because No Genuine and Substantial Issue of Fact Exists Regarding the Lack of Sufficient, Reliable Evidence Supporting PMRS's Proposed Labeling for Abuse-Deterrent Properties*

Among other bases for proposing to deny PMRS's NDA, the NOOH cites the requirement that FDA deny approval to applications that propose labeling that is false or misleading in any particular (see section 505(d)(7) of the FD&C Act; 21 CFR 314.125(b)(6)). On this basis, the November 16, 2017, complete response letter explained that the NDA in its current form is not approvable with the proposed labeling describing abuse-deterrent properties. PMRS proposed labeling that includes multiple statements that the product has properties that make it more difficult to manipulate for purposes of abuse and misuse than a conventional formulation (Ref. 6). These statements include the assertion that the product ''is formulated with inactive ingredients that make the capsule more difficult to manipulate for misuse and abuse'' and that ''the results of this testing demonstrated that [the product] capsules, in comparison to Roxicodone tablets, have increased resistance to physical and chemical extraction.'' (Ref. 6).[9]

Specifically, the complete response letter explained that PMRS submitted ''[n]o data . . . to support the proposed hypothesis that the presence of excipients or dye in the solution would create a deterrence to intravenous abuse'' (Ref. 5). Generally, PMRS's hypothesis is that commonly used methods of preparing a solution for injection, if applied to its product, will result in a solution that will look ''visually unappealing'' compared to a solution prepared from Roxicodone, and will have a dark, opaque, ''contaminated-looking'' appearance that will serve as a ''visual deterrent'' to abuse (Ref. 2). PMRS's NDA provided in vitro data intended to show that a solution prepared for injection would have such an appearance (Refs. 2 and 3).[10]

As CDER informed PMRS during the application process, CDER considered this in vitro data unable to prove that PMRS's hypothesis is correct that individuals would actually be deterred by the appearance of a solution prepared from this formulation (Ref. 8). Although a solution prepared from PMRS's product may appear a certain way based on the in vitro data provided, PMRS has produced no scientific data or information to establish that people who inject opioids would be less likely to do so because of this appearance or based upon knowledge that the solution contains other components of the drug product in addition to the API. To demonstrate that this formulation deters abuse, and thus to support the proposed labeling for abuse-deterrent properties, CDER asked PMRS to provide evidence sufficient to prove that people who abuse opioids by injection would be deterred from doing so based on the solution's appearance.[11]

Critically, however, PMRS's NDA and subsequent submissions in this proceeding contain no such data or information on this critical question, either from PMRS's studies of its own product or from any potentially relevant scientific literature. In lieu of scientifically valid evidence for the proposition that appearance deters abuse, PMRS simply reiterates how the solution appears. PMRS states, variously, that the ''dark, significant color is visually unappealing for potential intravenous abuse'' (Ref. 2); that ''PMRS considers this visual deterrent effective in classifying drug products as abuse deterrent'' (id.); that ''[t]he use of an FD&C dye was considered a deterrent to abuse as it

perform useless or unfruitful tasks.''), *cert. denied,* 362 U.S. 911 (1960).

[7] Under FDA Staff Manual Guide 1410.21, the Chief Scientist is authorized to perform all delegable functions of the Commissioner of Food and Drugs. (See FDA Staff Manual Guide 1410.21 ¶ 1.B.7).

[8] PMRS suggests that it has an absolute statutory right to a hearing on whether its NDA is approvable under section 505(c)(1)(B) of the FD&C Act without regard to whether it can satisfy the criteria for a hearing set forth in FDA's regulations, including the requirement that a person requesting a hearing must demonstrate with data and analysis that there is a genuine and substantial issue of fact that requires a hearing (April Submission at 6–7). PMRS is incorrect. FDA's duly issued summary judgment procedures have been consistently upheld and are fully compatible with section 505(c)(1)(B) of the FD&C Act. ''It is well established that the statutory grant of a public hearing is not absolute'' (*Community Nutrition Inst.* v. *Young,* 773 F.2d 1356, 1364 (D.C. Cir. 1985)). FDA has the authority to deny a hearing when it appears from the submission of the party requesting a hearing that no substantial issue of fact is in dispute (*Pineapple Growers Ass'n,* 673 F.2d at 1085–86; *Hynson,* 412 U.S. at 621; *Hess & Clark, Inc.* v. *FDA,* 495 F.2d 975, 983 (D.C. Cir. 1974)).

[9] In its latest submission, PMRS appears to propose revising its NDA labeling to include the statement ''Oxycodone HCl IR ADF capsules should be prescribed knowing meaningful abuse-deterrent properties have not been proven,'' among other labeling adjustments (August Submission at 5). First, PMRS cannot adjust the content of the NDA that is the subject of this hearing process in the middle of the process itself. Among other reasons, the question this proceeding seeks to resolve is not whether PMRS might formulate an NDA that might address some of the deficiencies cited in the NOOH. Rather, this process seeks to determine whether the application PMRS submitted to CDER for review should be denied approval as CDER proposes. PMRS may not change the substance of that application during this proceeding. Second, given that the ''ADF'' abbreviation of the product name PMRS retains in this revised language stands for ''Abuse Deterrent Formulation,'' it is difficult to see how this change, even if permissible, would remove the concern that is the primary focus of this order: that PMRS's labeling represents that its product possesses abuse-deterrent properties when the presence of such properties is not supported by substantial and reliable evidence. Consistent with the regulations governing this 21 CFR part 12 proceeding, this order evaluates PMRS's NDA as it was evaluated by CDER and not as PMRS might seek to modify that application now. If PMRS wishes to seek Agency review of a different NDA at this juncture, the appropriate avenue would be to submit a new application through the standard Agency process.

[10] According to CDER's review, there remain some questions concerning whether a solution extracted from PMRS's formulation would consistently have the dark or opaque appearance observed in PMRS's in vitro data. The appearance of an extracted solution of the product may vary, depending on the solvent used in extraction and filtering methods employed by experienced abusers. However, for the purposes of this order, the Chief Scientist assumes that the solution extracted from PMRS's formulation appears as a dark, opaque solution.

[11] CDER informed PMRS of the need for such evidence prior to PMRS's submission of the NDA:

''At this time, we are not aware of data that support a deterrent effect based on the presence of a dye in a formulation intended to be abuse-deterrent. Provide evidence that supports the concept that the incorporation of a dye into a formulation imparts abuse-deterrent effects to that formulation. A hypothetical argument that the presence of a dye will provide an abuse-deterrent effect is not sufficient to support labeling.'' (Ref. 8).

provides a visual deterrent once introduced to aqueous solution'' (id.); that ''the ready solubility of the excipients matching the solubility profile of the API . . . maximiz[es] deterrence by rendering [the product] less attractive or rewarding for injection due to the inability to isolate the API from the inactive ingredients for injection'' (Ref. 9); and that ''it was very important that excipients for this formulation have same [solubility] in order to provide a chemical deterrent for abuse'' (Ref. 2).[12] Despite these assertions and the in vitro data related to how the product looks in solution, PMRS has offered no evidence to establish that opioid-abusers will be deterred by the color or appearance of a solution prepared from PMRS's formulation.

PMRS has also failed to offer evidence to establish its proposed conclusion related to another deficiency cited in the complete response letter (Ref. 5), specifically, PMRS's failure to establish that its product formulation deters abuse by snorting. Despite CDER's requests that human testing be conducted to establish whether this formulation deters abuse by snorting (see Refs. 5 and 8), PMRS declined to conduct such testing or to provide any other information to show that its product functions to deter abuse by snorting. Without human testing, or other appropriate data and information, it is not possible to evaluate whether PMRS's formulation has properties that render it more or less likely to be snorted.[13] If the product were in fact less likely to be snorted, the product could result in shifting the pathway of abuse from snorting to injection. This shift would *increase* the product's overall risks associated with abuse compared to a conventional formulation, both because abuse by injection of any opioid carries additional risks particular to that route of abuse (Ref. 10) and because abuse by injection of PMRS's product in particular carries unknown additional risks associated with injection of the co-extracted excipients.[14]

The Chief Scientist concludes that PMRS has not created a genuine and substantial issue of fact justifying a hearing on this issue. As CDER informed PMRS during the review process and in the complete response letter, PMRS has not provided evidence that demonstrate its product deters abuse. Despite requesting a factual hearing and offering in vitro data intended to demonstrate how its product looks in solution, PMRS has not provided sufficient and reliable data or information that creates a genuine and substantial dispute of fact with respect to whether the appearance of such a solution deters abuse in the manner PMRS proposes to describe in its labeling. PMRS may have submitted evidence to show what the product looks like when prepared for injection but PMRS has not provided no clinical evidence—or indeed any evidence—that this appearance will deter abuse as PMRS's NDA represents in its proposed labeling. In addition, PMRS has failed to provide sufficient evidence to establish that the product formulation deters abuse by snorting. As a result, there exists no contested factual issue with respect to the information available to demonstrate whether PMRS's formulation possesses abuse-deterrent properties. Accordingly, the Chief Scientist denies PMRS's request for a factual hearing on this issue under §§ 12.24(b) and 314.200(g) because there exists no genuine and substantial issue of fact that would require such a hearing to resolve.

*B. PMRS's NDA Proposes Labeling That Is False and Misleading Under Section 505(d)(7) of the FD&C Act and Is Therefore Appropriately Denied Approval*

Having found that that is no genuine and substantial question of fact with respect to whether PMRS's proposed labeling is false or misleading, the Chief Scientist also finds that the Agency must therefore issue an order refusing to approve PMRS's NDA in its present form under section 505(d)(7) of the FD&C Act.

FDA makes approval decisions, including decisions regarding the content of FDA-approved prescription drug labeling, based on a comprehensive scientific evaluation of the available data and information, allowing only information for which there is a scientific basis to be included.[15] As discussed above, no evidence establishes the proposition that this formulation has the abuse-deterrent properties PMRS proposes to include in its product labeling.[16] The absence of such evidence in support of PMRS's assertions is particularly problematic in light of the novel and highly speculative nature of PMRS's abuse-deterrence hypothesis. It is well understood that people suffering from opioid use disorder—particularly people who abuse opioids by injection—routinely take extraordinary risks in connection with their opioid abuse. The individuals who abuse opioids by injection are known to be undeterred by such serious risks as disease transmission (including HIV and hepatitis C) associated with needle-sharing, injection-site infections, overdose, and even death (Ref. 10). Certain ''street'' opioids, such as black tar heroin, are commonly administered by injection despite their contaminated appearance (Ref. 11) and despite the real risks associated with the unknown composition and purity of such products (including, but not limited to, the presence of contaminants).

Against this backdrop, PMRS's unsupported assertions and in vitro data are insufficient to demonstrate that its product formulation will deter abuse. Given the lack of data establishing the effect of PMRS's formulation on its risks of abuse compared to a conventional formulation, the labeling statements PMRS has proposed suggesting that sufficient and reliable evidence exists and establishes that PMRS's formulation deters abuse would be false and misleading. Thus, the proposed labeling

[12] We note that PMRS provided some data and information regarding its particular choice of dye blend, arguing that the blend it selected was ''the most visually deterring'' of the colors evaluated ''as it resulted in a dark, opaque, 'contaminated-looking' solution'' (Ref. 2 at page 4). As this order discusses, this data does not constitute sufficient evidence for the proposition that people who inject opioids can reasonably be expected to be ''visually deterred'' from doing so based on the appearance of the solution prepared for injection.

[13] As previously noted, PMRS intended for its formulation to confer resistance to grinding (for the purpose of snorting) but ultimately conceded that the product has not been shown to have this property. See supra footnote 2.

[14] In June 2017 FDA sought withdrawal from the market of OPANA ER (oxymorphone HCl ER tablets (NDA 21610)) based on similar concerns (Ref. 12). Specifically, FDA requested that OPANA ER be withdrawn from the market after review of postmarket data showed a significant shift in the route of abuse from nasal to injection following the product's reformulation. The reformulated product had been intended to deter abuse by injection and snorting. Injection abuse of reformulated OPANA ER has been associated with serious adverse events, including numerous cases of thrombotic microangiopathy which are thought to have been related to injection of the excipients included to deter abuse (Refs. 12 and 13).

[15] See, *e.g.,* 21 CFR 201.56(a)(1) (providing that the labeling of prescription drugs must contain a summary of the essential scientific information needed for the safe and effective use of the drug), 21 CFR 201.56(a)(2) (providing that the labeling must be informative and accurate and neither promotional in tone nor false or misleading in any particular and that labeling must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading), and 21 CFR 201.56(a)(3) (providing that labeling must be based whenever possible on data derived from human experience).

[16] As noted previously, PMRS's claims that its product resists physical and chemical ''extraction'' appear to rest on a misunderstanding of how that term is used in the context of abuse-deterrent opioids. See supra footnote 1.

includes false and misleading statements suggesting that PMRS's product is expected to be safer than a conventional formulation with respect to the risks of abuse when this conclusion remains unproven.[17] Accordingly, the Chief Scientist has determined that PMRS has not submitted data or information that can support a conclusion that its product would deter abuse by injection and that PMRS's proposed labeling is false and misleading under section 505(d)(7) in the absence of such evidence. As a result, the Chief Scientist accepts CDER's proposal to refuse approval for PMRS's NDA in its present form.

*C. PMRS's Legal and Policy Arguments Are Unavailing*

Instead of providing data and information addressing the absence of genuine and substantial issues of fact discussed in the previous sections, the PMRS's submissions consists largely of legal and policy objections to FDA's approach to evaluating, labeling, and approving opioids, as well as requests for the Agency to take specific actions regarding other drug products premised on PMRS's proposed alternative policies regarding opioids. These legal and policy arguments do not raise a genuine and substantial issue of fact justifying a hearing. See § 12.24(b)(1) (''A hearing will not be granted on issues of policy or law.'').[18] Furthermore, a hearing will not be granted on the issue of whether FDA should take regulatory actions regarding other drug products which are not the subject of the NOOH.[19] Accordingly, this order does not address the merits of FDA's policies regarding abuse-deterrent opioids or PMRS's objections to those policies, except as they apply to the question of whether PMRS has raised a genuine and substantial issue of fact which precludes CDER's proposal to refuse to approve PMRS's NDA.[20] Instead, the Chief Scientist's order addresses only those aspects of the PMRS submissions that are at least potentially relevant to the question of whether PMRS has submitted data, information, or analysis that raises a genuine and substantial issue of fact justifying a hearing on the issue of whether PMRS's proposed abuse-deterrent labeling claims are false or misleading.

PMRS argues that CDER incorrectly proposed refusing to approve its NDA with the proposed abuse-deterrent labeling because CDER applied what PMRS considers the flawed approach to the evaluation and labeling of abuse-deterrent products contained in FDA's 2015 guidance for industry, ''Abuse-Deterrent Opioids—Evaluation and Labeling'' (Ref. 14) (the Guidance). Specifically, PMRS argues that the guidance's emphasis on premarket studies (*i.e.,* laboratory studies and human testing) is scientifically invalid and that FDA should only approve abuse-deterrent formulations with abuse-deterrent labeling claims based on post-market epidemiological data. PMRS contends that data from premarket studies of abuse deterrence cannot constitute ''substantial evidence'' that a product deters abuse and therefore results in abuse-deterrent labeling claims that are false and misleading (April Submission at 2–5). PMRS further argues that CDER improperly treated compliance with the guidance approach as a requirement for approval of abuse-deterrent labeling, rather than merely as a set of recommendations, in violation of the Administrative Procedure Act (APA) (April Submission at 5–7). The Chief Scientist finds these arguments unconvincing and not relevant to the matter at hand.

First, PMRS makes a policy argument that FDA, by following the approach described in the Guidance, routinely approves abuse-deterrent labeling claims that are too strong or overly broad based on premarket data. But this argument does not raise an issue of fact regarding the approvability of an NDA for a product bearing a labeling claim that PMRS characterizes as a ''more appropriately limited claim about abuse deterrence'' (April Submission at 2). As stated above, PMRS has not presented data, information, or analysis that support a conclusion that its product is approvable with *its own proposed labeling,* rendering the question of whether ''broader labeling statements'' (April Submission at 2) should be withheld until supported by post-market epidemiological data irrelevant for purposes of this order.[21] Even in its August submission, PMRS continues to suggest that its product should be labeled as possessing abuse-deterrent properties, even naming its product ''ADF'' or Abuse Deterrent Formulation, while simultaneously arguing that no evidence can demonstrate such properties pre-market (August Submission at 5).[22] If PMRS is correct that such properties cannot be established pre-market, then labeling its product with abuse-deterrent properties becomes even more transparently false and misleading. PMRS cannot have it both ways without admitting that their proposed labeling lacks a scientific basis. Further, even if FDA were to agree with PMRS that only labeling claims of the type proposed by PMRS should be approved based on premarket studies, this policy change would not alter the conclusion that PMRS has not raised a genuine and substantial issue of fact justifying a hearing regarding CDER's proposal to refuse to approve PMRS's NDA with the labeling described in the NDA.[23]

The Chief Scientist finds PMRS's APA claim similarly irrelevant to the question of whether a hearing should be granted. PMRS contends that, by recommending that PMRS follow the

[17] During the review process, PMRS proposed that its labeling include the following disclaimers: ''Abuse of TRADENAME by injection, as well as by the oral and nasal routes, is still possible,'' and ''there is no clinical evidence that TRADENAME has a reduced abuse liability compared to immediate-release oxycodone'' (Ref. 6). These disclaimers do not render PMRS's other abuse-deterrent labeling statements any less false and misleading. For example, the first disclaimer implies that the product has abuse-deterrent properties, while stating that these properties do not render the product abuse-proof. The second disclaimer conveys an assessment of the product's abuse-deterrent properties is not based on data from human studies but continues to suggest that the product possesses these (unproven) properties. In the context of the other labeling PMRS proposes related to abuse-deterrence, these disclaimers, if anything, render the NDA's proposed labeling even more misleading.

[18] Courts have uniformly recognized that an administrative hearing need not be held to resolve questions of law or policy (see *Citizens for Allegan County,* 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC,* 256 F.2d 233, 240 (5th Cir.), cert denied, 358 U.S. 872 (1958)).

[19] § 314.200(g)(8) (''A request for a hearing, and any subsequent grant or denial of a hearing, applies only to the drug products named in [the NOOH]'').

[20] Similarly, this order does not address PMRS's arguments that do not go to the specific deficiencies cited in the complete response letter and the NOOH, such as its argument that its product, as well as other opioid products, should not bear labeling consistent with chronic use and instead should only be labeled for management of acute pain.

[21] For similar reasons, the Chief Scientist does not address the merits of PMRS's legal argument that application of the approach described in the Guidance raises concerns under the First Amendment. PMRS contends that ''[i]t cannot be that an Agency can compel an applicant to forego a more limited truthful and non-misleading claim and to instead seek broader labeling claims that an applicant finds objectionable'' (April Submission at 4, footnote 4). Given that PMRS has not presented data, information, or analysis that support a conclusion that its product is approvable with what PMRS characterizes as more limited claims regarding abuse-deterrence, PMRS's First Amendment objections to broader labeling claims are not relevant to this proceeding.

[22] See supra footnotes 6 and 16.

[23] We note that the Guidance was developed after considerable deliberation by the Agency and after thorough consideration of stakeholder comments expressed at public meetings and submitted to the docket. If PMRS wants to provide further input on the Guidance, there is already a mechanism in place for PMRS to do so (see § 10.115(f)). A hearing on CDER's proposal to refuse to approve PMRS's NDA, however, is not the proper forum for effecting changes to FDA policy. See § 12.24(b)(1).

approach to evaluating abuse-deterrent opioids described in the Guidance, and by referring to the guidance in the complete response letter and other documents, CDER ''effectively converted a nonbinding guidance document into a requirement for abuse-deterrent labeling that has the force and effect of the law'' (April Submission at 7). But challenging FDA's recommended approach for study design to measure abuse-deterrent effectiveness pre-market is immaterial to the proposal to refuse PMRS's specific NDA because PMRS has provided no evidence—either of the type FDA recommended or otherwise—that this formulation deters abuse. As a result and as discussed in the previous section, PMRS's proposed labeling remains false and misleading because it represents abuse-deterrent properties for a formulation that has not been shown to actually possess those properties.

In sum, the Chief Scientist concludes that PMRS has raised no legal or policy argument that alters the determinations discussed in the previous sections.

*D. A Hearing is not Otherwise in the Public Interest*

In its August Submission, PMRS argues that a Part 12 hearing would be ''otherwise in the public interest'' within the meaning of § 314.200(g)(6) in order to resolve broader policy issues related to opioid abuse. The Chief Scientist disagrees and finds in her discretion that a Part 12 hearing on this NDA would not otherwise be in the public interest.

As discussed above, PMRS's submissions raise arguments relevant to FDA's regulation of opioid products and to the crisis of opioid abuse, generally. For example, PMRS argues that the ''emphasis on so-called abuse-deterrent formulations and labeling in response to the opioid epidemic has resulted in the market entry of additional misbranded products'' and that ''[s]uch false and misleading labeling serves only to confuse prescribers and patients about what the product is and . . . is not'' (April Submission at 4). In its submissions, PMRS also requests that FDA take specific regulatory action regarding several other specific opioid products.

The Agency continues to take a variety of steps to address the public health crisis created by opioid abuse and the resulting addiction and death. For example, in May 2017, the Commissioner of Food and Drugs (the Commissioner) announced the establishment of an Opioid Policy Steering Committee to explore and develop additional approaches or strategies FDA could deploy to combat the opioid crisis.[24] FDA has also held public hearings on topics relating to opioid abuse, including to receive stakeholder input on how FDA might, under its Risk Evaluation and Mitigation Strategy (REMS) authority, improve the safe use of opioid analgesics by curbing overprescribing to decrease the occurrence of new addictions and limit misuse and abuse of opioid analgesics.[25]

The Agency is also working to enhance prescriber and patient awareness of the safe use of opioids. In 2017, FDA notified holders of approved applications for IR opioid analgesics of the Agency's determination that a REMS is necessary for IR opioid analgesics to ensure that the benefits of these drugs continue to outweigh the risks. Under this new policy, the IR opioid analgesics that are intended to be used in the outpatient setting will be subject to the same REMS requirements as the Extended-Release/Long-Acting opioid analgesics.

In addition, the Agency is undertaking a study to improve its understanding of prescriber beliefs relating to use of opioid products with abuse-deterrent properties.[26] The Agency is evaluating currently-used nomenclature for such products, including by surveying doctors to better understand how they perceive these terms and to assess the clinical understanding that has developed around products with labeling for abuse-deterrent properties. Further, FDA is continuously monitoring the safety of approved opioid products based on post-market information, including through a focus on improving post-market data collection in this area.

As these examples show, the Agency is working to address the crisis of opioid addiction and abuse and recognizes the importance of seeking public comment and participation relevant to FDA's opioid-related policies. However, the Chief Scientist does not believe that a Part 12 hearing on the approvability of PMRS's NDA is an appropriate forum to address such concerns and finds in her discretion that such a hearing would not be in the public interest.

*E. Additional Issues Not Decided by This Order*

As described above, the Chief Scientist has determined that PMRS has not raised a genuine and substantial issue of fact that would warrant a hearing and that PMRS's proposed labeling containing abuse-deterrent representations would be false and misleading under section 505(d)(7) of the FD&C Act. Although the complete response letter and NOOH describe additional deficiencies in PMRS's NDA, it is not necessary to address these issues in this order because, even if resolved in PMRS's favor, PMRS's NDA would still be refused approval in its present form under section 505(d)(7) of the FD&C Act.[27]

## IV. Findings and Order

For the reasons described above, the Chief Scientist finds that PMRS has not raised any genuine and substantial issue of fact that would justify a hearing (see §§ 12.24(b)(1) and 314.200(g)(1)). Accordingly, PMRS's request for a hearing is denied. The record conclusively shows that the approval criteria set forth in section 505(d)(7) of the FD&C Act have not been met. Therefore, under section 505(d) of the FD&C Act of the FD&C Act, the Chief Scientist hereby denies approval to PMRS's NDA in its present form.

## V. References

The following references marked with an asterisk (*) are on display in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for reviewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* The reference without an asterisk is not on public display at *https://www.regulations.gov* because it has copyright restriction. 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. Clinical Review, Cross-Discipline Deputy Director Review and Summary Division Director Review, NDA 209155.
* 2. ''Module 3 Quality, 3.2.P.2.2 Drug Product,'' PMRS Inc., NDA 209155.
* 3. ''Module 2 Common Technical Document Summaries,'' PMRS, NDA 209155.

[24] See 82 FR 58572 (December 13, 2017).

[25] Id.

[26] See Scott Gottlieb, M.D., Commissioner of Food and Drugs, Remarks Delivered Before FDA's Scientific Meeting on Opioids (July 10, 2017), available at *https://www.fda.gov/newsevents/speeches/ucm566189.htm.*

[27] ''A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged even if accurate.'' § 12.24(b)(3). Furthermore, ''[a] hearing will not be granted on factual issues that are not determinative with respect to the action requested, *e.g.,* if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought[.]'' § 12.24(b)(4).

* 4. Proposed labeling for oxycodone HCl IR capsules, PMRS, NDA 209155 (Dec. 2017).
* 5. Complete Response letter, NDA 209155 (November 16, 2017).
* 6. ''Filing Communication Responses,'' PMRS, NDA 209155.
* 7. ''Request for Priority Review Designation,'' PMRS, NDA 209155.
* 8. ''Memorandum of Meeting Minutes'' for Type B, Pre-NDA, July 11, 2016 teleconference (August, 8, 2016).
* 9. ''NDA 209155 CMC Information Request 5–25–17,'' PMRS, NDA 209155.
* 10. Centers for Disease Control, ''Integrated Prevention Services for HIV Infection, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis for Persons Who Use Drugs Illicitly: Summary Guidance From the CDC and the U.S. Department of Health and Human Services,'' *Morbidity and Mortality Weekly Report,* vol. 61, pp. 1–40, 2012.
* 11. National Institute on Drug Abuse, ''What is heroin and how is it used?'', available at *https://www.drugabuse.gov/publications/research-reports/heroin/what-heroin* (accessed June 13, 2018).
* 12. FDA News Release, ''FDA requests removal of Opana ER for risks related to abuse'' (June 8, 2017), available at *https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.*
13. Hunt, R. et al., ''A Mechanistic Investigation of Thrombotic Microangiopathy Associated with IV Abuse of Opana ER,'' *Blood,* Feb. 16, 2017.
* 14. FDA Guidance for Industry ''Abuse-Deterrent Opioids—Evaluation and Labeling,'' available at *https://www.fda.gov/downloads/Drugs/Guidances/UCM334743.pdf.*

Dated: October 25, 2018.

**Denise Hinton,**

*Chief Scientist.*

[FR Doc. 2018–23710 Filed 10–29–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Meeting of the National Advisory Council on Nurse Education and Practice

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

**ACTION:** Notice.

**SUMMARY:** The National Advisory Council on Nurse Education and Practice (NACNEP or the Council) has scheduled a public meeting. Information about NACNEP and the agenda for this meeting can be found on the NACNEP website at *https://www.hrsa.gov/advisory-committees/nursing/index.html.*

**DATES:** November 19, 2018, 8:30 a.m.–4:15 p.m. ET.

**ADDRESSES:** This meeting will be held by teleconference and webinar. The conference call-in number is 1–888–455–0640; passcode: HRSA COUNCIL. The webinar link is *https://hrsa.connectsolutions.com/nacnep/.*

**FOR FURTHER INFORMATION CONTACT:** Tracy L. Gray, MBA, MS, RN, Division of Nursing and Public Health, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, 11N112, Rockville, Maryland 20857; 301–443–3346; or *DScott1@hrsa.gov.*

**SUPPLEMENTARY INFORMATION:** NACNEP provides advice and recommendations to the Secretary of Health and Human Services (Secretary) and the U.S. Congress on policy matters arising in the administration of Title VIII of the Public Health Service (PHS) Act, as amended, including the range of issues relating to nurse supply, education, and practice improvements. NACNEP provides an annual report to the Secretary and Congress describing the activities of NACNEP, including findings and recommendations made by NACNEP concerning the activities under this title.

During the November 19, 2018, meeting, NACNEP will continue discussing areas where nursing can take the lead in the transition of the health care system to value-based care through improvements to nurse education and practice, to advance the development of its 15th Report. In addition, the members will discuss strategic priorities and future directions for the Council and discuss possible topics for its 16th Report. Agenda items are subject to change as priorities dictate. Refer to the NACNEP website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written statements to NACNEP should be sent to Ms. Tracy L. Gray, Designated Federal Official, using the contact information above at least 3 business days prior to the meeting.

**Amy P. McNulty,**

*Acting Director, Division of the Executive Secretariat.*

[FR Doc. 2018–23685 Filed 10–29–18; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is jointly owned by an agency of the U.S. Government with Pontificia Universidad Catolica de Chile and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with Ami Gadhia, JD, LL.M., CLP, Technology Transfer and Patenting Specialist, National Center for Advancing Translational Sciences, NIH, 9800 Medical Center Drive, Rockville, MD 20850, Phone: 301–217–6098, or email *ami.gadhia@nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

**SUPPLEMENTARY INFORMATION:** Technology description follows.

c-Abl Tyrosine Kinase Inhibitory Compounds and Methods of Manufacture and Use

#### Description of Technology

The invention includes compounds that inhibit c-Abl tyrosine kinase, and methods of making them which include administering (i) a therapeutically effective amount of the compound or a stereoisomer, tautomer, pharmaceutically acceptable salt, solvate, or prodrug thereof; or (ii) a therapeutically effective amount of the pharmaceutical compositions to a patient with the disease which involves c-Abl tyrosine kinase, including the overexpression of it. In some embodiments, the compound inhibits c-Abl tyrosine kinase by binding to an allosteric site of the c-Abl tyrosine kinase. In some embodiments, the compound binds to a myristate pocket of the c-Abl tyrosine kinase.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further

development and evaluation under a research collaboration.

**Potential Commercial Applications**

• Novel therapeutics for neurodegenerative diseases AND other indications which involve c-Abl kinase (*e.g.,* lysosomal storage disorders, cancers, etc.).

**Competitive Advantages**

• Novel compounds that have a commercial advantage over those currently known because they are able to selectively bind to c-Abl at an allosteric site, can cross the blood-brain barrier, and show robust efficacy in several neurodegenerative models. All of this allows them to potentially treat neurodegenerative diseases, cancer etc.

**Development Stage**

• Pre-Clinical (in vivo validation).

**Inventors**

• Juan Marugan, Marc Ferrer, Noel Southall, Andres Dulcey, Xin Hu, Christopher Dextras, Daniel Talley, Alejandra Alvarez, Silvana Zanlungo.

*Intellectual Property:* 1. C-ABL TYROSINE KINASE INHIBITORY COMPOUND EMBODIMENTS AND METHODS OF MAKING AND USING THE SAME'' U.S. Provisional Patent Application NO. 62/641,126 filed on March 9, 2018 (HHS Ref. No. E–252–2017).

Licensing Contact: Ami Gadhia, JD, LL.M., CLP, 301–217–6098; *ami.gadhia@nih.gov.*

Dated: September 25, 2018.

**Lillianne M. Portilla Weingarten,**

*Technology Development Coordinator, National Center for Advancing Translational Sciences.*

[FR Doc. 2018–23616 Filed 10–29–18; 8:45 am]

BILLING CODE 4140–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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 Child Health and Human Development Special Emphasis Panel; NICHD K99 Teleconference Review.

*Date:* November 29, 2018.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20894 (Telephone Conference Call).

*Contact Person:* Helen Huang, Scientific Review Branch (SRB), DER, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, 6710B Rockledge Drive, Rm. 2125B, Bethesda, MD 20817, 301–435–8380, *helen.huang@nih.gov.*

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel; Pediatric Critical Care and Trauma Scientist Development Program (K12) Teleconference Review.

*Date:* December 3, 2018.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Helen Huang, Scientific Review Branch (SRB), DER, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, 6710B Rockledge Drive, Rm. 2125B, Bethesda, MD 20817, 301–435–8380, *helen.huang@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 24, 2018.

**Ronald J. Livingston, Jr.,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018–23615 Filed 10–29–18; 8:45 am]

BILLING CODE 4140–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Second Stage Review.

*Date:* November 19, 2018.

*Time:* 8:30 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892.

*Contact Person:* Kimberly Firth, Ph.D., National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7702, *firthkm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: October 24, 2018.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018–23614 Filed 10–29–18; 8:45 am]

BILLING CODE 4140–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Arthritis and Musculoskeletal and Skin 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; Ancillary Studies Application Review.

*Date:* November 2, 2018.

*Time:* 12:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Arthritis, Musculoskeletal and Skin Diseases, 6701 Democracy Boulevard, Room 814, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Helen Lin, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, 6701 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301–594–4952, *linh1@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; NIAMS Skin P30 Review Meeting.

*Date:* November 5–6, 2018.

*Time:* 8:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*Contact Person:* Kan Ma, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, 6701 Democracy Boulevard, Suite 814, Bethesda, MD 20892, 301–451–4838, *mak2@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; Training Grants Review.

*Date:* November 14, 2018.

*Time:* 10:00 a.m. to 1:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* 6701 Democracy Boulevard, Suite 820, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Yasuko Furumoto, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases 6701 Democracy Boulevard, Suite 820, Bethesda, MD 20892, 301–827–7835, *yasuko.furumoto@nih.gov.*

*Name of Committee:* National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; MSK P30 Review Meeting.

*Date:* November 15–16, 2018.

*Time:* 8:00 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Canopy by Hilton, 940 Rose Avenue, North Bethesda, Bethesda, MD 20852.

*Contact Person:* Yin Liu, MD, Ph.D., Scientific Review Branch, National Institute of Health, National Institute of Arthritis, Musculoskeletal and Skin Diseases, 6701 Democracy Boulevard, Suite 824, Bethesda, MD 20892, 301–594–8919, *liuy@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: October 24, 2018.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018–23613 Filed 10–29–18; 8:45 am]

**BILLING CODE 4140–01–P**

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## DEPARTMENT OF HOMELAND SECURITY

## Coast Guard

**[Docket No. USCG–2018–0879]**

## Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0088

**AGENCY:** Coast Guard, DHS.

**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0088, Voyage Planning for Tank Barge Transits in the Northeast United States. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before December 31, 2018.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG–2018–0879] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), ATTN: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr Ave. SE, STOP 7710, Washington, DC 20593–7710.

**FOR FURTHER INFORMATION CONTACT:** Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

**SUPPLEMENTARY INFORMATION:**

### Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2018–0879], and must be received by December 31, 2018.

### Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include

any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

**Information Collection Request**

*Title:* Voyage Planning for Tank Barge Transits in the Northeast United States.

*OMB Control Number:* 1625–0088.

*Summary:* The information collection requirement for a voyage plan serves as a preventive measure and assists in ensuring the successful execution and completion of a voyage in the First Coast Guard District. This rule (33 CFR 165.100) applies to primary towing vessels engaged in towing tank barges carrying petroleum oil in bulk as cargo.

*Need:* Section 311 of the Coast Guard Authorization Act of 1998, Public Law 105–383, 33 U.S.C. 1231, and 46 U.S.C. 3719 authorize the Coast Guard to promulgate regulations for towing vessel and barge safety for the waters of the Northeast subject to the jurisdiction of the First Coast Guard District. The regulation is contained in 33 CFR 165.100. The information for a voyage plan will provide a mechanism for assisting vessels towing tank barges to identify those specific risks, potential equipment failures, or human errors that may lead to accidents.

*Forms:* None.

*Respondents:* Owners and operators of towing vessels.

*Frequency:* On occasion.

*Hour Burden Estimate:* The estimated burden has increased from 880 hours to 937 hours a year due to an increase in the estimated annual number of responses.

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: October 25, 2018.

**James D. Roppel,**

*Acting Chief, U.S. Coast Guard, Office of Information Management.*

[FR Doc. 2018–23639 Filed 10–29–18; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2018–0497]**

### Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0015

**AGENCY:** Coast Guard, DHS.

**ACTION:** Thirty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Requests (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0015, Bridge Permit Application Guide. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

**DATES:** Comments must reach the Coast Guard and OIRA on or before November 29, 2018.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG–2018–0497] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* Alternatively, you may submit comments to OIRA using one of the following means:

(1) *Email: dhsdeskofficer@omb.eop.gov.*

(2) *Mail:* OIRA, 725 17th Street NW, Washington, DC 20503, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), ATTN: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr Ave. SE, STOP 7710, Washington, DC 20593–7710.

**FOR FURTHER INFORMATION CONTACT:** Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

**SUPPLEMENTARY INFORMATION:**

**Public Participation and Request for Comments**

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection. The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2018–0497], and must be received by November 29, 2018.

**Submitting Comments**

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at *https://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0015.

**Previous Request for Comments**

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (83 FR 42522, August 22, 2018) required by 44 U.S.C. 3506(c)(2). That

Notice elicited no comments. Accordingly, no changes have been made to the Collections.

**Information Collection Request**

*Title:* Bridge Permit Application Guide.

*OMB Control Number:* 1625–0015.

*Summary:* The collection of information is a request for a bridge permit submitted as an application for approval by the Coast Guard of any proposed bridge project. An applicant must submit to the Coast Guard a letter of application along with letter-size drawings (plans) and maps showing the proposed project and its location.

*Need:* 33 U.S.C. 401, 491, and 525 authorize the Coast Guard to approve plans and locations for all bridges and causeways that go over navigable waters of the United States.

*Forms:* None.

*Respondents:* Public and private owners of bridges over navigable waters of the United States.

*Frequency:* On occasion.

*Hour Burden Estimate:* The estimated burden has increased from 12,354 hours to 17,607 hours a year due to the increase in the annual number of respondents.

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: October 25, 2018.

**James D. Roppel,**

*Acting Chief, U.S. Coast Guard, Office of Information Management.*

[FR Doc. 2018–23638 Filed 10–29–18; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Safety and Environmental Enforcement

**[19XE8370SD//EEGG600000// ED1OS0000.JR0000]**

### Notice of Public Meeting

**AGENCY:** Bureau of Safety and Environmental Enforcement (BSEE), Interior.

**ACTION:** Notice of public meeting.

**SUMMARY:** The Bureau of Safety and Environmental Enforcement (BSEE) is hosting a public meeting to discuss advancement of a low-emission spray combustion unit for responding to oil spills.

**DATES:** This public meeting will be held on December 10, 2018 from 9 to 11 a.m.

**ADDRESSES:** The meeting will be held in Room 121 at 1201 Elmwood Park Blvd., New Orleans, LA 70123.

**FOR FURTHER INFORMATION CONTACT:** Karen N. Stone, (703) 787–1810 or email *karen.stone@bsee.gov.*

**SUPPLEMENTARY INFORMATION:** This notice is to inform the interested public that BSEE, Oil Spill Preparedness Division (OSPD), Response Research Branch will be conducting a public meeting to discuss advancement of a low-emission spray combustion unit being designed to burn water-in-oil emissions. System integration including platform/barge configurations will be discussed to ready the unit towards use in oil spill cleanup operations.

Dated: October 24, 2018.

**Scott A. Angelle,**

*Director, Bureau of Safety and Environmental Enforcement.*

[FR Doc. 2018–23709 Filed 10–29–18; 8:45 am]

**BILLING CODE 4310–VH–P**

## INTERNATIONAL TRADE COMMISSION

**[Inv. No. 337–TA–1063]**

### Certain X-Ray Breast Imaging Devices and Components Thereof; Notice of a Commission Determination To Review the Final Initial Determination In-Part; Extension of the Target Date

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to review the final initial determination (''ID'') in-part and extend the target date for completion of the investigation until January 25, 2019.

**FOR FURTHER INFORMATION CONTACT:** Amanda Pitcher Fisherow, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2737. Copies of non-confidential documents filed in connection with this investigation are or 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 *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.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted this investigation on August 1, 2017, based on a complaint and supplement, filed on behalf of Hologic, Inc. of Marlborough, Massachusetts (''Hologic''). 82 FR 35829–24 (Aug. 1, 2017). The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain x-ray breast imaging and components thereof by reason of infringement of certain claims of U.S. Patent No. 7,831,296 (''the '296 patent''); U.S. Patent No. 8,452,379 (''the '379 patent''); U.S. Patent No. 7,688,940 (''the '940 patent''); U.S. Patent No. 7,986,765 (''the '765 patent''); and U.S. Patent No. 7,123,684 (''the '684 patent''). The complaint further alleges that an industry in the United States exists as required by section 337. The Notice of Investigation named FUJIFILM Corporation of Tokyo, Japan; FUJIFILM Medical Systems USA, Inc. of Stamford, Connecticut; and FUJIFILM Techno Products Co., Ltd. of Hanamaki-Shi Iwate, Japan (collectively, ''Fujifilm'') as respondents. The Office of Unfair Import Investigations (''OUII'') was named as a party. On January 18, 2018, the '765 patent was terminated in its entirety from the investigation. *See* Order No. 18 (Jan. 18, 2018) (unreviewed).

On July 26, 2018, the ALJ issued the final ID and found a violation of section 337 has occurred. On August 8, 2018, Fujifilm and OUII each filed petitions for review of the final ID. On August 16, 2018, OUII and Hologic filed responses to the petitions for review.

Having examined the record of this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in part. Specifically, the Commission has determined to review the ID's findings on (1) *in rem* jurisdiction and importation; (2) all findings concerning infringement; (3) claim construction of the ''dose'' limitations of the '379 and '296 patents; (3) claim construction of the limitations including terms of degree (*i.e.,* similar, substantially less, much less, and substantially higher) in the '379 and '296 patents; (4) the ''control''/''motion control'' and ''processor'' limitations of the '379 and '296 patents; (5) the technical prong of domestic industry for the '379 and '296 patents; (6) claim construction of the ''control'' limitations of the '940 patent;

(7) anticipation by the Kopans 2000 Army Report for the '379 and '296 patents; (8) anticipation by MGH/GE Prototype #2 for the '379 and '296 patents; (9) obviousness based on the publicly available MGH/GE References related to the MGH/GE Prototypes for the '379 and '296 patents; (10) anticipation by GE Senographe 2000D System and/or Manual for the '940 patent; (11) obviousness based on GE Senographe 2000D System and/or Manual with Dornheim for the '940 patent; (12) obviousness based on Niklason article, the GE Senographe DMR System and Dornheim for the '940 patent; and (13) indefiniteness under 35 U.S.C. 112 for the '940 patent.

In connection with its review, the Commission is interested in responses to the following questions:

1. Was the argument that ''conventional mammogram,'' as used in the '379 and '296 patents, should be construed to include diagnostic images waived? *See, e.g.,* OUII Petition for Review at 9–12; Complainant's Resp. to OUII Petition at 2–3.

2. Does the claimed ''dose'' for a ''conventional mammogram,'' as used in the '379 and '296 patents, meet the indefiniteness standard set forth in *Nautilus, Inc.* v. *Biosig Instruments, Inc.,* 134 S. Ct. 2120 (2014). The Commission is most interested in a discussion of the relevant Federal Circuit precedent.

3. To what extent are the ID's findings on whether the ''dose'' for a conventional mammogram has changed over time necessary in establishing whether the ''dose'' for conventional mammogram is definite/indefinite? *See* ID at 60–61.

4. Please discuss whether the terms of degree, as used in the asserted claims of '379 and '296 patents, are indefinite. The Commission is interested in evidence that would provide an understanding of the terms to a person of ordinary skill in the art and the relevant case law.

5. The asserted claims of the '379 and '296 patents require a comparison of different x-ray doses and in particular, to a dose used for a conventional mammogram. Does the specification, claims, prosecution history, or extrinsic record shed light on whether the comparison is made to a conventional two-dimensional system or whether the comparison is made to the two-dimensional mode on a device that performs both two-dimensional and three-dimensional imaging? *See, e.g.,* Fujifilm Petition for Review at 17.

6. Would claims 1, 2, and 22 of the '940 patent be anticipated by the GE Senographe 2000D System and/or Manual if the Commission were to find that the claims allow for the anti-scatter grid to be completely removed? *See, e.g.,* Fujifilm Petition for Review at 55–59.

The parties are requested to brief only the discrete issues above, with reference to the applicable law and evidentiary record. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005. 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

The Commission has also determined to extend the target date for completion of this investigation until January 25, 2019.

*Written Submissions:* The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on public interest, remedy, and bonding. Complainant and the OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainant is also requested to state the date that the subject patents expire and the HTSUS numbers under which the accused products are imported. Complainant is further requested to supply the names of known importers of the Respondents' products at issue in this investigation. Also specifically, with respect to the public interest, the Commission requests briefing on the following issue:

Please discuss whether the accused Fujifilm products have been proven to be more effective in screening for breast cancer than comparable systems available in the United States (*e.g.,* systems from Hologic, Siemens, or GE). Please include evidence to support your position.

The written submissions and proposed remedial orders must be filed no later than close of business on November 5, 2018. Reply submissions must be filed no later than the close of business on November 13, 2018. Opening submissions are limited to 75 pages. Reply submissions are limited to 50 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit eight true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) Of the Commission's Rules of Practice and Procedure (19 CFR 2.10.4(f)). Submissions should refer to the investigation number (''Inv. No. 337–TA–1063'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. 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,[1] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 24, 2018.

**Jessica Mullan,**

*Attorney Advisor.*

[FR Doc. 2018–23618 Filed 10–29–18; 8:45 am]

**BILLING CODE 7020–02–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–392]**

### Importer of Controlled Substances Application: Cambrex High Point, Inc.

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before November 29, 2018. Such persons may also file a written request for a hearing on the application on or before November 29, 2018.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:**

The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on July 16, 2018, Cambrex High Point, Inc., 4180 Mendenhall Oaks Parkway, High Point, North Carolina 27265–8017 applied to be registered as an importer of the following basic class of controlled substance:

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Poppy Straw Concentrate. | 9670 | II |

The company plans to import the listed controlled substance for clinical trial narcotic material for bulk manufacture.

Dated: October 22, 2018.

**John J. Martin,**

*Assistant Administrator.*

[FR Doc. 2018–23699 Filed 10–29–18; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–392]**

### Importer of Controlled Substances Registration

**ACTION:** Notice of registration.

**SUMMARY:** The registrant listed below has applied for and been granted registration by the Drug Enforcement Administration (DEA) as an importer of schedule I or schedule II controlled substances.

**SUPPLEMENTARY INFORMATION:**

The company listed below applied to be registered as an importer of various basic classes of controlled substances. Information on the previously published notice is listed in the table below. No comments or objections were submitted and no requests for hearing were submitted for this notice.

| Company | FR Docket | Published |
|---|---|---|
| Cody Laboratories, Inc. | 83 FR 37524 | August 1, 2018. |

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of the listed registrant to import the applicable basic classes of schedule I or II controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the DEA has granted a registration as an importer for schedule II controlled substances to the above listed company.

[1] All contract personnel will sign appropriate nondisclosure agreements.

Dated: October 11, 2018.

**John J. Martin,**

*Assistant Administrator.*

[FR Doc. 2018–23684 Filed 10–29–18; 8:45 am]

BILLING CODE 4410–09–P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–392]**

### Bulk Manufacturer of Controlled Substances Registration

**ACTION:** Notice of registration.

**SUMMARY:** Registrants listed below have applied for and been granted registration by the Drug Enforcement Administration (DEA) as bulk manufacturers of various classes of schedule I and II controlled substances.

**SUPPLEMENTARY INFORMATION:** The companies listed below applied to be registered as bulk manufacturers of various basic classes of controlled substances. Information on previously published notices is listed in the table below. No comments or objections were submitted for these notices.

| Company | FR docket | Published |
|---|---|---|
| Johnson Matthey Pharmaceutical Materials Inc. | 83 FR 27632. | June 13, 2018. |
| Alcami Wisconsin Corporation. | 83 FR 27628. | June 13, 2018. |

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of these registrants to manufacture the applicable basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated each of the company's maintenance of effective controls against diversion by inspecting and testing each company's physical security systems, verifying each company's compliance with state and local laws, and reviewing each company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a registration as a bulk manufacturer to the above listed companies.

Dated: October 22, 2018.

**John J. Martin,**

*Assistant Administrator.*

[FR Doc. 2018–23698 Filed 10–29–18; 8:45 am]

BILLING CODE 4410–09–P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–392]**

### Bulk Manufacturer of Controlled Substances Application: Insys Manufacturing, LLC

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before December 31, 2018.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on August 22, 2018, Insys Manufacturing, LLC, 2700 Oakmont Drive, Round Rock, Texas 78665–1019 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Marihuana ..... | 7360 | I |
| Tetrahydrocannabinols. | 7370 | I |

The company plans to manufacture bulk synthetic active pharmaceutical ingredients (APIs) for product development and distribution to its customers. No other activity for these drug codes are authorized for this registration.

Dated: October 22, 2018.

**John J. Martin,**

*Assistant Administrator.*

[FR Doc. 2018–23696 Filed 10–29–18; 8:45 am]

BILLING CODE 4410–09–P

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–392]**

### Importer of Controlled Substances Application: United States Pharmacopeial Convention

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before November 29, 2018. Such persons may also file a written request for a hearing on the application on or before November 29, 2018.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:**

The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on August 17, 2018, United States Pharmacopeial

Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852–1717, applied to be registered as an importer of the following basic class of the controlled substance:

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Oxymorphone ..... | 9652 | II |

The company plans to import the bulk controlled substance for distribution of analytical reference standards to its customers for research and analytical purposes.

Dated: October 22, 2018.

**John J. Martin,**

*Assistant Administrator.*

[FR Doc. 2018–23701 Filed 10–29–18; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–392]**

### Importer of Controlled Substances Application: Sharp (Bethlehem), LLC

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before November 29, 2018. Such persons may also file a written request for a hearing on the application on or before November 29, 2018.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:**

The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on August 30, 2018, Sharp (Bethlehem), LLC, 2400 Baglyos Circle, Bethlehem, Pennsylvania 18020, applied to be registered as an importer of the following basic class of controlled substances:

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Gamma Hydroxybutyric Acid. | 2010 | I |

The company plans to import dosage forms of the listed controlled substances to conduct clinical trials.

Approval of permit applications will occur only when the registrant's activity is consistent with what is authorized under to 21 U.S.C. 952 (a)(2).

Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: October 22, 2018.

**John J. Martin,**

*Assistant Administrator.*

[FR Doc. 2018–23705 Filed 10–29–18; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–392]**

### Importer of Controlled Substances Application: Fisher Clinical Services, Inc.

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before November 29, 2018. Such persons may also file a written request for a hearing on the application on or before November 29, 2018.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on August 17, 2018, Fisher Clinical Services Inc., 7554 Schantz Road, Allentown, Pennsylvania 18106, applied to be registered as an importer of the following basic classes of controlled substances:

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Psilocybin ..... | 7437 | I |
| Methylphenidate | 1724 | II |
| Levorphanol ..... | 9220 | II |
| Noroxymorphone. | 9668 | II |
| Tapentadol ..... | 9780 | II |

The company plans to import the listed controlled substances for clinical trials.

Dated: October 22, 2018.

**John J. Martin,**

*Assistant Administrator.*

[FR Doc. 2018–23702 Filed 10–29–18; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–392]**

### Bulk Manufacturer of Controlled Substances Application: Sigma Aldrich Research

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before December 31, 2018.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been delegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on June 14, 2018, Sigma Aldrich Research, 1–3 Strathmore Road, Natick, Massachusetts 01760–2447 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Cathinone | 1235 | I |
| Mephedrone (4-Methyl-N-methylcathinone) | 1248 | I |
| Lysergic acid diethylamide | 7315 | I |
| 3,4-Methylenedioxymethamphetamine | 7405 | I |
| Dimethyltryptamine | 7435 | I |
| 5-Methoxy-N,N-diisopropyltryptamine | 7439 | I |
| MDPV (3,4-Methylenedioxypyrovalerone) | 7535 | I |
| Heroin | 9200 | I |
| Normorphine | 9313 | I |
| Norlevorphanol | 9634 | I |
| Amphetamine | 1100 | II |
| Nabilone | 7379 | II |
| Cocaine | 9041 | II |
| Codeine | 9050 | II |
| Ecgonine | 9180 | II |
| Levorphanol | 9220 | II |
| Meperidine | 9230 | II |
| Methadone | 9250 | II |
| Morphine | 9300 | II |
| Thebaine | 9333 | II |
| Levo-alphacetylmethadol | 9648 | II |
| Remifentanil | 9739 | II |
| Sufentanil | 9740 | II |
| Carfentanil | 9743 | II |
| Fentanyl | 9801 | II |

The company plans to manufacture reference standards.

Dated: October 11, 2018.

**John J. Martin,**

*Assistant Administrator.*

[FR Doc. 2018–23695 Filed 10–29–18; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–392]**

### Importer of Controlled Substances Application: Catalent CTS, LLC

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before November 29, 2018. Such persons may also file a written request for a hearing on the application on or before November 29, 2018.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:**

The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on July 17, 2018, Catalent CTS, LLC, 10245 Hickman Mills Drive, Kansas City,

Missouri 64137–1418 applied to be registered as an importer of the following basic classes of controlled substances:

| Controlled substance | Drug code | Schedule |
|---|---|---|
| Gamma Hydroxybutyric Acid. | 2010 | I |
| Marihuana Extract | 7350 | I |
| Marihuana | 7360 | I |
| Tetrahydrocannabinols | 7370 | I |

The company plans to import finished dosage unit products containing gamma-hydroxybutryic acid and marihuana extracts for clinical trial studies. These marihuana extracts compounds are listed under drug code 7350. No other activity for these drug codes is authorized for this registration. Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a) (2). Authorization will not extend to the import of FDA-approved or non-approved finished dosage forms for commercial sale.

Dated: October 19, 2018.

**John J. Martin,**

*Assistant Administrator.*

[FR Doc. 2018–23686 Filed 10–29–18; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

## Eric Lee Knight, M.D.; Decision and Order

On February 6, 2018, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Eric Lee Knight, M.D. (hereinafter, Registrant), of Derry, New Hampshire. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposes the revocation of Registrant's Certificate of Registration on the ground that he does ''not have authority to handle controlled substances in the State of New Hampshire, the state in which . . . [he is] registered with the DEA.'' *Id.* (citing 21 U.S.C. 823(f) and 824(a)(3)).

Regarding jurisdiction, the OSC alleges that Registrant holds DEA Certificate of Registration No. BK7282940 at the registered address of 93 ½ Walnut Hill Road, Derry, New Hampshire 03038.[1] OSC, at 1. This registration authorizes Registrant to dispense controlled substances in schedules II through V as a practitioner. *Id.* The OSC alleges that this registration expires on December 31, 2018. *Id.*

The substantive ground for the proceeding, as alleged in the OSC, is that Registrant is ''without authority to handle controlled substances in New Hampshire, the state in which [he is] registered with the DEA.'' *Id.* Specifically, the OSC alleges that the State of New Hampshire Board of Medicine (hereinafter, Board) issued an Order of Emergency License Suspension and Notice of Hearing on September 25, 2017. *Id.* at 1–2. On the following day, September 26, 2017, Registrant entered into a written agreement ''not to practice medicine [including the writing of] prescriptions . . . until further order of the Board.'' *Id.* at 2.

The OSC notifies Registrant of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The OSC also notifies Registrant of the opportunity to submit a corrective action plan. OSC, at 2–3 (citing 21 U.S.C. 824(c)(2)(C)).

### Adequacy of Service

In a Declaration dated April 27, 2018, a Diversion Investigator (hereinafter, DI), who describes herself as being assigned to the DEA Boston Field Division-Manchester (New Hampshire) District Office, states that after two unsuccessful attempts at serving the OSC on Registrant, she and two Task Force Officers traveled to the residence of Registrant on February 16, 2018, and ''[a]fter displaying our credentials to Dr. Knight, I presented the original copy of the . . . [OSC] to Dr. Knight.'' (Government Exhibit (hereinafter, GX) 8 at 2–3 (Declaration of DEA Diversion Investigator).

In its Request for Final Agency Action dated May 3, 2018, the Government represents that ''[m]ore than 30-days have passed since Registrant received the . . . [OSC]; however, Registrant has not submitted to DEA a request for hearing.'' Request for Final Agency Action, at 2. In its Request for Final Agency Action—Addendum dated September 26, 2018, the Government represents that Registrant has not ''corresponded in writing or otherwise with regard to his position on a hearing before DEA.'' Request for Final Agency Action—Addendum, at 2. The Government requests the issuance of a Final Order revoking Registrant's DEA registration. *Id.* at 4.

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government personally served the OSC on Registrant on February 16, 2018. I also find that more than 30 days have now passed since the date the Government served the OSC. Further, based on the Government's written representations, I find that neither Registrant, nor anyone purporting to represent him, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Registrant has waived his right to a hearing and his right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

### Findings of Fact

### Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. BK7282940 at the registered address of 93 ½ Walnut Hill Road, Derry, New Hampshire 03038. GX 1 (Certification of Registration), at 1. Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Registrant's registration expires on December 31, 2018. *Id.*

### The Status of Registrant's State License

In this case, the Board issued an Order of Emergency License Suspension and Notice of Hearing on September 25, 2017. The Board's Order suspended Registrant's New Hampshire medical license until further order of the Board. GX 3 (Order of Emergency License Suspension and Notice of Hearing), at 13. On October 9, 2017, the Board accepted Registrant's agreement ''not to practice medicine . . . [including the writing of] prescriptions . . . until further order of the Board.'' GX 4 (Preliminary Agreement Not to Practice), at 1.

According to New Hampshire's online records, of which I take official notice, Registrant's license to practice medicine is still suspended.[2] New Hampshire

[1] The OSC erroneously lists the number of Registrant's address on Walnut Hill Road as 92 ½.

[2] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a

Online Licensing, *http://www.nhlicenses.nh.gov* (last visited October 18, 2018).

Accordingly, I find that Registrant currently is not licensed to engage in the practice of medicine in New Hampshire, the State in which he is registered with the DEA.

**Discussion**

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA), ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . ., to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess State authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the State in which he practices. *See, e.g., Hooper, supra,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Blanton, supra,* 43 FR at 27,617.

In this case, according to the Board, the Registrant is alleged to have engaged in numerous acts of professional misconduct based upon, *inter alia,* inappropriate personal relationships with patients, as well as his issuance of controlled substance prescriptions for no legitimate medical purpose in violation of New Hampshire law. GX 3, at 3–9. As a result of Registrant's alleged misconduct, on September 25, 2017, the Board issued its Order of Emergency License Suspension and Notice of Hearing. On September 26, 2017, Registrant entered into a Preliminary Agreement Not to Practice, whereby he agreed, *inter alia,* ''not to practice medicine . . . [including the writing of] prescriptions . . . until further order of the Board.'' GX 4, at 1. On October 9, 2017, the Board accepted Registrant's Preliminary Agreement Not to Practice. GX 4, at 3. Consequently, Registrant is not currently authorized to handle controlled substances in the State of New Hampshire, the State in which he is registered with the Agency and, therefore, he is not entitled to maintain his DEA registration. *Hooper, supra,* 76 FR at 71,371–72, *Blanton, supra,* 43 FR at 27,617. Accordingly, I will order that Registrant's registration be revoked, that any pending application for the renewal or modification of his registration be denied, and that any pending application by Registrant for a registration in New Hampshire be denied. 21 U.S.C. 824(a)(3) and 823(f).

**Order**

Pursuant to 28 CFR 0.100(b) and the authority thus vested in me by 21 U.S.C. 824(a), I order that DEA Certificate of Registration No. BK7282940 issued to Eric Lee Knight, M.D., be, and it hereby is, revoked. Pursuant to 28 CFR 0.100(b) and the authority thus vested in me by 21 U.S.C. 823(f), I further order that any pending application of Eric Lee Knight, M.D., to renew or modify this registration, as well as any other pending application by him for registration in the State of New Hampshire, be, and it hereby is, denied. This Order is effective November 29, 2018.

Dated: October 18, 2018.

**Uttam Dhillon,**

*Acting Administrator.*

[FR Doc. 2018–23708 Filed 10–29–18; 8:45 am]

BILLING CODE 4410–09–P

party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration within 20 calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have 20 calendar days to file a response.

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

### Affirmative Decisions on Petitions for Modification Granted in Whole or in Part

**AGENCY:** Mine Safety and Health Administration (MSHA), Labor.

**ACTION:** Notice.

**SUMMARY:** The Federal Mine Safety and Health Act of 1977 and the Code of Federal Regulations govern the application, processing, and disposition of petitions for modification. This **Federal Register** notice notifies the public that MSHA has investigated and issued a final decision on certain mine operator petitions to modify a safety standard.

**ADDRESSES:** Copies of the final decisions are posted on MSHA's website at *https://www.msha.gov/regulations/rulemaking/petitions-modification.* The public may inspect the petitions and final decisions during normal business hours in MSHA's Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202. All visitors are required to check in at the receptionist's desk in Suite 4E401.

**FOR FURTHER INFORMATION CONTACT:** Barbara Barron at 202–693–9447 (voice), *barron.barbara@dol.gov* (email), or 202–693–9441 (fax). [These are not toll-free numbers].

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

Under section 101 of the Federal Mine Safety and Health Act of 1977, a mine operator may petition and the Secretary of Labor (Secretary) may modify the application of a mandatory safety standard to that mine if the Secretary determines that: (1) An alternative method exists that will guarantee no less protection for the miners affected than that provided by the standard; or (2) the application of the standard will result in a diminution of safety to the affected miners.

MSHA bases the final decision on the petitioner's statements, any comments and information submitted by interested persons, and a field investigation of the conditions at the mine. In some instances, MSHA may approve a

petition for modification on the condition that the mine operator complies with other requirements noted in the decision.

**II. Granted Petitions for Modification**

On the basis of the findings of MSHA's investigation, and as designee of the Secretary, MSHA has granted or partially granted the following petitions for modification:

• *Docket Number:* M–2016–033–C.
*FR Notice:* 81 FR 81811 (11/18/2016).
*Petitioner:* Mach Mining LLC, P.O. Box 300, Johnston City, Illinois 62951.
*Mine:* Mach No. 1 Mine, MSHA I.D. No. 11–03141, located in Williamson County, Illinois.
*Regulation Affected:* 30 CFR 75.503 (Permissible electric face equipment; maintenance) and 30 CFR 18.35(a)(5)(i) (Portable (trailing) cables and cords).

• *Docket Number:* M–2017–013–C.
*FR Notice:* 82 FR 34700 (7/26/2017).
*Petitioner:* Texas Westmoreland Coal Company, P.O. Box 915, Jewett, Texas 75846.
*Mine:* Jewett Mine, MSHA I.D. No. 41–03164, located in Leon County, Texas.
*Regulation Affected:* 30 CFR 77.803 (Fail safe ground check circuits on high-voltage resistance grounded systems).

• *Docket Number:* M–2017–019–C.
*FR Notice:* 82 FR 49684 (10/26/2017).
*Petitioner:* Marfork Coal Company, LLC, 500 Lee Street East, Suite 701 (25301), Post Office Box 2548, Charleston, West Virginia 25329.
*Mine:* Slip Ridge Cedar Grove Mine, MSHA I.D. No. 46–09048, located in Raleigh County, West Virginia.
*Regulation Affected:* 30 CFR 75.360 (Preshift examination at fixed intervals).

• *Docket Number:* M–2017–021–C.
*FR Notice:* 82 FR 60045 (12/18/2017).
*Petitioner:* Rosebud Mining Company, 301 Market Street, Kittanning, Pennsylvania 16201.
*Mines:* Lowry Mine, MSHA I.D. No. 36–09287 and Heilwood Mine, MSHA I.D. No. 36–09407, located in Indiana County, Pennsylvania; Penfield Mine, MSHA I.D. No. 36–09355, located in Clearfield County, Pennsylvania; and Mine 78, MSHA I.D. No. 36–09371, located in Somerset County, Pennsylvania.
*Regulation Affected:* 30 CFR 75.503 (Permissible electric face equipment; maintenance) and 30 CFR 18.35(a)(5)(i) (Portable (trailing) cables and cords).

• *Docket Number:* M–2018–013–C.
*FR Notice:* 83 FR 17686 (4/23/2018).
*Petitioner:* The Coteau Properties Company, 204 County Road, Beulah, North Dakota 58523–9475.
*Mine:* Freedom Mine, MSHA I.D. No. 32–00595, located in Mercer County, North Dakota.
*Regulation Affected:* 30 CFR 77.1607(u) (Loading and haulage equipment; operation).

• *Docket Number:* M–2018–001–M.
*FR Notice:* 83 FR 4929 (2/2/2018).
*Petitioner:* Martin Marietta Kansas City, LLC, 1099 18th Street, Suite 2150, Denver, Colorado 80202.
*Mines:* Randolph Deep Mine, MSHA I.D. No. 23–02308, located in Clay County, Missouri; Stamper Underground Mine, MSHA I.D, No. 23–02232 and Parkville Quarry, MSHA I.D. No. 23–01883, located in Platte County, Missouri.
*Regulation Affected:* 30 CFR 49.6(a)(1) (Equipment and maintenance requirements).

• *Docket Number:* M–2018–002–M.
*FR Notice:* 83 FR 7780 (2/22/2018).
*Petitioner:* Central Plains Cement Company, 1801 Wewatta Street, Suite 1000, Denver, Colorado 80202.
*Mine:* Sugar Creek Underground Mine, MSHA I.D. No. 23–02171, located in Jackson County, Missouri.
*Regulation Affected:* 30 CFR 49.6(a)(1) (Equipment and maintenance requirements).

**Roslyn B. Fontaine,**
*Deputy Director, Office of Standards, Regulations, and Variances.*

[FR Doc. 2018–23649 Filed 10–29–18; 8:45 am]
**BILLING CODE 4520–43–P**

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## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

**[Docket No. OSHA–2016–0005]**

### Preparations for the 36th Session of the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCEGHS)

**AGENCY:** Occupational Safety and Health Administration (OSHA), Department of Labor.

**ACTION:** Notice of public meeting.

**SUMMARY:** This notice is to advise interested persons that on Tuesday, November 13, 2018, OSHA will conduct a public meeting to discuss proposals in preparation for the 36th session of the United Nations Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCEGHS) to be held December 5 through December 7, 2018, in Geneva, Switzerland. OSHA, along with the U.S. Interagency Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Coordinating Group, plans to consider the comments and information gathered at this public meeting when developing the U.S. Government positions for the UNSCEGHS meeting. OSHA also will give an update on the Regulatory Cooperation Council (RCC).

Also on Tuesday, November 13, 2018, the Department of Transportation (DOT), Pipeline and Hazardous Materials Safety Administration (PHMSA) will conduct a public meeting (See Docket No. PHMSA–2018–0024 Notice No. 2018–11) to discuss proposals in preparation for the 54th session of the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCE TDG) to be held November 26 through December 4, 2018, in Geneva, Switzerland. During this meeting, PHMSA is also requesting comments relative to potential new work items that may be considered for inclusion in its international agenda. PHMSA will also provide an update on recent actions to enhance transparency and stakeholder interaction through improvements to the international standards portion of its website.

**DATES:** Tuesday, November 13, 2018.

**ADDRESSES:** Both meetings will be held at the DOT Headquarters Conference Center, West Building, Oklahoma City Conference Room, 1200 New Jersey Avenue SE, Washington, DC 20590.

*Times and Locations:* PHMSA public meeting: 9 a.m. to 12 p.m. EDT, Oklahoma City Conference Room, OSHA public meeting: 1 p.m. to 4 p.m. EDT, Oklahoma City Conference Room

*Advanced Meeting Registration:* DOT requests that attendees pre-register for these meetings by completing the form at: *https://www.surveymonkey.com/r/XGN8J7X.*

Attendees may use the same form to pre-register for both meetings. Failure to pre-register may delay your access into the DOT Headquarters building. Additionally, if you are attending in person, arrive early to allow time for security checks necessary to access the building.

Conference call-in and ''Skype meeting'' capability will be provided for both meetings. Information on how to access the conference call and ''Skype meeting'' will be posted when available at: *https://www.phmsa.dot.gov/international-program/international-program-overview* under Upcoming Events. This information will also be posted on OSHA's Hazard Communication website on the international tab at: *https://*

*www.osha.gov/dsg/hazcom/hazcom_international.html#meeting-notice.*

**FOR FURTHER INFORMATION CONTACT:** At the Department of Transportation, please contact Mr. Steven Webb or Mr. Aaron Wiener, Office of Hazardous Materials Safety, Department of Transportation, Washington, DC 20590, telephone: (202) 366–8553.

At the Department of Labor, please contact Ms. Maureen Ruskin, OSHA Directorate of Standards and Guidance, Department of Labor, Washington DC 20210, telephone: (202) 693–1950, email: *ruskin.maureen@dol.gov.*

**SUPPLEMENTARY INFORMATION:**

*The OSHA Meeting:* OSHA is hosting an open informal public meeting of the U.S. Interagency GHS Coordinating Group to provide interested groups and individuals with an update on GHS-related issues and an opportunity to express their views orally and in writing for consideration in developing U.S. Government positions for the upcoming UNSCEGHS meeting.

General topics on the agenda include:

- Review of Working Papers.
- Correspondence Group updates.
- Regulatory Cooperation Council (RCC) update.

Information on the work of the UNSCEGHS including meeting agendas, reports, and documents from previous sessions can be found on the United Nations Economic Commission for Europe (UNECE) Transport Division website located at the following web address: *http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.*

The UNSCEGHS bases its decisions on Working papers. The Working Papers for the 36th session of the UNSCEGHS are located at: *https://www.unece.org/trans/main/dgdb/dgsubc3/c32018.html.*

Informal Papers submitted to the UNSCEGHS provide information for the Sub-Committee and are used either as a mechanism to provide information to the Sub-Committee or as the basis for future Working Papers. Informal Papers for the 36th session of the UNSCEGHS are located at: *https://www.unece.org/trans/main/dgdb/dgsubc4/c4inf35.html.*

In addition to participating at the public meeting, interested parties may submit comments on the Working and Informal Papers for the 36th session of the UNSCEGHS to the docket established for International/Globally Harmonized System (GHS) efforts at *http://www.regulations.gov,* Docket No. OSHA–2016–0005.

*The PHMSA Meeting:* The **Federal Register** notice and additional detailed information relating to PHMSA's public meeting will be available upon publication at: *http://www.regulations.gov* (Docket No. PHMSA–2018–0024; Notice No. 2018–11), and on the PHMSA website at: *https://www.phmsa.dot.gov/international-program/international-program-overview.*

The primary purpose of PHMSA's meeting is to prepare for the 54th session of the UNSCE TDG. This session represents the third meeting scheduled for the 2017–2018 biennium. UNSCOE will consider proposals for the 21st Revised Edition of the *United Nations Recommendations on the Transport of Dangerous Goods* (Model Regulations), which may be implemented into relevant domestic, regional, and international regulations from January 1, 2021. Copies of working documents, informal documents, and the meeting agenda may be obtained from the United Nations (UN) Transport Division's website at *https://www.unece.org/trans/main/dgdb/dgsubc3/c32018.html.*

During this meeting, PHMSA is also soliciting input relative to preparing for the 54th session of the UNSCE TDG as well as potential new work items which may be considered for inclusion in its international agenda. Following the 54th session of the UNSCE TDG, a copy of the Sub-Committee's report will be available at the UN Transport Division's website at *http://www.unece.org/trans/main/dgdb/dgsubc3/c3rep.html.*

Additional information regarding the UNSCE TDG and related matters can be found on PHMSA's website at *https://www.phmsa.dot.gov/international-program/international-program-overview.*

*Authority and Signature:* This document was prepared under the direction of Loren Sweatt, Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), and Secretary's Order 1–2012 (77 FR 3912), (Jan. 25, 2012).

Signed at Washington, DC, on October 24, 2018.

**Loren Sweatt,**

*Deputy Assistant Secretary of Labor for Occupational Safety and Health.*

[FR Doc. 2018–23647 Filed 10–29–18; 8:45 am]

BILLING CODE 4510–26–P

## DEPARTMENT OF LABOR

### Office of Workers' Compensation Programs

### Proposed Extension of Existing Collection; Comment Request

**ACTION:** Notice.

**SUMMARY:** The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that 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 on respondents can be properly assessed. Currently, the Office of Workers' Compensation (OWCP) is soliciting comments concerning the proposed collection: Waiver of Service by Registered or Certified Mail for Employers and/or Insurance Carriers (LS–801) and Waiver of Service by Registered or Certified Mail for Claimants and Authorized Representatives (LS–802). A copy of the proposed information collection request can be obtained by contacting the office listed below in the address section of this Notice.

**DATES:** Written comments must be submitted to the office listed in the addresses section below on or before December 31, 2018.

**ADDRESSES:** You may submit comments by mail, delivery service, or by hand to Ms. Yoon Ferguson, U.S. Department of Labor, 200 Constitution Ave. NW, Room S–3323, Washington, DC 20210; by fax (202) 354–9647; or email to *ferguson.yoon@dol.gov.* Please use only one method of transmission for comments (mail/delivery, fax or email). Please note that comments submitted after the comment period will not be considered.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The Office of Workers' Compensation Programs (OWCP) administers the Longshore and Harbor Workers' Compensation Act (LHWCA). The Act provides benefits to workers' injured in maritime employment on the navigable waters of the United States or in an adjoining area customarily used by an

employer in loading, unloading, repairing, or building a vessel. In addition, several acts extend the Longshore Act's coverage to certain other employees.

The Longshore and Harbor Workers' Compensation Act (LHWCA), at 33 U.S.C. 919(e), requires that any order rejecting or making an LHWCA award (a compensation order) be filed in the appropriate district director's office of the Office of Workers' Compensation Programs (OWCP), and that copies be sent by registered or certified mail to the claimant and the employer. The implementing regulations at 20 CFR 702.349(b) allow parties and their representatives to waive certified mail service and consent to electronic service instead. The compensation order notifies Employers/Carriers that payment of LHWCA compensation is due within 10 days of filing. If compensation is not paid within that time frame, an additional 20% in compensation must be paid [see LHWCA § 914(f)].

The information collected will be used by OWCP to more efficiently serve compensation orders by email instead of by registered or certified mail. Form LS–801 will be completed by the employer/insurance carrier and/or an authorized representative and forwarded to the District Director indicating waiver of service by registered or certified mail and designation of receipt by email instead. The LS–802 will be completed by the claimants and/or an authorized representative and forwarded to the District Director indicating waiver of service by registered or certified mail and designation of receipt by email instead. This information collection is currently approved for use through February 28, 2019.

## II. Review Focus

The Department of Labor is particularly interested in comments which:

* 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 submissions of responses.

## III. Current Actions

The Department of Labor seeks the extension of approval of this information collection in order to carry out its responsibility to meet the statutory requirements to provide compensation or death benefits under the Act to workers and survivors covered by the Act.

*Agency:* Office of Workers' Compensation Programs.

*Type of Review:* Extension.

*Title:* Request for Electronic Service of Orders—Waiver of Certified Mail Requirements.

*OMB Number:* 1240–0053.

*Agency Number:* LS–801 and LS–802.

*Affected Public:* Claimants, employers, large insurance companies, and representatives.

*Total Respondents:* 9,240.

*Total Annual Responses:* 9,240.

*Estimated Total Burden Hours:* 770.

*Estimated Time per Response:* 5 minutes.

*Frequency:* On occasion.

*Total Burden Cost (capital/startup):* $0.

*Total Burden Cost (operating/maintenance):* $0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: October 25, 2018.

**Yoon Ferguson,**

*Agency Clearance Officer, Office of Workers' Compensation Programs, US Department of Labor.*

[FR Doc. 2018–23674 Filed 10–29–18; 8:45 am]

**BILLING CODE 4510–CF–P**

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# NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

## National Endowment for the Arts

## Arts Advisory Panel Meetings

**AGENCY:** National Endowment for the Arts.

**ACTION:** Notice of meetings.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that 28 meetings of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference.

**DATES:** See the **SUPPLEMENTARY INFORMATION** section for individual meeting times and dates. All meetings are Eastern time and ending times are approximate.

**ADDRESSES:** National Endowment for the Arts, Constitution Center, 400 7th St. SW, Washington, DC 20506.

**FOR FURTHER INFORMATION CONTACT:** Further information with reference to these meetings can be obtained from Ms. Sherry Hale, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; *hales@arts.gov,* or call 202/682–5696.

**SUPPLEMENTARY INFORMATION:** The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of July 5, 2016, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5, United States Code.

The upcoming meetings are:

*Visual Arts (review of applications):* This meeting will be closed.
*Date and time:* November 29, 2018; 11:30 a.m. to 1:30 p.m.

*Visual Arts (review of applications):* This meeting will be closed.
*Date and time:* November 29, 2018; 2:30 p.m. to 4:30 p.m.

*Visual Arts (review of applications):* This meeting will be closed.
*Date and time:* November 30, 2018; 11:30 a.m. to 1:30 p.m.

*Visual Arts (review of applications):* This meeting will be closed.
*Date and time:* November 30, 2018; 2:30 p.m. to 4:30 p.m.

*Museums (review of applications):* This meeting will be closed.
*Date and time:* December 4, 2018; 11:30 a.m. to 1:30 p.m.

*Museums (review of applications):* This meeting will be closed.
*Date and time:* December 4, 2018; 2:30 p.m. to 4:30 p.m.

*Presenting & Multidisciplinary Works (review of applications):* This meeting will be closed.
*Date and time:* December 4, 2018; 2:00 p.m. to 4:00 p.m.

*Museums (review of applications):* This meeting will be closed.
*Date and time:* December 5, 2018; 11:30 a.m. to 1:30 p.m.

*Museums (review of applications):* This meeting will be closed.
*Date and time:* December 5, 2018; 2:30 p.m. to 4:30 p.m.

*Presenting & Multidisciplinary Works (review of applications):* This meeting will be closed.

*Date and time:* December 5, 2018; 2:00 p.m. to 4:00 p.m.
*Our Town (review of applications):* This meeting will be closed.
*Date and time:* December 5, 2018; 2:30 p.m. to 5:00 p.m.
*Arts Education (review of applications):* This meeting will be closed.
*Date and time:* December 6, 2018; 11:30 a.m. to 1:30 p.m.
*Arts Education (review of applications):* This meeting will be closed.
*Date and time:* December 6, 2018; 2:30 p.m. to 4:30 p.m.
*Presenting & Multidisciplinary Works (review of applications):* This meeting will be closed.
*Date and time:* December 6, 2018; 2:00 p.m. to 4:00 p.m.
*Our Town (review of applications):* This meeting will be closed.
*Date and time:* December 6, 2018; 11:00 a.m. to 1:30 p.m.
*Our Town* (review of applications): This meeting will be closed.
*Date and time:* December 6, 2018; 2:30 p.m. to 5:00 p.m.
*Presenting & Multidisciplinary Works (review of applications):* This meeting will be closed.
*Date and time:* December 7, 2018; 2:00 p.m. to 4:00 p.m.
*Folk & Traditional Arts (review of applications):* This meeting will be closed.
*Date and time:* December 11, 2018; 1:00 p.m. to 3:00 p.m.
*Our Town (review of applications):* This meeting will be closed.
*Date and time:* December 11, 2018; 11:00 a.m. to 1:30 p.m.
*Our Town (review of applications):* This meeting will be closed.
*Date and time:* December 11, 2018; 2:30 p.m. to 5:00 p.m.
*Arts Education (review of applications):* This meeting will be closed.
*Date and time:* December 12, 2018; 1:30 p.m. to 3:30 p.m.
*Media Arts (review of applications):* This meeting will be closed.
*Date and time:* December 12, 2018; 2:30 p.m. to 4:30 p.m.
*Our Town (review of applications):* This meeting will be closed.
*Date and time:* December 12, 2018; 11:00 a.m. to 1:30 p.m.
*Folk & Traditional Arts (review of applications):* This meeting will be closed.
*Date and time:* December 13, 2018; 1:00 p.m. to 3:00 p.m.
*Local Arts Agencies (review of applications):* This meeting will be closed.
*Date and time:* December 13, 2018; 1:00 p.m. to 3:00 p.m.
*Local Arts Agencies (review of applications):* This meeting will be closed.
*Date and time:* December 13, 2018; 3:30 p.m. to 5:30 p.m.
*Media Arts (review of applications):* This meeting will be closed.
*Date and time:* December 13, 2018; 11:30 a.m. to 1:30 p.m.
*Our Town (review of applications):* This meeting will be closed.
*Date and time:* December 13, 2018; 2:30 p.m. to 5:00 p.m.

Dated: October 25, 2018.

**Sherry Hale,**

*Staff Assistant, National Endowment for the Arts.*

[FR Doc. 2018–23660 Filed 10–29–18; 8:45 am]

BILLING CODE 7537–01–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.

**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 advise the Chairman of the National Endowment for the Humanities (NEH) with respect to policies, programs and procedures for carrying out his functions; 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; and to consider gifts offered to NEH and make recommendations thereon to the Chairman.

**DATES:** The meeting will be held on Thursday, November 15, 2018, from 9:00 a.m. until 12:00 p.m., and Friday, November 16, 2018, from 9:00 a.m. until adjourned.

**ADDRESSES:** The meeting will be held at Constitution Center, 400 7th Street SW, Washington, DC 20506. See **SUPPLEMENTARY INFORMATION** for room numbers.

**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 Committee meetings of the National Council on the Humanities will be held on November 15, 2018, as follows: The policy discussion session (open to the public) will convene at 9:00 a.m. until approximately 10:30 a.m., followed by the discussion of specific grant applications and programs before the Council (closed to the public) from 10:30 a.m. until 12:00 p.m. The following Committees will meet in the NEH offices:

Digital Humanities: Room 4085.
Education Programs: Room 2002.
Federal/State Partnership: Room 4089.
Preservation and Access: Room 4002.
Public Programs: Room P002.
Research Programs: Room P003.

The plenary session of the National Council on the Humanities will convene on November 16, 2018, at 9:00 a.m. in the Conference Center at Constitution Center. The agenda for the morning session (open to the public) will be as follows:

A. Minutes of the Previous Meeting
B. Reports
1. Chairman's Remarks
2. Senior Deputy Chairman's Remarks
1. Presentation by guest speaker Kaywin Feldman, Minneapolis Institute of Art
3. Congressional Affairs and Budget Reports
4. Reports on Policy and General Matters
a. Digital Humanities
b. Education Programs
c. Federal/State Partnership
d. Preservation and Access
e. Public Programs
f. Research Programs

The remainder of the plenary session will be for consideration of specific applications and therefore will be closed to the public.

As identified above, portions of the meeting of the National Council on the Humanities 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. The closed sessions 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.

Please note that individuals planning to attend the public sessions of the meeting are subject to security screening

procedures. If you wish to attend any of the public sessions, please inform NEH as soon as possible by contacting Melanie Gaylord at (202) 606–8322 or *gencounsel@neh.gov.* Please also provide advance notice of any special needs or accommodations, including for a sign language interpreter.

Dated: October 24, 2018.

**Elizabeth Voyatzis,**

*Committee Management Officer.*

[FR Doc. 2018–23591 Filed 10–29–18; 8:45 am]

**BILLING CODE 7536–01–P**

## NUCLEAR REGULATORY COMMISSION

**[NRC–2018–0155]**

## Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Draft NUREG; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft NUREG, NUREG/BR–0204, Rev. 3, ''Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest.'' This document provides instructions to prepare NRC Form 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)), NRC Form 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)), and NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). NRC Forms 540 and 541 must be prepared for low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility. NRC Form 542 is required only if processors and collectors of low-level radioactive waste are shipping low-level radioactive waste attributed to others for disposal at a licensed low-level radioactive waste land disposal facility.

**DATES:** Submit comments by December 31, 2018. 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 before this date.

**ADDRESSES:** You may submit comments by any of the following methods:

- Federal Rulemaking Website: Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0155. Address questions about dockets IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- Mail comments to: May Ma, Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Lloyd Desotell, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–5969, email: *Lloyd.Desotell@nrc.gov;* or Karen Pinkston, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–3650, email: *Karen.Pinkston@nrc.gov;* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

**SUPPLEMENTARY INFORMATION:**

### I. Obtaining Information and Submitting Comments

*A. Obtaining Information*

Please refer to Docket ID NRC–2018–0155 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–2018–0155.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://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.* NUREG/BR–0204, Rev. 3, ''Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest'' is available in ADAMS under Accession No. ML18261A002. The NRC has prepared a draft regulatory analysis for this proposed guidance. The analysis examines the costs and benefits of the alternatives considered by the NRC. The NRC requests public comment on the draft regulatory analysis. The draft regulatory analysis can be found under ADAMS Accession No. ML18275A039. Comments on the draft analysis may be submitted to the NRC as indicated under Section I.B, ''Submitting Comments.''
- *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.

*B. Submitting Comments*

Please include Docket ID NRC–2018–0155 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

### II. Discussion

NUREG/BR–0204, Rev. 3, ''Instructions for Completing the NRC's Uniform Low-Level Radioactive Waste Manifest,'' provides guidance on completing NRC Forms 540, 541, and 542 (*i.e.,* the NRC's Uniform Low-Level Waste Manifest). The last revision to this NUREG/BR, Rev. 2, was published in July 1998. In SECY–13–0001, ''Staff Recommendations for Improving the Integration of the Ongoing 10 CFR part 61 Rulemaking Initiatives'' (ADAMS Accession No. ML12199A412), staff noted that stakeholders suggested that NUREG/BR–0204 needs to be rewritten and that assumptions concerning the reporting of certain hard-to-detect isotopes (*i.e.,* H–3, C–14, Tc-99 and I–129) on the Uniform Waste Manifest should be revisited. To address these stakeholder comments, the NRC staff held two public workshops in March and June of 2013 to collect comments specifically on NUREG/BR–0204. Comments received on the NUREG/BR–0204, Rev. 2, as a result of these workshops can be found on the Federal Rulemaking website (*www.regulations.gov*) under Docket ID NRC–2013–0035. Many of the comments received focused on the reporting of the hard-to-detect isotopes

(*i.e.,* H–3, C–14, Tc-99 and I–129) on the Uniform Low-Level Radioactive Waste Manifest.

In 2013, the NRC staff also identified additional changes that may be needed for the Uniform Low-Level Radioactive Waste Manifest forms and associated guidance in NUREG/BR–0204 as a part of the ongoing part 61 of title 10 of the Code of **Federal Register** (10 CFR) rulemaking (Docket ID *NRC–2009–0257*). The 10 CFR part 61 rulemaking, however, had not progressed far enough for the specific changes to the Uniform Low-Level Radioactive Waste Manifest forms and NUREG/BR–0204 to be known with certainty.

Therefore, staff developed Regulatory Information Summary (RIS–15–002) to address stakeholder concerns regarding the reporting of hard-to-detect radionuclides on the Uniform Low-Level Radioactive Waste Manifest. This RIS, titled ''Reporting of H-3, C-14, Tc-99, and I-129 on the Uniform Waste Manifest'' (ADAMS Accession No. ML14272A217), informs addressees of the option to use indirect methods to determine the activity of H-3, C-14, Tc-99, and I-129 reported on the Uniform Low-Level Radioactive Waste Manifest when the radionuclide is present at a concentration less than the lower limit of detection (LLD). The request for comments on draft RIS was published on in the **Federal Register** on June 2, 2014 (79 FR 31348), and the final RIS was published on February 18, 2015.

In September of 2017, the NRC received direction from the Commission on the part 61 rulemaking in SRM–SECY–16–0106 (ADAMS Accession No. ML17251B147), and the NRC staff determined that there was enough certainty in the portions of the part 61 rulemaking that affected the Uniform Low-Level Radioactive Waste Manifest to issue a draft of the manifest forms and the instructions in NUREG/BR–0204 for comment. The NRC staff considered the comments received in 2013 when revising these documents. Major areas of revision include: Updated references to Department of Transportation (DOT) regulations to reflect the current DOT regulations, additional discussion on the reporting of inventories based on LLD values, the potential use of indirect methods to determine these inventories, including the use of indirect methods in waste classification, clarification of the certification statement on Form 540, and overall improvements to the clarity of NUREG/BR–0204.

The NRC is requesting public comments on the draft revised Uniform Low-Level Radioactive Waste Manifest (NRC Forms 540, 541, and 542) and on the draft Rev. 3 to NUREG/BR–0204, and on the draft regulatory analysis. The NRC staff will consider any comments received in preparing the final version of Rev. 3 and the revised NRC Forms 540, 541, and 542. In responding, commenters are encouraged to provide specific suggestions and the basis for suggestions offered. Specifically, the NRC staff requests comment on the following questions:

1. Do the proposed revised Uniform Low-Level Radioactive Waste Manifest Forms 540, 541, and 542 request all of the information that is needed for the transport and disposal of low-level radioactive waste to be safely managed? Is there any additional information that should be collected?

2. Is any additional guidance or clarification needed in the instructions for filling out the Uniform Low-Level Radioactive Waste Manifest Forms in NUREG/BR–0204?

3. NRC Form 541 has lists of container description codes (note 1), waste descriptor codes (note 2), and sorption and solidification media (note 3) that have not been updated recently. Are there any items that should be added to these lists based on new technology or changes to industry practices? Are there any items on these lists that should be deleted because they are no longer in use or for any other reason? Should the items in the lists be combined in any way?

Dated at Rockville, Maryland, this 25th day of October, 2018.

For the Nuclear Regulatory Commission.

**Andrea L. Kock,**

*Deputy Director, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 2018–23694 Filed 10–29–18; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

**[NRC–2018–0001]**

## Sunshine Act Meetings

**TIME AND DATE:** Weeks of October 29, November 5, 12, 19, 26, December 3, 2018.

**PLACE:** Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

**STATUS:** Public and Closed.

**MATTERS TO BE CONSIDERED:**

**Week of October 29, 2018**

*Monday, October 29, 2018*

9:00 a.m. Transformation at the NRC (Public) (Contact: Kevin Williams: 301–415–1611)

This meeting will be webcast live at the web address—*http://www.nrc.gov/.*

**Week of November 5, 2018—Tentative**

There are no meetings scheduled for the week of November 5, 2018.

**Week of November 12, 2018—Tentative**

There are no meetings scheduled for the week of November 12, 2018.

**Week of November 19, 2018—Tentative**

There are no meetings scheduled for the week of November 19, 2018.

**Week of November 26, 2018—Tentative**

*Thursday, November 29, 2018*

10:00 a.m. Briefing on Security Issues (Closed Ex. 1)

**Week of December 3, 2018**

*Monday, December 3, 2018*

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public) (Contact: Larniece McKoy Moore: 301–415–1942)

This meeting will be webcast live at the web address—*http://www.nrc.gov/.*

*Thursday, December 6, 2018*

10:00 a.m. Meeting with Advisory Committee on Reactor Safeguards (Public) (Contact: Mark Banks: 301–415–3718)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

**CONTACT PERSON FOR MORE INFORMATION:** For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Kimberly Meyer-Chambers, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on

requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or you may email *Patricia.Jimenez@nrc.gov* or *Wendy.Moore@nrc.gov.*

Dated at Rockville, Maryland, this 25th day of October, 2018.

For the Nuclear Regulatory Commission.

**Denise L. McGovern,**

*Policy Coordinator, Office of the Secretary.*

[FR Doc. 2018–23764 Filed 10–26–18; 11:15 am]

**BILLING CODE 7590–01–P**

## NUCLEAR REGULATORY COMMISSION

**[Docket Nos. 52–025 and 52–026; NRC–2008–0252]**

## Southern Nuclear Operating Company, Inc., Vogtle Electric Generating Plant, Units 3 and 4; Changes to Tier 2* Departure Evaluation Process

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Exemption and combined license amendment; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is granting an exemption for prior NRC approval of any departure from Tier 2* information or any departure from Tier 2 information that involves a change to or departure from Tier 2* information, provided that specified criteria are not met, and is issuing License Amendment Nos. 142 and 141 to Combined Licenses (COLs) NPF–91 and NPF–92, respectively. The COLs were issued to Southern Nuclear Operating Company, Inc., and Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC, MEAG Power SPVJ, LLC, MEAG Power SPVP, LLC, and the City of Dalton, Georgia (collectively SNC); for construction and operation of the Vogtle Electric Generating Plant (VEGP) Units 3 and 4, located in Burke County, Georgia.

The granting of the exemption allows the imposition of License Condition 2.D.13 asked for in the amendment request. Because the acceptability of the exemption was determined in part by the acceptability of the amendment, the exemption and amendment are being issued concurrently.

**DATES:** The exemption and amendment were issued on September 20, 2018.

**ADDRESSES:** Please refer to Docket ID NRC–2008–0252 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0252. Address questions about NRC Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document. The request for the amendment and exemption was submitted by letter dated December 21, 2017, and available in ADAMS under Accession No. ML17355A416.
- *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.

**FOR FURTHER INFORMATION CONTACT:** Chandu Patel, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3025; email: *Chandu.Patel@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Introduction

The NRC is granting an exemption from paragraphs B.5.a, B.6.b, and B.6.c of section VIII, ''Processes for Changes and Departures,'' of Appendix D, of Part 52 of Title 10 of the *Code of Federal Regulations* (10 CFR), and issuing License Amendment No. to COLs, NPF–91 and NPF–92, to SNC. With the requested amendment, SNC sought proposed License Condition 2.D.13 and proposed changes that would revise the Updated Final Safety Analysis Report Tier 2 information.

Part of the justification for granting the exemption was provided by the review of the amendment. Because the exemption is necessary in order to issue the requested license amendment, the NRC granted the exemption and issued the amendment concurrently, rather than in sequence. This included issuing a combined safety evaluation containing the NRC staff's review of both the exemption request and the license amendment. The exemption met all applicable regulatory criteria set forth in Sections 50.12 and 52.7 of 10 CFR part 52. The license amendment was found to be acceptable as well. The combined safety evaluation is available in ADAMS under Accession No. ML18207A262.

Identical exemption documents (except for referenced unit numbers and license numbers) were issued to SNC for VEGP Units 3 and 4 (COLs NPF–91 and NPF–92). The exemption documents for VEGP Units 3 and 4 can be found in ADAMS under Accession Nos. ML18235A031 and ML18235032, respectively. The exemption is reproduced (with the exception of abbreviated titles and additional citations) in Section II of this document. The amendment documents for COLs NPF–91 and NPF–92 are available in ADAMS under Accession Nos. ML18235A033 and ML18235A035, respectively. A summary of the amendment documents is provided in Section III of this document.

### II. Exemption

Reproduced below is the exemption document issued to VEGP Units 3 and 4. It makes reference to the combined safety evaluation that provides the reasoning for the findings made by the NRC (and listed under Item 1) in order to grant the exemption:

1. In a letter dated December 21, 2017, as supplemented by letters dated April 6, May 11, June 18, August 3, August 10, and September 13, 2018, SNC requested from the Commission an exemption from the requirements of 10 CFR part 52, Appendix D, ''Design Certification Rule for the AP1000 Design,'' Section VIII, ''Processes for Changes and Departures,'' paragraphs VIII.B.5.a, VIII.B.6.b, and VIII.B.6.c, for prior NRC approval of any departure from Tier 2* information or any departure from Tier 2 information that involves a change to or departure from Tier 2* information, provided that specified criteria are not met. SNC specified the criteria in a new license condition in license amendment request (LAR) 17–037, ''Changes to the Tier 2* Departure Evaluation Process,'' which SNC submitted together with the exemption request. The proposed license condition would allow SNC to apply the change process for Tier 2 information in 10 CFR part 52, Appendix D, Section VIII.B.5, to a

proposed departure from Tier 2* information in the UFSAR (which includes the plant-specific design certification document (DCD), provided the criteria in the new condition are not met. For the reasons set forth in Section 3.2 of the NRC staff's Safety Evaluation, which can be found at ADAMS Accession No. ML18207A262, the Commission finds that:

A. the exemption is authorized by law;

B. the exemption presents no undue risk to public health and safety;

C. the exemption is consistent with the common defense and security;

D. special circumstances are present in that the application of the rule in this circumstance is not necessary to serve the underlying purpose of the rule;

2. Accordingly, SNC is granted an exemption from the requirements to obtain prior NRC approval for any departure from Tier 2* information and an exemption from the requirement to obtain prior NRC approval for any departure from Tier 2 information that involves a change to or departure from Tier 2* information, as described in the licensee's request dated December 21, 2017, as supplemented by letters dated April 6, May 11, June 18, August 3, August 10, and September 13, 2018, provided that each of the criteria in License Condition 2.D.(13)(a) is not met for each such departure. These exemptions are related to, and necessary for the granting of License Amendment No. 142, which is being issued concurrently with this exemption.

3. As explained in Section 6.0 of the NRC staff's Safety Evaluation (ADAMS Accession No. ML18207A262), this exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment needs to be prepared in connection with the issuance of the exemption.

4. This exemption is effective as of the date of its issuance.

## III. License Amendment Request

By letter dated December 21, 2017 (ADAMS Accession No. ML17355A416), SNC requested that the NRC amend the COLs for VEGP, Units 3 and 4, COLs NPF–91 and NPF–92. The proposed amendment is described in Section I of this **Federal Register** notice.

The Comission has determined for these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or COL, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** on February 13, 2018 (83 FR 6234). Public comments were received during the 30-day comment period. The staff's responses to the comments appear in Section 5.0 of the Safety Evaluation.

The Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments.

## IV. Conclusion

Using the reasons set forth in the combined safety evaluation, the staff granted the exemption and issued the amendment that SNC requested on September 20, 2018. The exemption and amendment were issued on September 20, 2018, as part of a combined package to the licensee (ADAMS Accession No. ML18235A029).

Dated at Rockville, Maryland, this 25th day of October 2018.

For the Nuclear Regulatory Commission.

**Jennifer L. Dixon-Herrity,**

*Chief, Licensing Branch 4, Division of Licensing, Siting, and Environmental Analysis, Office of New Reactors.*

[FR Doc. 2018–23627 Filed 10–29–18; 8:45 am]

BILLING CODE 7590–01–P

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# NUCLEAR REGULATORY COMMISSION

## Revised 658th Meeting of the Advisory Committee on Reactor Safeguards (ACRS)

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold meetings on November 1–3, 2018, Three White Flint North, 11601 Landsdown Street, North Bethesda, MD 20852.

**Thursday, November 1, 2018, Conference Room 1C3 & 1C5, Three White Flint North, 11601 Landsdown Street, North Bethesda, MD 20852**

*8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman* (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

*8:35 a.m.–10:30 a.m.: Waterford Steam Electric Station, Unit 3 License Renewal Application* (Open)—The Committee will have briefings by and discussion with representatives of the NRC staff and Entergy regarding the safety evaluation associated with the subject license renewal application.

*10:45 a.m.–12:45 p.m.: River Bend Nuclear Generating Station, Unit 1 License Renewal Application* (Open)—The Committee will have briefings by and discussion with representatives of the NRC staff and Entergy regarding the safety evaluation associated with the subject license renewal application.

*1:45 p.m.–2:45 p.m.: Preparation for Meeting with Commission* (Open)—The Committee will prepare for the upcoming meeting with the Commission in December.

*3 p.m.–6 p.m.: Preparation of ACRS Reports* (Open)—The Committee will continue its discussion of proposed ACRS reports.

**Friday, November 2, 2018, Conference Room 1C3 & 1C5, Three White Flint North, 11601 Landsdown Street, North Bethesda, MD 20852**

*8:30 a.m.–10 a.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee and Reconciliation of ACRS Comments and Recommendations* (Open/Closed)—The Committee will hear discussion of the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS meetings. [**Note:** A portion of this meeting may be closed pursuant to 5 U.S.C. 552b (c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy].

*10:15 a.m.–12 p.m.: Preparation of ACRS Reports* (Open)—The Committee will continue its discussion of proposed ACRS reports.

*1 p.m.–6 p.m.: Preparation of ACRS Reports* (Open)—The Committee will continue its discussion of proposed ACRS reports and retreat items.

**Saturday, November 3, 2018, Conference Room 1C3 & 1C5, Three White Flint North, 11601 Landsdown Street, North Bethesda, MD 20852**

*8:30 p.m.–12 p.m.: Preparation of ACRS Reports* (Open)—The Committee will continue its discussion of proposed ACRS reports and retreat items.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 4, 2017 (82 FR 46312). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff (Telephone: 301–415–5844, Email: *Quynh.Nguyen@nrc.gov*), 5 days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience. The bridgeline number for the meeting is 866–822–3032, passcode 8272423#.

Thirty-five hard copies of each presentation or handout should be provided 30 minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the Cognizant ACRS Staff one day before meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the Cognizant ACRS Staff with a CD containing each presentation at least 30 minutes before the meeting.

In accordance with Subsection 10(d) of Public Law 92–463 and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room at *pdr.resource@nrc.gov,* or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC website at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/#ACRS/*.

Video teleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–6702), between 7:30 a.m. and 3:45 p.m. (ET), at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

**Note:** The ''Waterford Steam Electric Station, Unit 3 License Renewal Application'' meeting was listed on the previous notice as ending at 10 a.m. but is currently scheduled to end at 10:30 a.m.

Dated: October 24, 2018.

**Russell E. Chazell,**

*Federal Advisory Committee Management Officer, Office of the Secretary.*

[FR Doc. 2018–23619 Filed 10–29–18; 8:45 am]

**BILLING CODE 7590–01–P**

## OFFICE OF PERSONNEL MANAGEMENT

### Federal Salary Council; Meeting Notice

**AGENCY:** Office of Personnel Management.

**ACTION:** Notice of meeting.

**SUMMARY:** The Federal Salary Council will meet on Tuesday, November 13, 2018, at the time and location shown below. The Council is an advisory body composed of representatives of Federal employee organizations and experts in the fields of labor relations and pay policy. The Council makes recommendations to the President's Pay Agent (the Secretary of Labor and the Directors of the Office of Management and Budget and the Office of Personnel Management) about the locality pay program for General Schedule employees. The Council's recommendations cover the establishment or modification of locality pay areas, the coverage of salary surveys, the process of comparing Federal and non-Federal rates of pay, and the level of comparability payments that should be paid.

The Council will hear public testimony about the locality pay program, review the results of pay comparisons, and formulate its recommendations to the President's Pay Agent on pay comparison methods, locality pay rates, and locality pay areas and boundaries for 2020.

The meeting is open to the public. Individuals who wish to provide testimony or present material at the meeting should contact the Office of Personnel Management using the telephone number or email address provided below. In addition, please be aware that the Council asks that oral testimony at the meeting be limited to 5 minutes per speaker.

**DATES:** Tuesday, November 13, 2018, at 1:00 p.m.

**ADDRESSES:** Office of Personnel Management, 1900 E Street NW, Room 1350, Washington, DC 20415.

**FOR FURTHER INFORMATION CONTACT:** Brenda L. Roberts, Deputy Associate Director, Pay and Leave, Office of Personnel Management, 1900 E Street NW, Room 7H31, Washington, DC 20415–8200. Phone (202) 606–2838; FAX (202) 606–0824; or email at *pay-leave-policy@opm.gov.*

For The President's Pay Agent.

**Alexys Stanley,**

*Regulatory Affairs Analyst.*

[FR Doc. 2018–23630 Filed 10–29–18; 8:45 am]

**BILLING CODE 6329–39–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–84481; File No. SR–CboeEDGX–2018–037]**

### Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Permit the Listing and Trading of P.M.-Settled Series on Certain Broad-Based Index Options on a Pilot Basis

October 24, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on October 11, 2018, Cboe EDGX Exchange, Inc. filed with the Securities and Exchange Commission (the ''Commission'' or ''SEC'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX Options'') proposes to permit the listing and trading of P.M.-settled series on certain broad-based index options on a pilot basis. [The text of the proposed rule change is provided below.] [sic]

The text of the proposed rule change is also available on the Exchange's

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change*

1. Purpose

The proposed rule change permits the listing and trading of P.M.-settled series on certain broad-based index options on a pilot basis.[3] First, the proposed rule change would permit the listing and trading of XSP options with third-Friday-of-the-month expiration dates, whose exercise settlement value will be based on the closing index value on the expiration day (''P.M.-settled'') for an initial period of twelve months (the ''XSPPM Pilot Program'') from the date of approval of this proposed rule change. Second, the proposed rule change would permit the listing and trading of P.M.-settled options on broad-based indexes with weekly expirations (''Weeklys'') and end-of-month expirations (''EOMs'') for an initial period of 12 months (the ''Nonstandard Expirations Pilot Program'') from the date of approval of this proposed rule change.

XSPPM Pilot Program

Proposed Rule 29.11(a)(6) permits the listing and trading, in addition to A.M.-settled XSP options, of P.M.-settled XSP options with third-Friday-of-the-month expiration dates on a pilot basis for an initial period of 12 months from the date of approval of this proposed rule change. XSP options are A.M.-settled pursuant to the generic listing criteria in Rule 29.11(a)(5). The Exchange believes permitting the trading of XSP options on a P.M.-settled basis will encourage greater trading in XSP options.

Other than settlement and closing time on the last trading day (as discussed below), contract terms for P.M.-settled XSP options will be the same as the A.M.-settled XSP options. The proposed contract would use a $100 multiplier. The minimum trading increments, strike price intervals, and expirations would be the same as the A.M.-settled XSP option series. P.M.-settled XSP options would have European-style exercise. The Exchange will also have flexibility to open for trading additional series in response to customer demand.

The proposed rule change amends Rule 29.10(a) to state that, on their last trading day, transactions in P.M.-settled XSP options may be effected on the Exchange between the hours of 9:30 a.m. and 4:00 p.m. Eastern time (as opposed to the normal trading hours for non-expiring P.M.-settled XSP options, which are from 9:30 a.m. to 4:15 p.m. Eastern time). XSP options are typically priced in the market based on corresponding futures values. The primary listing markets for the component securities that comprise the S&P 500 Index close trading in those securities at 4:00 p.m. The primary listing exchanges for the component securities disseminate closing prices of the component securities, which are used to calculate the exercise settlement value of the S&P 500 Index. The Exchange believes that, under normal trading circumstances, the primary listing markets have sufficient bandwidth to prevent any data queuing that would cause any trades that are executed prior to the closing time from being reported after 4:00 p.m. Despite the fact that the exercise settlement value will be fixed at or soon after 4:00 p.m., if the Exchange did not close trading in expiring P.M.-settled XSP options at 4:00 p.m. on their last trading day, trading in expiring P.M.-settled XSP options would continue for an additional fifteen minutes until 4:15 p.m. and would not be able to be priced on corresponding futures values, but rather the known cash value. At the same time, the prices of non-expiring P.M.-settled XSP option series would continue to move and be priced in response to changes in corresponding futures prices.

A potential pricing divergence could occur between 4:00 p.m. and 4:15 p.m. on the final trading day in expiring P.M.-settled XSP options (*e.g.* switch from pricing off of futures to cash). Further, the switch from pricing off of futures to cash can be a difficult and risky switchover for liquidity providers. As a result, without closing expiring contracts at 4:00 p.m., it is foreseeable that Market-Makers could react by widening spreads in order to compensate for the additional risk. Therefore, the Exchange believes that, in order to mitigate potential investor confusion and the potential for increased costs to investors, it is appropriate to cease trading in the expiring P.M.-settled XSP contracts at 4:00 p.m. The Exchange does not believe the proposed change will impact volatility on the underlying cash market at the close on third Fridays. Further, other options exchanges close trading in certain options on the last trading day for certain classes.[4]

If the Exchange were to propose an extension of the XSPPM Pilot Program or should the Exchange propose to make the XSPPM Pilot Program permanent, the Exchange would submit a filing proposing such amendments to the XSPPM Pilot Program. Further, any positions established under the XSPPM Pilot Program would not be impacted by the expiration of the XSPPM Pilot Program. For example, if the Exchange lists a P.M.-settled XSP option that expires after the XSPPM Pilot Program expires (and is not extended), then those positions would continue to exist. If the pilot were not extended, then the positions could continue to exist. However, any further trading in those series would be restricted to transactions where at least one side of the trade is a closing transaction.

As part of the XSPPM Pilot Program, the Exchange will submit a pilot report to the Commission at least two months prior to the expiration date of the pilot. This annual report will contain an analysis of volume, open interest, and trading patterns. The analysis would examine trading in the proposed option product as well as trading in the securities that comprise the S&P 500 Index. In addition, for series that exceed certain minimum open interest parameters, the annual report will provide analysis of index price volatility and, if needed, share trading activity.

The annual report will contain the following volume and open interest data:

(1) Monthly volume aggregated for all trades;

(2) monthly volume aggregated by expiration date;

[3] The Exchange is authorized to list for trading options that overlie the Mini-SPX Index (''XSP'') and the Russell 2000 Index (''RUT''). *See* Rule 29.11(a).

[4] *See* Cboe Options Rule 24.6, Interpretations and Policies .01 (options with Quarterly Index Expirations), .03 (Cboe S&P 500 A.M./P.M. Basis options), .04 (P.M.-settled SPX options with third Friday-of-the-month expiration and P.M.-settled XSP options), and .05 (MSCI EAFE Index options).

(3) monthly volume for each individual series;

(4) month-end open interest aggregated for all series;

(5) month-end open interest aggregated by expiration date; and

(6) month-end open interest for each individual series.

The annual report will also contain the information noted above for expiration Friday A.M.-settled XSP option series, if applicable, for the period covered in the annual report. In addition to the annual report, the Exchange will provide the Commission with interim reports of the information listed in (1) through (6) above.

In the annual report, the annual report would contain the following analysis of trading patterns in expiration Friday, P.M.-settled XSP option series in the XSPPM Pilot Program:

(1) A time series analysis of open interest; and

(2) an analysis of the distribution of trade sizes.

Also, for series that exceed certain minimum parameters, the annual report will also contain the following analysis related to index price changes and, if needed, underlying share trading volume at the close on expiration Fridays:

(1) A comparison of index price changes at the close of trading on a given expiration Friday with comparable price changes from a control sample. The data will include a calculation of percentage price changes for various time intervals and compare that information to the respective control sample. Raw percentage price change data as well as percentage price change data normalized for prevailing market volatility, as measured by an appropriate index as agreed by the Commission and the Exchange, would be provided; and

(2) a calculation of share volume for a sample set of the component securities representing an upper limit on share trading that could be attributable to expiring in-the-money series. The data, if needed, will include a comparison of the calculated share volume for securities in the sample set to the average daily trading volumes of those securities over a sample period.

The minimum open interest parameters, control sample, time intervals, method for randomly selecting the component securities, and sample periods would be determined by the Exchange and the Commission.

Additionally, the Exchange will provide the Commission with any additional data or analyses the Commission requests because it deems such data or analyses necessary to determine whether the XSPPM Pilot Program is consistent with the Exchange Act. The Exchange will make public all data and analyses it submits to the Commission under the XSPPM Pilot Program.

Other exchanges currently have pilots that permit P.M.-settled index options.[5]

Nonstandard Expirations Pilot Program

The proposed rule change permits the listing and trading, on a pilot basis, of P.M.-settled options on broad-based indexes with nonstandard expiration dates for an initial period of 12 months from the date of approval of this proposed rule change. The Nonstandard Expirations Pilot Program will permit both Weeklys and EOMs as discussed below. Contract terms for the Weekly and EOM expirations will be similar to those of the A.M.-settled broad-based index options, except that the Weekly and EOM expirations will be P.M.-settled.

Proposed Rule 29.11(j)(1) permits the Exchange to open for trading Weeklys on any broad-based index eligible for standard options trading to expire on any Monday, Wednesday, or Friday (other than the third Friday-of-the-month or days that coincide with an EOM). Weeklys will be subject to all provisions of Rule 29.11 and will be treated the same as options on the same underlying index that expire on the third Friday of the expiration month. However, Weeklys will be P.M.-settled, and new Weekly series may be added up to and including on the expiration date for an expiring Weekly.

The maximum number of expirations that may be listed for each Weekly (*i.e.,* a Monday expiration, a Wednesday expiration, or Friday expiration, as applicable) in a given class will be the same as the maximum number of expirations permitted in Rule 29.11(a)(3) for standard options on the same broad-based index.[6] Weeklys would not need to be for consecutive Monday, Wednesday, or Friday expirations, as applicable. However, the expiration date of a non-consecutive expiration would not be permitted beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively. Weeklys that are first listed in a given class could expire up to four weeks from the actual listing date. If the last trading day of a month is a Monday, Wednesday, or Friday and the Exchange lists EOMs and Weeklys, as applicable, in a given class, the Exchange will list an EOM instead of a Weekly in the given class. Other expirations in the same class are not counted as part of the maximum number of Weeklys for a broad-based index class. If the Exchange is not open for business on a respective Monday, the normally Monday expiring Weeklys would expire on the following business day. If the Exchange is not open for business on a respective Wednesday or Friday, the normally Wednesday or Friday expiring Weekly will expire on the previous business day.

Proposed Rule 29.11(a)(2) [sic] permits the Exchange to open for trading EOMs on any broad-based index eligible for standard options trading to expire on the last trading day of the month. EOMs will be subject to all provisions of Rule 29.11 and treated the same as options on the same underlying index that expire on the third Friday of the expiration month. However, EOMs will be P.M.-settled, and new series of EOMs may be added up to and including on the expiration date for an expiring EOM.

The maximum number of expirations that may be listed for EOMs in a given class is the same as the maximum number of expirations permitted in Rule 29.11(a)(3) for standard options on the same broad-based index.[7] EOMs need not be for consecutive end-of-month expirations. However, the expiration date of a non-consecutive expiration may not be beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively. EOMs that are first listed in a given class may expire up to four weeks from the actual listing date. Other expirations in the same class are not counted as part of the maximum number of EOMs for a broad-based index class.

The proposed rule change amends Rule 29.11(c)(5)(C) to provide that the lowest strike interval for series of XSP options listed under the Nonstandard Expirations Pilot Program will be $0.50. With respect to XSP, this is consistent with the minimum strike interval for XSP options listed under the Short Term Series Program.[8] Additionally, this is consistent with the minimum strike interval for options on the Standard & Poor's Depository Receipts Trust (SPY), which is an ETF that like XSP tracks the performance of 1/10th

[5] *See* Cboe Options Rule 24.9, Interpretation and Policy .14 and Phlx Rule 1101A, Commentary .05.

[6] Pursuant to Rule 29.11(a)(3), the Exchange may list up to six expiration months at any one time. Therefore, pursuant to the proposed rule change, the Exchange may list a maximum of six Weekly expirations under the Nonstandard Expirations Pilot Program.

[7] *Id.*

[8] *See* Rule 29.11(c)(5)(C).

the value of the S&P 500 Index, with weekly expirations.[9]

Weeklys and EOMs will be subject to the same rules that currently govern the trading of standard monthly broad-based index options, including sales practice rules, margin requirements, and floor trading procedures. Contract terms for Weeklys and EOMs will be the same as those for standard monthly broad-based index options. Since Weeklys and EOMs will be new types of series, and not a new class, the Exchange proposes that Weeklys and EOMs will be aggregated for any applicable reporting and other requirements.[10] Pursuant to new proposed Rule 29.11(j)(4), expiring transactions in Weeklys and EOMs may be effected on the Exchange between the hours of 9:30 a.m. and 4:00 p.m. (Eastern time).

As stated above, this proposed rule change establishes a Nonstandard Expirations Pilot Program for broad-based index options on a pilot basis, for an initial period of 12 months from the date of approval of this proposed rule change. If the Exchange were to propose an extension of the Nonstandard Expirations Pilot Program or should the Exchange propose to make it permanent, the Exchange would submit a filing proposing such amendments. Further, any positions established under the Nonstandard Expirations Pilot Program would not be impacted by the expiration of the pilot. For example, if the Exchange lists a Weekly or EOM that expires after the Nonstandard Expirations Pilot Program expires (and is not extended), then those positions would continue to exist. However, any further trading in those series would be restricted to transactions where at least one side of the trade is a closing transaction.

As part of the Nonstandard Expirations Pilot Program, the Exchange will submit a pilot report to the Commission at least two months prior to the expiration date of the pilot (the ''annual report''). The annual report will contain an analysis of volume, open interest, and trading patterns. In addition, for series that exceed certain minimum open interest parameters, the annual report will provide analysis of the index price volatility, and, if needed, share trading activity.

For all Weekly and EOM series, the annual report will contain the following volume and open interest data for each broad-based index overlying Weekly and EOM options:

(1) Monthly volume aggregated for all Weekly and EOM series;

(2) Volume in Weekly and EOM series aggregated by expiration date;

(3) Month-end open interest aggregated for all Weekly and EOM series;

(4) Month-end open interest for EOM series aggregated by expiration date and open interest for Weekly series aggregated by expiration date;

(5) Ratio of monthly aggregate volume in Weekly and EOM series to total monthly class volume; and

(6) Ratio of month-end open interest in EOM series to total month-end class open interest and ratio of open interest in each Weekly series to total class open interest.

In addition, the annual report will contain the information noted above for standard expiration Friday, A.M.-settled series, if applicable, for the period covered in the annual report as well as for the six-month period prior to the initiation of the pilot.

Upon request by the SEC, the Exchange will provide a data file containing: (1) Weekly and EOM option volume data aggregated by series, and

(2) Weekly open interest for each expiring series and EOM month-end open interest for expiring series.

In the annual report, the Exchange also proposes to identify Weekly and EOM trading patterns by undertaking a time series analysis of open interest in Weekly and EOM series aggregated by expiration date compared to open interest in near-term standard expiration Friday A.M.-settled series in order to determine whether users are shifting positions from standard series to Weekly and EOM series. In addition, to the extent that data on other weekly or monthly P.M.-settled products from other exchanges is publicly available, the report will also compare open interest with these options in order to determine whether users are shifting positions from other weekly or monthly P.M.-settled products to the Weekly and EOM series. Declining open interest in standard series or the weekly or monthly P.M.-settled products of other exchanges accompanied by rising open interest in Weekly and EOM series would suggest that users are shifting positions.

For each Weekly and EOM expiration that has open interest that exceeds certain minimum thresholds, the annual report will contain the following analysis related to index price changes and, if needed, underlying share trading volume at the close on expiration dates:

(1) A comparison of index price changes at the close of trading on a given expiration date with comparable price changes from a control sample. The data will include a calculation of percentage price changes for various time intervals and compare that information to the respective control sample. Raw percentage price change data as well as percentage price change data normalized for prevailing market volatility, as measured by an appropriate index agreed to by the Commission and the Exchange, will be provided; and

(2) If needed, a calculation of share volume for a sample set of the component securities representing an upper limit on share trading that could be attributable to expiring in-the-money Weekly and EOM series. The data, if needed, will include a comparison of the calculated share volume for securities in the sample set to the average daily trading volumes of those securities over a sample period.

The minimum open interest parameters, control sample, time intervals, method for selecting the component securities, and sample periods will be determined by the Exchange and the Commission.

Additionally, the Exchange will provide the Commission with any additional data or analyses the Commission requests because it deems such data or analyses necessary to determine whether the Nonstandard Expirations Pilot Program is consistent with the Exchange Act. The Exchange will make public all data and analyses it submits to the Commission under the Nonstandard Expirations Pilot Program. Other exchanges currently have pilots that have weekly and end-of-month expirations.[11]

## Additional Information

Precedent exists for P.M.-settled broad-based index options, as other options exchanges list P.M.-settled broad-based index options.[12] The

[9] *See* Rule 19.6, Interpretation and Policy .05(f).

[10] Rule 29.5(a) requires Options Members to comply with the applicable rules of Cboe Options with respect to position limits for broad-based index options for options traded on Cboe Options. Cboe Options Rule 24.4, Interpretation and Policy .03 sets forth the reporting requirements for certain market indexes that do not have position limits, including XSP and RUT, and would apply to XSP and RUT options traded on the Exchange pursuant to Rule 29.5(a); *see also* Cboe Options Rule 24.4(b), which provides that Weeklys and EOMs will be aggregated with option contracts on the same broad-based index and will be subject to the overall position limit, and would apply to Weeklys/EOMs traded on the Exchange pursuant to Rule 29.5(a). The Exchange notes that the proposed aggregation is consistent with the aggregation requirements or other types of option series (*e.g.* quarterly expiring options) that may be listed on the Exchange and that do not expire on the customary ''third Friday'' (*see* Cboe Options Rule 24.4(e)).

[11] *See* Cboe Options Rule 24.9(e); and Phlx Rule 1101A(b)(vii).

[12] *See, e.g.,* Cboe Options Rule 24.9(a)(4) (OEX not listed as A.M.-settled) and Interpretation and Policy .14 (permits listing of P.M.-settled SPX and XSP

Continued

Exchange does not believe that any market disruptions will be encountered with the introduction of listing P.M.-settled options on the Exchange. The Exchange will monitor for any such disruptions or the development of any factors that would cause such disruptions.

The Exchange notes that P.M.-settled options predominate in the over-the-counter (''OTC'') market, and the Exchange is not aware of any adverse effects in the stock market attributable to the P.M.-settlement feature. The Exchange is merely proposing to offer a P.M.-settled product in an exchange environment that offers the benefit of added transparency, price discovery, and stability. In response to any potential concerns that disruptive trading conduct could occur as a result of the concurrent listing and trading of two index option products based on the same index but for which different settlement methodologies exist (*i.e.,* one is A.M.-settled and one is P.M.-settled), the Exchange notes that Cboe Options lists and trades both A.M.-settled and P.M.-settled SPX options, and Phlx lists and trades both A.M.-settled and P.M.-settled NDX options. The Exchange is not aware of any market disruptions occurring as a result of these exchanges offering both products.

The adoption of P.M.-settled options on an exchange that lists A.M.-settled options in the same class would provide greater spread opportunities. This manner of trading in different products allows a market participant to take advantage of the different expiration times, providing expanded trading opportunities. In the options market currently, market participants regularly trade similar or related products in conjunction with each other, which contributes to overall market liquidity.

The Exchange represents it has an adequate surveillance program in place for index options. The Exchange is a member of the Intermarket Surveillance Group (''ISG''), which is comprised of an international group of exchanges, market centers, and market regulators. The purpose of ISG is to provide a framework for the sharing of information and the coordination of regulatory efforts among exchanges trading securities and related products to address potential intermarket manipulations and trading abuses. ISG plays a crucial role in information sharing among markets that trade securities, options on securities, security futures products, and futures and options on broad-based security indexes. A list of identifying current ISG members is available at *https://www.isgportal.org/isgPortal/public/members.htm*.

The Exchange has analyzed its capacity and represents that it believes the Exchange and OPRA have the necessary systems capacity to handle the additional traffic associated with the listing of P.M.-settled XSP and Weekly/EOM option series up to the proposed number of possible expirations and strike prices. The Exchange believes any additional traffic that would be generated from the introduction of P.M.-settled XSP and Weekly/EOM options series will be manageable. The Exchange believes its Members will not have a capacity issue as a result of this proposed rule change. The Exchange also represents that it does not believe this expansion will cause fragmentation of liquidity. The Exchange will monitor the trading volume associated with the additional options series listed as a result of this proposed rule change and the effect (if any) of these additional series on market fragmentation and on the capacity of the Exchange's automated systems.

P.M.-settled options would be subject to all provisions of Rule 29.11. P.M.-settled options would be subject to the same rules that govern the trading of A.M.-settled options overlying the same indexes, including sales practice rules, margin requirements, and floor trading procedures. P.M.-settled options will be subject to the margin requirements set forth in Chapter 28 and the position limits set forth in Rule 29.5. Chapter 28 imposes the margin requirements of either Cboe Options or the New York Stock Exchange on Exchange Options Members. Similarly, Rule 29.5 imposes position (and exercise) limits for broad-based index options of Cboe Options on Exchange Options Members. Since P.M.-settled options will be a new type of series, and not a new class, the Exchange proposes that the P.M.-settled options will be aggregated for any applicable reporting and other requirements.[13] Currently, there are no position limits on RUT and XSP options.[14] Therefore, there will be no position limits on P.M.-settled RUT and XSP options. P.M.-settled XSP options and Weekly/EOM broad-based index options are currently authorized for listing on Cboe Options,[15] and thus the same margin requirements and position and exercise limits that apply to these products as listed and traded on Cboe Options will apply to these products when listed and traded on the Exchange. The proposed rule change will also result in similar regulatory treatment for similar option products.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[16] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[17] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes the proposed rule change will attract order flow to the Exchange, increase the variety of listed options to investors, and provide a valuable hedge tool to investors. The Exchange believes the proposed rule change will also remove impediments to and perfect the mechanism of a free and open market, and in general protect investors by expanding the ability of investors to hedge risks against market movements stemming from economic releases or market events that occur during the month and at the end of the month. Accordingly, the Exchange believes that P.M.-settled options will create greater trading and hedging opportunities and flexibility, and

options); and PHLX Rule 1101A, Commentary .05 (permits listing of P.M.-settled NDX options).

[13] *See* Rule 29.5(a), which requires Options Members to comply with the applicable rules of Cboe Options with respect to position limits for broad-based index options for options traded on Cboe Options. Cboe Options Rule 24.4(b), which applies to index options traded on the Exchange pursuant to Rule 29.5(a), provides that Nonstandard Expirations will be aggregated with option contracts on the same broad-based index and subject to the overall position limit. Additionally, Cboe Options Rule 24.4(d), which applies to index options traded on the Exchange pursuant to Rule 29.5(a), positions in reduced-value index options will be aggregated with positions in full-value indices. The Exchange notes that the proposed aggregation is consistent with the aggregation requirements for other types of option series (*e.g.* quarterly expiring options) that are listed on the Exchange and that do not expire on the customary ''third Friday.'' *See* Cboe Options Rule 24.4 (which applies to the Exchange pursuant to Rule 29.5(a)).

[14] *See* Cboe Options Rule 24.4(a) (which applies to the Exchange pursuant to Rule 29.5(a)).

[15] Similarly, pursuant to Cboe Options Chapter 12, Cboe Options Trading Permit Holders may request to have New York Stock Exchange margin requirements apply to their trading.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

provide customers with the ability to more closely tailor their investment objectives.

The Commission has previously stated that when cash-settled index options were first introduced in the 1980s, they generally utilized closing-price settlement procedures (*i.e.,* P.M. settlement). The Commission stated it became concerned about the impact of P.M. settlement on cash-settled index options on the markets for the underlying stocks at the close on expiration Fridays, especially during the quarterly expirations of the third Friday of March, June, September, and December when options, index futures, and options on index futures all expire simultaneously. The Commission expressed concerns that P.M. settlement was believed to have contributed to above-average volume and added market volatility on those days, which sometimes led to sharp price movements during the last hour of trading, as a consequence of which the close of trading on the quarterly expiration Friday became known as the ''triple witching hour.'' The Commission observed that besides contributing to investor anxiety, heightened volatility during the expiration periods created the opportunity for manipulation and other abusive trading practices in anticipation of the liquidity constraints.[18]

However, the Exchange believes that the above concerns that have led to the transition to A.M. settlement for index derivatives have been largely mitigated. It believes that expiration pressure in the underlying cash markets at the close has been greatly reduced with the advent of multiple primary listing and unlisted trading privilege markets, and that trading is now widely dispersed among many market centers. Additionally, the Exchange notes that opening procedures in the 1990s were deemed acceptable to mitigate one-sided order flow driven by index option expiration and that the New York Stock Exchange and Nasdaq Stock Market, LLC each use an automated closing cross procedures and has a closing order type that facilitates orderly closings. These closing procedures on the exchanges on which the components of the S&P 500 Index trade are well-equipped to mitigate imbalance pressure at the close. In addition, after-hours trading now provides market participants with an alternative to help offset market-on-close imbalances.[19]

Other exchanges currently have pilots that permit P.M.-settled index options[20] and Weekly/EOM options.[21]

The proposed rule change to permit transactions on the Exchange in P.M.-settled XSP and Weekly/EOM options on their last trading day between the hours of 9:30 a.m. and 4:00 p.m. Eastern time (as opposed to the normal trading hours for non-expiring P.M.-settled XSP and Weekly/EOM options, which are from 9:30 a.m. to 4:15 p.m. Eastern time) will prevent potential pricing divergence that could occur between 4:00 p.m. and 4:15 p.m. on the final trading day in expiring P.M.-settled XSP options. Without closing expiring contracts at 4:00 p.m., it is foreseeable that Market-Makers would react by widening spreads in order to compensate for the additional risk. Therefore, the Exchange believes that, in order to mitigate potential investor confusion and the potential for increased costs to investors, it is appropriate to cease trading in the expiring P.M.-settled XSP and Weekly/EOM contracts at 4:00 p.m. The Exchange does not believe the proposed change will impact volatility on the underlying cash market at the close on third Fridays. Further, the other options exchanges close trading in certain options on the last trading day for certain classes.[22]

The Exchange has analyzed its capacity and represents that it believes the Exchange and OPRA have the necessary systems capacity to handle the additional traffic associated with the listing of P.M.-settled options. The Exchange believes any additional traffic that may be generated from the introduction of P.M.-settled options will be manageable. The Exchange represents that it has in place adequate surveillance procedures to monitor trading in these options thereby helping to ensure the maintenance of a fair and orderly market.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. P.M.-settled options would be available for trading on the Exchange to all market participants. The Exchange believes the proposed rule change will increase the variety of listed options to investors, and provide valuable hedge tools to investors. The listing of P.M.-settled options will enhance competition by providing investors with an additional investment vehicle, through which investors can gain and hedge exposure to the stocks that compose the applicable broad-based indexes. Additionally, markets participants are welcome to become Members and trade at the Exchange if they determine this proposed rule change has made the Exchange more attractive or favorable. Further, this product could offer a competitive alternative to other existing investment products that seek to allow Members to gain broad market exposure. Finally, all options exchanges are free to compete by listing and trading index options that are P.M.-settled. Other exchanges currently have pilots that permit P.M.-settled index options[23] or Weeklys/EOMs.[24]

The proposed rule change to permit transactions on the Exchange in P.M.-settled XSP and Weekly/EOM options on their last trading day between the hours of 9:30 a.m. and 4:00 p.m. Eastern time (as opposed to the normal trading hours for non-expiring P.M.-settled XSP and Weekly/EOM options, which are from 9:30 a.m. to 4:15 p.m. Eastern time) will prevent potential pricing divergence that could occur between 4:00 p.m. and 4:15 p.m. on the final trading day in expiring P.M.-settled XSP and Weekly/EOM options. Without closing expiring contracts at 4:00 p.m., it is foreseeable that Market-Makers would react by widening spreads in order to compensate for the additional risk. Therefore, the Exchange believes that, in order to mitigate potential investor confusion and the potential for increased costs to investors, it is appropriate to cease trading in the expiring P.M.-settled XSP and Weekly/EOM contracts at 4:00 p.m. The Exchange does not believe the proposed change will impact volatility on the underlying cash market at the close on third Fridays. Further, the other options exchanges close trading in certain options on the last trading day for certain classes.[25]

[18] *See* Securities Exchange Act Release No. 65256 (September 2, 2011), 76 FR 55569 (September 9, 2011) (SR–C2–2011–008) (order approving listing of SPXPM options on C2); *see also* Securities Exchange Act Release No. 81293 (August 2, 2017), 82 FR 151 (August 8, 2017) (SR–Phlx–2017–04) (or approving listing of NDXPM options on Phlx).

[19] *See id.*

[20] *See* Cboe Options Rule 24.9, Interpretation and Policy .14; and Phlx Rule 1101A, Commentary .05.

[21] *See* Cboe Options Rule 24.9(e); and Phlx Rule 1101A(b)(vii).

[22] *See* Cboe Options Rule 24.6, Interpretations and Policies .01 (options with Quarterly Index Expirations), .03 (Cboe S&P 500 a.m./PM Basis options), .04 (P.M.-settled SPX options with third Friday-of-the-month expiration and P.M.-settled XSP options), and .05 (MSCI EAFE Index options).

[23] *See* Cboe Options Rule 24.9, Interpretation and Policy .14 and Phlx Rule 1101A, Interpretation and Policy .05.

[24] *See* Cboe Options Rule 24.9(e); and Phlx Rule 1101A(b)(vii).

[25] *See* Cboe Options Rule 24.6, Interpretations and Policies .01 (options with Quarterly Index

Continued

The Exchange believes that the proposed rule change will relieve any burden on, or otherwise promote, competition, as the rules are substantially the same as those of other options exchanges, as noted above.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Exchange neither solicited nor received comments on the proposed rule change.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. by order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeEDGX–2018–037 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–2018–037. 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–2018–037, and should be submitted on or before November 20, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018–23625 Filed 10–29–18; 8:45 am]

**BILLING CODE 8011–01–P**

Expirations), .03 (Cboe S&P 500 a.m./PM Basis options), .04 (P.M.-settled SPX options with third Friday-of-the-month expiration and P.M.-settled XSP options), and .05 (MSCI EAFE Index options).

[26] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

### Sunshine Act Meetings

**TIME AND DATE:** 2:00 p.m. on Thursday, November 1, 2018.

**PLACE:** The meeting will be held at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

**STATUS:** This meeting will be closed to the public.

**MATTERS TO BE CONSIDERED:** Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

Commissioner Peirce, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matters of the closed meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

**CONTACT PERSON FOR MORE INFORMATION:** For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Brent J. Fields from the Office of the Secretary at (202) 551–5400.

Dated: October 25, 2018.

**Lynn M. Powalski,**

*Deputy Secretary.*

[FR Doc. 2018–23773 Filed 10–26–18; 11:15 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–84476; File No. SR–BX–2018–048]**

### Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delete the Current Rules on Arbitration

October 24, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 9, 2018, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The Exchange proposes to delete the current rules on arbitration (''Current Arbitration Rules''), under the 10000 Series (Rules 10001 through 10102), and incorporate by reference The Nasdaq

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Stock Market LLC's (''Nasdaq'') rules on arbitration at General 6 (''Proposed Arbitration Rules''), into General 6 of the Exchange's rulebook's (''Rulebook'') shell structure.[3]

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqbx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the 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 delete the rules on arbitration, currently under the 10000 Series (Rules 10001 through 10102), and incorporate by reference the Nasdaq rules on arbitration at General 6 of Nasdaq's rulebook into General 6 of the Exchange's Rulebook.

The Exchange adopted the Current Arbitration Rules to ensure a fair and efficient manner in which to handle any dispute, claim or controversy arising out of, or in connection with, the business of any Member of the Exchange. To help administer the process of dispute resolution, the Exchange and FINRA are parties to a Regulatory Contract, pursuant to which FINRA has agreed to perform certain functions and provide access to certain services, including: Member regulation and registration; non-real time market surveillance; examinations and investigations; and dispute resolution. FINRA currently operates the largest securities dispute resolution forum in the United States,[4] and has given the Exchange access to these services. Under the Current Arbitration Rules, Members and associated persons of a Member are subject to the FINRA Code of Arbitration Procedure.

Because the Affiliated Exchanges are also parties to similar Regulatory Contracts with FINRA that make their members and associated persons of such members subject to the FINRA Code of Arbitration Procedure, the Exchange believes it is pertinent that a common set of rules on arbitration be included in the General section of the Rulebook's shell. Nasdaq completed this process recently[5] and, pursuant to subsequent filings, the intention is to replace the existing arbitration rules for each of the Affiliated Exchanges by incorporating the Nasdaq rules on arbitration by reference.

Therefore, the Exchange will incorporate by reference the Proposed Arbitration Rules in ''General 6 Arbitration'' of the shell's ''General Equity and Options Rules'' section.

The relocation and harmonization of the arbitration rules is part of the Exchange's continued effort to promote efficiency and conformity of its processes with those of its Affiliated Exchanges.[6] The Exchange believes that the adoption and placement of the Proposed Arbitration Rules to their new location in the shell will facilitate the use of the Rulebook by Members[7] of the Exchange who are members of other Affiliated Exchanges. Moreover, the proposed changes are of a conforming nature and will not amend the substance of the adopted rules other than to update the language to that of the Proposed Arbitration Rules, and to make conforming cross-reference changes.

BX will continue to file proposed rule changes to amend its General 6 Rules until such time as it receives an exemption from the Securities and Exchange Commission, pursuant to its authority under Section 36 of the Exchange Act of 1934 (''Act'') and Rule 0–12[8] thereunder, from the Section 19(b) filing requirements to separately file a proposed rule change to amend General 6.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by promoting efficiency and structural conformity of the Exchange's processes with those of the Affiliated Exchanges and to make the Exchange's Rulebook easier to read and more accessible to its Members. The Exchange believes that the adoption and harmonization of the arbitration rules and cross-reference updates are of a non-substantive nature.

### *B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes do not impose a burden on competition because, as previously stated, they are (i) of a non-substantive nature, (ii) intended to harmonize the structure of the Exchange's rules with those of its Affiliated Exchanges, and (iii) intended to organize the Rulebook in a way that it will ease the Members' navigation and reading of the rules across the Affiliated Exchanges.

### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were either solicited or received.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and

[3] Recently, the Exchange added a shell structure to its Rulebook with the purpose of improving efficiency and readability and to align its rules closer to those of its five sister exchanges, The Nasdaq Stock Market LLC; Nasdaq PHLX LLC; Nasdaq ISE, LLC; Nasdaq GEMX, LLC; and Nasdaq MRX, LLC (''Affiliated Exchanges''). The shell structure currently contains eight (8) Chapters which, once complete, will apply a common set of rules to the Affiliated Exchanges. *See* Securities Exchange Act Release No. 82174 (November 29, 2017), 82 FR 57492 (December 5, 2017) (SR–BX–2017–054).

[4] *http://www.finra.org/arbitration-and-mediation.*

[5] *See* Securities Exchange Act Release No. 83834 (August 13, 2018), 83 FR 41115 (August 17, 2018) (SR–NASDAQ–2018–067).

[6] *See* footnote 3.

[7] Exchange Rule 0120(i).

[8] *See* 17 CFR 240.0–12; Securities Exchange Act Release No. 39624 (February 5, 1998), 63 FR 8101 (February 18, 1998).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

subparagraph (f)(6) of Rule 19b–4 thereunder.[12]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov. Please include File Number SR–BX–2018–048 on the subject line.*

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2018–048. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2018–048 and should be submitted on or before November 20, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018–23620 Filed 10–29–18; 8:45 am]

**BILLING CODE 8011–01–P**

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[13] 17 CFR 200.30–3(a)(12).

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–84478; File No. SR–ISE–2018–85]**

## Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delete Current Rules on Arbitration, under Chapter 18

October 24, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 9, 2018, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to delete the current rules on arbitration (''Current Arbitration Rules''), under Chapter 18, and incorporate by reference The Nasdaq Stock Market LLC's (''Nasdaq'') rules on arbitration at General 6 (''Proposed Arbitration Rules''), into General 6 of the Exchange's rulebook's (''Rulebook'') shell structure.[3]

The text of the proposed rule change is available on the Exchange's website at *http://ise.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the 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 delete the rules on arbitration, currently under Chapter 18, and incorporate by reference the Nasdaq rules on arbitration at General 6 of Nasdaq's rulebook into General 6 of the Exchange's Rulebook.

The Exchange adopted the Current Arbitration Rules to ensure a fair and efficient manner in which to handle any dispute, claim or controversy arising out of, or in connection with, the business of any Member of the Exchange. To help administer the process of dispute resolution, the Exchange and FINRA are parties to a Regulatory Contract, pursuant to which FINRA has agreed to perform certain functions and provide access to certain services, including: Member regulation and registration; non-real time market surveillance; examinations and investigations; and dispute resolution. FINRA currently operates the largest securities dispute resolution forum in the United States,[4] and has given the Exchange access to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Recently, the Exchange added a shell structure to its Rulebook with the purpose of improving efficiency and readability and to align its rules closer to those of its five sister exchanges, The Nasdaq Stock Market LLC; Nasdaq BX, Inc.; Nasdaq PHLX LLC; Nasdaq GEMX, LLC; and Nasdaq MRX, LLC (''Affiliated Exchanges''). The shell structure currently contains eight (8) Chapters which, once complete, will apply a common set of rules to the Affiliated Exchanges. *See* Securities Exchange Act Release No. 82173 (November 29, 2017), 82 FR 57505 (December 5, 2017) (SR–ISE–2017–102).

[4] *http://www.finra.org/arbitration-and-mediation.*

these services. Under the Current Arbitration Rules, Members and associated persons of a Member are subject to the FINRA Code of Arbitration Procedure.

Because the Affiliated Exchanges are also parties to similar Regulatory Contracts with FINRA that make their members and associated persons of such members subject to the FINRA Code of Arbitration Procedure, the Exchange believes it is pertinent that a common set of rules on arbitration be included in the General section of the Rulebook's shell. Nasdaq completed this process recently [5] and, pursuant to subsequent filings, the intention is to replace the existing arbitration rules for each of the Affiliated Exchanges by incorporating the Nasdaq rules on arbitration by reference.

Therefore, the Exchange will incorporate by reference the Proposed Arbitration Rules in ''General 6 Arbitration'' of the shell's ''General Rules'' section.

The relocation and harmonization of the arbitration rules is part of the Exchange's continued effort to promote efficiency and conformity of its processes with those of its Affiliated Exchanges.[6] The Exchange believes that the adoption and placement of the Proposed Arbitration Rules to their new location in the shell will facilitate the use of the Rulebook by Members of the Exchange who are members of other Affiliated Exchanges. Moreover, the proposed changes are of a conforming nature and will not amend the substance of the adopted rules other than to update the language to that of the Proposed Arbitration Rules, and to make conforming cross-reference changes.

ISE will continue to file proposed rule changes to amend its General 6 Rules until such time as it receives an exemption from the Securities and Exchange Commission, pursuant to its authority under Section 36 of the Exchange Act of 1934 (''Act'') and Rule 0–12 [7] thereunder, from the Section 19(b) filing requirements to separately file a proposed rule change to amend General 6.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by promoting efficiency and structural conformity of the Exchange's processes with those of the Affiliated Exchanges and to make the Exchange's Rulebook easier to read and more accessible to its Members. The Exchange believes that the adoption and harmonization of the arbitration rules and cross-reference updates are of a non-substantive nature.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes do not impose a burden on competition because, as previously stated, they are (i) of a non-substantive nature, (ii) intended to harmonize the structure of the Exchange's rules with those of its Affiliated Exchanges, and (iii) intended to organize the Rulebook in a way that it will ease the Members' navigation and reading of the rules across the Affiliated Exchanges.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were either solicited or received.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [10] and subparagraph (f)(6) of Rule 19b–4 thereunder.[11]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov. Please include File Number SR–ISE–2018–85 on the subject line.*

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2018–85. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 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

[5] *See* Securities Exchange Act Release No. 83834 (August 13, 2018), 83 FR 41115 (August 17, 2018) (SR–NASDAQ–2018–067).

[6] *See* footnote 3.

[7] *See* 17 CFR 240.0–12; Securities Exchange Act Release No. 39624 (February 5, 1998), 63 FR 8101 (February 18, 1998).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2018–85 and should be submitted on or before November 20, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018–23622 Filed 10–29–18; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–84479; File No. SR–MRX–2018–32]**

## Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delete Current Rules on Arbitration, Under Chapter 18

October 24, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 9, 2018, Nasdaq MRX, LLC (''MRX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to delete the current rules on arbitration (''Current Arbitration Rules''), under Chapter 18, and incorporate by reference The Nasdaq Stock Market LLC's (''Nasdaq'') rules on arbitration at General 6 (''Proposed Arbitration Rules''), into General 6 of the Exchange's rulebook's (''Rulebook'') shell structure.[3]

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqmrx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the 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 delete the rules on arbitration, currently under Chapter 18, and incorporate by reference the Nasdaq rules on arbitration at General 6 of Nasdaq's rulebook into General 6 of the Exchange's Rulebook.

The Exchange adopted the Current Arbitration Rules to ensure a fair and efficient manner in which to handle any dispute, claim or controversy arising out of, or in connection with, the business of any Member of the Exchange. To help administer the process of dispute resolution, the Exchange and FINRA are parties to a Regulatory Contract, pursuant to which FINRA has agreed to perform certain functions and provide access to certain services, including: member regulation and registration; non-real time market surveillance; examinations and investigations; and dispute resolution. FINRA currently operates the largest securities dispute resolution forum in the United States,[4] and has given the Exchange access to these services. Under the Current Arbitration Rules, Members and associated persons of a Member are subject to the FINRA Code of Arbitration Procedure.

Because the Affiliated Exchanges are also parties to similar Regulatory Contracts with FINRA that make their members and associated persons of such members subject to the FINRA Code of Arbitration Procedure, the Exchange believes it is pertinent that a common set of rules on arbitration be included in the General section of the Rulebook's shell. Nasdaq completed this process recently[5] and, pursuant to subsequent filings, the intention is to replace the existing arbitration rules for each of the Affiliated Exchanges by incorporating the Nasdaq rules on arbitration by reference.

Therefore, the Exchange will incorporate by reference the Proposed Arbitration Rules in ''General 6 Arbitration'' of the shell's ''General Rules'' section.

The relocation and harmonization of the arbitration rules is part of the Exchange's continued effort to promote efficiency and conformity of its processes with those of its Affiliated Exchanges.[6] The Exchange believes that the adoption and placement of the Proposed Arbitration Rules to their new location in the shell will facilitate the use of the Rulebook by Members of the Exchange who are members of other Affiliated Exchanges. Moreover, the proposed changes are of a conforming nature and will not amend the substance of the adopted rules other than to update the language to that of the Proposed Arbitration Rules, and to make conforming cross-reference changes.

MRX will continue to file proposed rule changes to amend its General 6 Rules until such time as it receives an exemption from the Securities and Exchange Commission, pursuant to its authority under Section 36 of the Exchange Act of 1934 (''Act'') and Rule 0–12[7] thereunder, from the Section 19(b) filing requirements to separately file a proposed rule change to amend General 6.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by promoting efficiency and structural conformity of the Exchange's processes

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Recently, the Exchange added a shell structure to its Rulebook with the purpose of improving efficiency and readability and to align its rules closer to those of its five sister exchanges, The Nasdaq Stock Market LLC; Nasdaq BX, Inc.; Nasdaq PHLX LLC; Nasdaq ISE, LLC; and Nasdaq GEMX, LLC (''Affiliated Exchanges''). The shell structure currently contains eight (8) Chapters which, once complete, will apply a common set of rules to the Affiliated Exchanges. *See* Securities Exchange Act Release No. 82172 (November 29, 2017), 82 FR 57495 (December 5, 2017) (SR–MRX–2017–26).

[4] *http://www.finra.org/arbitration-and-mediation.*

[5] *See* Securities Exchange Act Release No. 83834 (August 13, 2018), 83 FR 41115 (August 17, 2018) (SR–NASDAQ–2018–067).

[6] *See* footnote 3.

[7] *See* 17 CFR 240.0–12; Securities Exchange Act Release No. 39624 (February 5, 1998), 63 FR 8101 (February 18, 1998).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

with those of the Affiliated Exchanges and to make the Exchange's Rulebook easier to read and more accessible to its Members. The Exchange believes that the adoption and harmonization of the arbitration rules and cross-reference updates are of a non-substantive nature.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes do not impose a burden on competition because, as previously stated, they are (i) of a non-substantive nature, (ii) intended to harmonize the structure of the Exchange's rules with those of its Affiliated Exchanges, and (iii) intended to organize the Rulebook in a way that it will ease the Members' navigation and reading of the rules across the Affiliated Exchanges.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were either solicited or received.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [10] and subparagraph (f)(6) of Rule 19b–4 thereunder.[11]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MRX–2018–32 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–MRX–2018–32. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of 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–MRX–2018–32 and should be submitted on or before November 20, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018–23623 Filed 10–29–18; 8:45 am]

**BILLING CODE 8011–01–P**

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–84480; File No. SR–CboeBZX–2018–066]**

## Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Permit the Listing and Trading of P.M.-Settled Series on Certain Broad-Based Index Options on a Pilot Basis

October 24, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 11, 2018, Cboe BZX Exchange, Inc. filed with the Securities and Exchange Commission (the ''Commission'' or ''SEC'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX Options'') proposes to permit the listing and trading of P.M.-settled series on certain broad-based index options on a pilot basis.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 the Statutory Basis for, the Proposed Rule Change*

1. Purpose

The proposed rule change permits the listing and trading of P.M.-settled series on certain broad-based index options on a pilot basis.[3] First, the proposed rule change would permit the listing and trading of XSP options with third-Friday-of-the-month expiration dates, whose exercise settlement value will be based on the closing index value on the expiration day (''P.M.-settled'') for an initial period of twelve months (the ''XSPPM Pilot Program'') from the date of approval of this proposed rule change. Second, the proposed rule change would permit the listing and trading of P.M.-settled options on broad-based indexes with weekly expirations (''Weeklys'') and end-of-month expirations (''EOMs'') for an initial period of 12 months (the ''Nonstandard Expirations Pilot Program'') from the date of approval of this proposed rule change.

XSPPM Pilot Program

Proposed Rule 29.11(a)(6) permits the listing and trading, in addition to A.M.-settled XSP options, of P.M.-settled XSP options with third-Friday-of-the-month expiration dates on a pilot basis for an initial period of 12 months from the date of approval of this proposed rule change. XSP options are A.M.-settled pursuant to the generic listing criteria in Rule 29.11(a)(5). The Exchange believes permitting the trading of XSP options on a P.M.-settled basis will encourage greater trading in XSP options.

Other than settlement and closing time on the last trading day (as discussed below), contract terms for P.M.-settled XSP options will be the same as the A.M.-settled XSP options. The proposed contract would use a $100 multiplier. The minimum trading increments, strike price intervals, and expirations would be the same as the A.M.-settled XSP option series. P.M.-settled XSP options would have European-style exercise. The Exchange will also have flexibility to open for trading additional series in response to customer demand.

The proposed rule change amends Rule 29.10(a) to state that, on their last trading day, transactions in P.M.-settled XSP options may be effected on the Exchange between the hours of 9:30 a.m. and 4:00 p.m. Eastern time (as opposed to the normal trading hours for non-expiring P.M.-settled XSP options, which are from 9:30 a.m. to 4:15 p.m. Eastern time). XSP options are typically priced in the market based on corresponding futures values. The primary listing markets for the component securities that comprise the S&P 500 Index close trading in those securities at 4:00 p.m. The primary listing exchanges for the component securities disseminate closing prices of the component securities, which are used to calculate the exercise settlement value of the S&P 500 Index. The Exchange believes that, under normal trading circumstances, the primary listing markets have sufficient bandwidth to prevent any data queuing that would cause any trades that are executed prior to the closing time from being reported after 4:00 p.m. Despite the fact that the exercise settlement value will be fixed at or soon after 4:00 p.m., if the Exchange did not close trading in expiring P.M.-settled XSP options at 4:00 p.m. on their last trading day, trading in expiring P.M.-settled XSP options would continue for an additional fifteen minutes until 4:15 p.m. and would not be able to be priced on corresponding futures values, but rather the known cash value. At the same time, the prices of non-expiring P.M.-settled XSP option series would continue to move and be priced in response to changes in corresponding futures prices.

A potential pricing divergence could occur between 4:00 p.m. and 4:15 p.m. on the final trading day in expiring P.M.-settled XSP options (*e.g.* switch from pricing off of futures to cash). Further, the switch from pricing off of futures to cash can be a difficult and risky switchover for liquidity providers. As a result, without closing expiring contracts at 4:00 p.m., it is foreseeable that Market-Makers could react by widening spreads in order to compensate for the additional risk. Therefore, the Exchange believes that, in order to mitigate potential investor confusion and the potential for increased costs to investors, it is appropriate to cease trading in the expiring P.M.-settled XSP contracts at 4:00 p.m. The Exchange does not believe the proposed change will impact volatility on the underlying cash market at the close on third Fridays. Further, other options exchanges close trading in certain options on the last trading day for certain classes.[4]

If the Exchange were to propose an extension of the XSPPM Pilot Program or should the Exchange propose to make the XSPPM Pilot Program permanent, the Exchange would submit a filing proposing such amendments to the XSPPM Pilot Program. Further, any positions established under the XSPPM Pilot Program would not be impacted by the expiration of the XSPPM Pilot Program. For example, if the Exchange lists a P.M.-settled XSP option that expires after the XSPPM Pilot Program expires (and is not extended), then those positions would continue to exist. If the pilot were not extended, then the positions could continue to exist. However, any further trading in those series would be restricted to transactions where at least one side of the trade is a closing transaction.

As part of the XSPPM Pilot Program, the Exchange will submit a pilot report to the Commission at least two months prior to the expiration date of the pilot. This annual report will contain an analysis of volume, open interest, and trading patterns. The analysis would examine trading in the proposed option product as well as trading in the securities that comprise the S&P 500 Index. In addition, for series that exceed certain minimum open interest parameters, the annual report will provide analysis of index price volatility and, if needed, share trading activity.

The annual report will contain the following volume and open interest data:

(1) Monthly volume aggregated for all trades;

(2) monthly volume aggregated by expiration date;

(3) monthly volume for each individual series;

(4) month-end open interest aggregated for all series;

(5) month-end open interest aggregated by expiration date; and

(6) month-end open interest for each individual series.

The annual report will also contain the information noted above for expiration Friday A.M.-settled XSP option series, if applicable, for the period covered in the annual report. In addition to the annual report, the Exchange will provide the Commission with interim reports of the information listed in (1) through (6) above.

[3] The Exchange is authorized to list for trading options that overlie the Mini-SPX Index (''XSP'') and the Russell 2000 Index (''RUT''). *See* Rule 29.11(a).

[4] *See* Cboe Options Rule 24.6, Interpretations and Policies .01 (options with Quarterly Index Expirations), .03 (Cboe S&P 500 A.M./P.M. Basis options), .04 (P.M.-settled SPX options with third Friday-of-the-month expiration and P.M.-settled XSP options), and .05 (MSCI EAFE Index options).

In the annual report, the annual report would contain the following analysis of trading patterns in expiration Friday, P.M.-settled XSP option series in the XSPPM Pilot Program:

(1) A time series analysis of open interest; and

(2) an analysis of the distribution of trade sizes.

Also, for series that exceed certain minimum parameters, the annual report will also contain the following analysis related to index price changes and, if needed, underlying share trading volume at the close on expiration Fridays:

(1) A comparison of index price changes at the close of trading on a given expiration Friday with comparable price changes from a control sample. The data will include a calculation of percentage price changes for various time intervals and compare that information to the respective control sample. Raw percentage price change data as well as percentage price change data normalized for prevailing market volatility, as measured by an appropriate index as agreed by the Commission and the Exchange, would be provided; and

(2) a calculation of share volume for a sample set of the component securities representing an upper limit on share trading that could be attributable to expiring in-the-money series. The data, if needed, will include a comparison of the calculated share volume for securities in the sample set to the average daily trading volumes of those securities over a sample period.

The minimum open interest parameters, control sample, time intervals, method for randomly selecting the component securities, and sample periods would be determined by the Exchange and the Commission.

Additionally, the Exchange will provide the Commission with any additional data or analyses the Commission requests because it deems such data or analyses necessary to determine whether the XSPPM Pilot Program is consistent with the Exchange Act. The Exchange will make public all data and analyses it submits to the Commission under the XSPPM Pilot Program.

Other exchanges currently have pilots that permit P.M.-settled index options.[5]

Nonstandard Expirations Pilot Program

The proposed rule change permits the listing and trading, on a pilot basis, of P.M.-settled options on broad-based indexes with nonstandard expiration dates for an initial period of 12 months from the date of approval of this proposed rule change. The Nonstandard Expirations Pilot Program will permit both Weeklys and EOMs as discussed below. Contract terms for the Weekly and EOM expirations will be similar to those of the A.M.-settled broad-based index options, except that the Weekly and EOM expirations will be P.M.-settled.

Proposed Rule 29.11(j)(1) permits the Exchange to open for trading Weeklys on any broad-based index eligible for standard options trading to expire on any Monday, Wednesday, or Friday (other than the third Friday-of-the-month or days that coincide with an EOM). Weeklys will be subject to all provisions of Rule 29.11 and will be treated the same as options on the same underlying index that expire on the third Friday of the expiration month. However, Weeklys will be P.M.-settled, and new Weekly series may be added up to and including on the expiration date for an expiring Weekly.

The maximum number of expirations that may be listed for each Weekly (*i.e.,* a Monday expiration, a Wednesday expiration, or Friday expiration, as applicable) in a given class will be the same as the maximum number of expirations permitted in Rule 29.11(a)(3) for standard options on the same broad-based index.[6] Weeklys would not need to be for consecutive Monday, Wednesday, or Friday expirations, as applicable. However, the expiration date of a non-consecutive expiration would not be permitted beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively. Weeklys that are first listed in a given class could expire up to four weeks from the actual listing date. If the last trading day of a month is a Monday, Wednesday, or Friday and the Exchange lists EOMs and Weeklys, as applicable, in a given class, the Exchange will list an EOM instead of a Weekly in the given class. Other expirations in the same class are not counted as part of the maximum number of Weeklys for a broad-based index class. If the Exchange is not open for business on a respective Monday, the normally Monday expiring Weeklys would expire on the following business day. If the Exchange is not open for business on a respective Wednesday or Friday, the normally Wednesday or Friday expiring Weekly will expire on the previous business day.

Proposed Rule 29.11(a)(2) [sic] permits the Exchange to open for trading EOMs on any broad-based index eligible for standard options trading to expire on the last trading day of the month. EOMs will be subject to all provisions of Rule 29.11 and treated the same as options on the same underlying index that expire on the third Friday of the expiration month. However, EOMs will be P.M.-settled, and new series of EOMs may be added up to and including on the expiration date for an expiring EOM.

The maximum number of expirations that may be listed for EOMs in a given class is the same as the maximum number of expirations permitted in Rule 29.11(a)(3) for standard options on the same broad-based index.[7] EOMs need not be for consecutive end-of-month expirations. However, the expiration date of a non-consecutive expiration may not be beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively. EOMs that are first listed in a given class may expire up to four weeks from the actual listing date. Other expirations in the same class are not counted as part of the maximum number of EOMs for a broad-based index class.

The proposed rule change amends Rule 29.11(c)(5)(C) to provide that the lowest strike interval for series of XSP options listed under the Nonstandard Expirations Pilot Program will be $0.50. With respect to XSP, this is consistent with the minimum strike interval for XSP options listed under the Short Term Series Program.[8] Additionally, this is consistent with the minimum strike interval for options on the Standard & Poor's Depository Receipts Trust (SPY), which is an ETF that like XSP tracks the performance of 1/10th the value of the S&P 500 Index, with weekly expirations.[9]

Weeklys and EOMs will be subject to the same rules that currently govern the trading of standard monthly broad-based index options, including sales practice rules, margin requirements, and floor trading procedures. Contract terms for Weeklys and EOMs will be the same as those for standard monthly broad-based index options. Since Weeklys and EOMs will be new types of series, and not a new class, the Exchange proposes that Weeklys and EOMs will be aggregated for any applicable reporting

[5] *See* Cboe Options Rule 24.9, Interpretation and Policy .14 and Phlx Rule 1101A, Commentary .05.

[6] Pursuant to Rule 29.11(a)(3), the Exchange may list up to six expiration months at any one time. Therefore, pursuant to the proposed rule change, the Exchange may list a maximum of six Weekly expirations under the Nonstandard Expirations Pilot Program.

[7] *Id.*

[8] *See* Rule 29.11(c)(5)(C).

[9] *See* Rule 19.6, Interpretation and Policy .05(f).

and other requirements.[10] Pursuant to new proposed Rule 29.11(j)(4), transactions in expiring Weeklys and EOMs may be effected on the Exchange between the hours of 9:30 a.m. and 4:00 p.m. (Eastern time).

As stated above, this proposed rule change establishes a Nonstandard Expirations Pilot Program for broad-based index options on a pilot basis, for an initial period of 12 months from the date of approval of this proposed rule change. If the Exchange were to propose an extension of the Nonstandard Expirations Pilot Program or should the Exchange propose to make it permanent, the Exchange would submit a filing proposing such amendments. Further, any positions established under the Nonstandard Expirations Pilot Program would not be impacted by the expiration of the pilot. For example, if the Exchange lists a Weekly or EOM that expires after the Nonstandard Expirations Pilot Program expires (and is not extended), then those positions would continue to exist. However, any further trading in those series would be restricted to transactions where at least one side of the trade is a closing transaction.

As part of the Nonstandard Expirations Pilot Program, the Exchange will submit a pilot report to the Commission at least two months prior to the expiration date of the pilot (the ''annual report''). The annual report will contain an analysis of volume, open interest, and trading patterns. In addition, for series that exceed certain minimum open interest parameters, the annual report will provide analysis of the index price volatility, and, if needed, share trading activity.

For all Weekly and EOM series, the annual report will contain the following volume and open interest data for each broad-based index overlying Weekly and EOM options:

(1) Monthly volume aggregated for all Weekly and EOM series;

(2) Volume in Weekly and EOM series aggregated by expiration date;

(3) Month-end open interest aggregated for all Weekly and EOM series;

(4) Month-end open interest for EOM series aggregated by expiration date and open interest for Weekly series aggregated by expiration date;

(5) Ratio of monthly aggregate volume in Weekly and EOM series to total monthly class volume; and

(6) Ratio of month-end open interest in EOM series to total month-end class open interest and ratio of open interest in each Weekly series to total class open interest.

In addition, the annual report will contain the information noted above for standard expiration Friday, A.M.-settled series, if applicable, for the period covered in the annual report as well as for the six-month period prior to the initiation of the pilot.

Upon request by the SEC, the Exchange will provide a data file containing:

(1) Weekly and EOM option volume data aggregated by series, and

(2) Weekly open interest for each expiring series and EOM month-end open interest for expiring series.

In the annual report, the Exchange also proposes to identify Weekly and EOM trading patterns by undertaking a time series analysis of open interest in Weekly and EOM series aggregated by expiration date compared to open interest in near-term standard expiration Friday A.M.-settled series in order to determine whether users are shifting positions from standard series to Weekly and EOM series. In addition, to the extent that data on other weekly or monthly P.M.-settled products from other exchanges is publicly available, the report will also compare open interest with these options in order to determine whether users are shifting positions from other weekly or monthly P.M.-settled products to the Weekly and EOM series. Declining open interest in standard series or the weekly or monthly P.M.-settled products of other exchanges accompanied by rising open interest in Weekly and EOM series would suggest that users are shifting positions.

For each Weekly and EOM expiration that has open interest that exceeds certain minimum thresholds, the annual report will contain the following analysis related to index price changes and, if needed, underlying share trading volume at the close on expiration dates:

(1) A comparison of index price changes at the close of trading on a given expiration date with comparable price changes from a control sample. The data will include a calculation of percentage price changes for various time intervals and compare that information to the respective control sample. Raw percentage price change data as well as percentage price change data normalized for prevailing market volatility, as measured by an appropriate index agreed to by the Commission and the Exchange, will be provided; and

(2) If needed, a calculation of share volume for a sample set of the component securities representing an upper limit on share trading that could be attributable to expiring in-the-money Weekly and EOM series. The data, if needed, will include a comparison of the calculated share volume for securities in the sample set to the average daily trading volumes of those securities over a sample period.

The minimum open interest parameters, control sample, time intervals, method for selecting the component securities, and sample periods will be determined by the Exchange and the Commission.

Additionally, the Exchange will provide the Commission with any additional data or analyses the Commission requests because it deems such data or analyses necessary to determine whether the Nonstandard Expirations Pilot Program is consistent with the Exchange Act. The Exchange will make public all data and analyses it submits to the Commission under the Nonstandard Expirations Pilot Program. Other exchanges currently have pilots that have weekly and end-of-month expirations.[11]

## Additional Information

Precedent exists for P.M.-settled broad-based index options, as other options exchanges list P.M.-settled broad-based index options.[12] The Exchange does not believe that any market disruptions will be encountered with the introduction of listing P.M.-settled options on the Exchange. The Exchange will monitor for any such disruptions or the development of any factors that would cause such disruptions.

The Exchange notes that P.M.-settled options predominate in the over-the-counter (''OTC'') market, and the Exchange is not aware of any adverse effects in the stock market attributable to the P.M.-settlement feature. The

[10] Rule 29.5(a) requires Options Members to comply with the applicable rules of Cboe Options with respect to position limits for broad-based index options for options traded on Cboe Options. Cboe Options Rule 24.4, Interpretation and Policy .03 sets forth the reporting requirements for certain market indexes that do not have position limits, including XSP and RUT, and would apply to XSP and RUT options traded on the Exchange pursuant to Rule 29.5(a); *see also* Cboe Options Rule 24.4(b), which provides that Weeklys and EOMs will be aggregated with option contracts on the same broad-based index and will be subject to the overall position limit, and would apply to Weeklys/EOMs traded on the Exchange pursuant to Rule 29.5(a). The Exchange notes that the proposed aggregation is consistent with the aggregation requirements or other types of option series (*e.g.,* quarterly expiring options) that may be listed on the Exchange and that do not expire on the customary ''third Friday'' (*see* Cboe Options Rule 24.4(e)).

[11] *See* Cboe Options Rule 24.9(e); and Phlx Rule 1101A(b)(vii).

[12] *See, e.g.,* Cboe Options Rule 24.9(a)(4) (OEX not listed as A.M.-settled) and Interpretation and Policy .14 (permits listing of P.M.-settled SPX and XSP options); and PHLX Rule 1101A, Commentary .05 (permits listing of P.M.-settled NDX options).

Exchange is merely proposing to offer a P.M.-settled product in an exchange environment that offers the benefit of added transparency, price discovery, and stability. In response to any potential concerns that disruptive trading conduct could occur as a result of the concurrent listing and trading of two index option products based on the same index but for which different settlement methodologies exist (*i.e.,* one is A.M.-settled and one is P.M.-settled), the Exchange notes that Cboe Options lists and trades both A.M.-settled and P.M.-settled SPX options, and Phlx lists and trades both A.M.-settled and P.M.-settled NDX options. The Exchange is not aware of any market disruptions occurring as a result of these exchanges offering both products.

The adoption of P.M.-settled options on an exchange that lists A.M.-settled options in the same class would provide greater spread opportunities. This manner of trading in different products allows a market participant to take advantage of the different expiration times, providing expanded trading opportunities. In the options market currently, market participants regularly trade similar or related products in conjunction with each other, which contributes to overall market liquidity.

The Exchange represents it has an adequate surveillance program in place for index options. The Exchange is a member of the Intermarket Surveillance Group (''ISG''), which is comprised of an international group of exchanges, market centers, and market regulators. The purpose of ISG is to provide a framework for the sharing of information and the coordination of regulatory efforts among exchanges trading securities and related products to address potential intermarket manipulations and trading abuses. ISG plays a crucial role in information sharing among markets that trade securities, options on securities, security futures products, and futures and options on broad-based security indexes. A list of identifying current ISG members is available at *https://www.isgportal.org/isgPortal/public/members.htm.*

The Exchange has analyzed its capacity and represents that it believes the Exchange and OPRA have the necessary systems capacity to handle the additional traffic associated with the listing of P.M.-settled XSP and Weekly/EOM option series up to the proposed number of possible expirations and strike prices. The Exchange believes any additional traffic that would be generated from the introduction of P.M.-settled XSP and Weekly/EOM options series will be manageable. The Exchange believes its Members will not have a capacity issue as a result of this proposed rule change. The Exchange also represents that it does not believe this expansion will cause fragmentation of liquidity. The Exchange will monitor the trading volume associated with the additional options series listed as a result of this proposed rule change and the effect (if any) of these additional series on market fragmentation and on the capacity of the Exchange's automated systems.

P.M.-settled options would be subject to all provisions of Rule 29.11. P.M.-settled options would be subject to the same rules that govern the trading of A.M.-settled options overlying the same indexes, including sales practice rules, margin requirements, and floor trading procedures. P.M.-settled options will be subject to the margin requirements set forth in Chapter 28 and the position limits set forth in Rule 29.5. Chapter 28 imposes the margin requirements of either Cboe Options or the New York Stock Exchange on Exchange Options Members. Similarly, Rule 29.5 imposes position (and exercise) limits for broad-based index options of Cboe Options on Exchange Options Members. Since P.M.-settled options will be a new type of series, and not a new class, the Exchange proposes that the P.M.-settled options will be aggregated for any applicable reporting and other requirements.[13] Currently, there are no position limits on RUT and XSP options.[14] Therefore, there will be no position limits on P.M.-settled RUT and XSP options. P.M.-settled XSP options and Weekly/EOM broad-based index options are currently authorized for listing on Cboe Options,[15] and thus the same margin requirements and position and exercise limits that apply to these products as listed and traded on Cboe Options will apply to these products when listed and traded on the Exchange. The proposed rule change will also result in similar regulatory treatment for similar option products.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[16] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[17] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes the proposed rule change will attract order flow to the Exchange, increase the variety of listed options to investors, and provide a valuable hedge tool to investors. The Exchange believes the proposed rule change will also remove impediments to and perfect the mechanism of a free and open market, and in general protect investors by expanding the ability of investors to hedge risks against market movements stemming from economic releases or market events that occur during the month and at the end of the month. Accordingly, the Exchange believes that P.M.-settled options will create greater trading and hedging opportunities and flexibility, and provide customers with the ability to more closely tailor their investment objectives.

The Commission has previously stated that when cash-settled index options were first introduced in the 1980s, they generally utilized closing-price settlement procedures (*i.e.,* P.M. settlement). The Commission stated it became concerned about the impact of P.M. settlement on cash-settled index options on the markets for the underlying stocks at the close on expiration Fridays, especially during the quarterly expirations of the third Friday of March, June, September, and December when options, index futures,

[13] *See* Rule 29.5(a), which requires Options Members to comply with the applicable rules of Cboe Options with respect to position limits for broad-based index options for options traded on Cboe Options. Cboe Options Rule 24.4(b), which applies to index options traded on the Exchange pursuant to Rule 29.5(a), provides that Nonstandard Expirations will be aggregated with option contracts on the same broad-based index and subject to the overall position limit. Additionally, Cboe Options Rule 24.4(d), which applies to index options traded on the Exchange pursuant to Rule 29.5(a), positions in reduced-value index options will be aggregated with positions in full-value indices. The Exchange notes that the proposed aggregation is consistent with the aggregation requirements for other types of option series (*e.g.* quarterly expiring options) that are listed on the Exchange and that do not expire on the customary ''third Friday.'' *See* Cboe Options Rule 24.4 (which applies to the Exchange pursuant to Rule 29.5(a)).

[14] *See* Cboe Options Rule 24.4(a) (which applies to the Exchange pursuant to Rule 29.5(a)).

[15] Similarly, pursuant to Cboe Options Chapter 12, Cboe Options Trading Permit Holders may request to have New York Stock Exchange margin requirements apply to their trading.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

and options on index futures all expire simultaneously. The Commission expressed concerns that P.M. settlement was believed to have contributed to above-average volume and added market volatility on those days, which sometimes led to sharp price movements during the last hour of trading, as a consequence of which the close of trading on the quarterly expiration Friday became known as the ''triple witching hour.'' The Commission observed that besides contributing to investor anxiety, heightened volatility during the expiration periods created the opportunity for manipulation and other abusive trading practices in anticipation of the liquidity constraints.[18]

However, the Exchange believes that the above concerns that have led to the transition to A.M. settlement for index derivatives have been largely mitigated. It believes that expiration pressure in the underlying cash markets at the close has been greatly reduced with the advent of multiple primary listing and unlisted trading privilege markets, and that trading is now widely dispersed among many market centers. Additionally, the Exchange notes that opening procedures in the 1990s were deemed acceptable to mitigate one-sided order flow driven by index option expiration and that the New York Stock Exchange and Nasdaq Stock Market, LLC each use an automated closing cross procedures and has a closing order type that facilitates orderly closings. These closing procedures on the exchanges on which the components of the S&P 500 Index trade are well-equipped to mitigate imbalance pressure at the close. In addition, after-hours trading now provides market participants with an alternative to help offset market-on-close imbalances.[19]

Other exchanges currently have pilots that permit P.M.-settled index options[20] and Weekly/EOM options.[21]

The proposed rule change to permit transactions on the Exchange in P.M.-settled XSP and Weekly/EOM options on their last trading day between the hours of 9:30 a.m. and 4:00 p.m. Eastern time (as opposed to the normal trading hours for non-expiring P.M.-settled XSP and Weekly/EOM options, which are from 9:30 a.m. to 4:15 p.m. Eastern time) will prevent potential pricing divergence that could occur between 4:00 p.m. and 4:15 p.m. on the final trading day in expiring P.M.-settled XSP options. Without closing expiring contracts at 4:00 p.m., it is foreseeable that Market-Makers would react by widening spreads in order to compensate for the additional risk. Therefore, the Exchange believes that, in order to mitigate potential investor confusion and the potential for increased costs to investors, it is appropriate to cease trading in the expiring P.M.-settled XSP and Weekly/EOM contracts at 4:00 p.m. The Exchange does not believe the proposed change will impact volatility on the underlying cash market at the close on third Fridays. Further, the other options exchanges close trading in certain options on the last trading day for certain classes.[22]

The Exchange has analyzed its capacity and represents that it believes the Exchange and OPRA have the necessary systems capacity to handle the additional traffic associated with the listing of P.M.-settled options. The Exchange believes any additional traffic that may be generated from the introduction of P.M.-settled options will be manageable. The Exchange represents that it has in place adequate surveillance procedures to monitor trading in these options thereby helping to ensure the maintenance of a fair and orderly market.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. P.M.-settled options would be available for trading on the Exchange to all market participants. The Exchange believes the proposed rule change will increase the variety of listed options to investors, and provide valuable hedge tools to investors. The listing of P.M.-settled options will enhance competition by providing investors with an additional investment vehicle, through which investors can gain and hedge exposure to the stocks that compose the applicable broad-based indexes. Additionally, markets participants are welcome to become Members and trade at the Exchange if they determine this proposed rule change has made the Exchange more attractive or favorable. Further, this product could offer a competitive alternative to other existing investment products that seek to allow Members to gain broad market exposure. Finally, all options exchanges are free to compete by listing and trading index options that are P.M.-settled. Other exchanges currently have pilots that permit P.M.-settled index options[23] or Weeklys/EOMs.[24]

The proposed rule change to permit transactions on the Exchange in P.M.-settled XSP and Weekly/EOM options on their last trading day between the hours of 9:30 a.m. and 4:00 p.m. Eastern time (as opposed to the normal trading hours for non-expiring P.M.-settled XSP and Weekly/EOM options, which are from 9:30 a.m. to 4:15 p.m. Eastern time) will prevent potential pricing divergence that could occur between 4:00 p.m. and 4:15 p.m. on the final trading day in expiring P.M.-settled XSP and Weekly/EOM options. Without closing expiring contracts at 4:00 p.m., it is foreseeable that Market-Makers would react by widening spreads in order to compensate for the additional risk. Therefore, the Exchange believes that, in order to mitigate potential investor confusion and the potential for increased costs to investors, it is appropriate to cease trading in the expiring P.M.-settled XSP and Weekly/EOM contracts at 4:00 p.m. The Exchange does not believe the proposed change will impact volatility on the underlying cash market at the close on third Fridays. Further, the other options exchanges close trading in certain options on the last trading day for certain classes.[25]

The Exchange believes that the proposed rule change will relieve any burden on, or otherwise promote, competition, as the rules are substantially the same as those of other options exchanges, as noted above.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Exchange neither solicited nor received comments on the proposed rule change.

[18] *See* Securities Exchange Act Release No. 65256 (September 2, 2011), 76 FR 55569 (September 9, 2011) (SR–C2–2011–008) (order approving listing of SPXPM options on C2); *see also* Securities Exchange Act Release No. 81293 (August 2, 2017), 82 FR 151 (August 8, 2017) (SR–Phlx–2017–04) (or approving listing of NDXPM options on Phlx).

[19] *See id.*

[20] *See* Cboe Options Rule 24.9, Interpretation and Policy .14; and Phlx Rule 1101A, Commentary .05.

[21] *See* Cboe Options Rule 24.9(e); and Phlx Rule 1101A(b)(vii).

[22] *See* Cboe Options Rule 24.6, Interpretations and Policies .01 (options with Quarterly Index Expirations), .03 (Cboe S&P 500 AM/PM Basis options), .04 (P.M.-settled SPX options with third Friday-of-the-month expiration and P.M.-settled XSP options), and .05 (MSCI EAFE Index options).

[23] *See* Cboe Options Rule 24.9, Interpretation and Policy .14 and Phlx Rule 1101A, Interpretation and Policy .05.

[24] *See* Cboe Options Rule 24.9(e); and Phlx Rule 1101A(b)(vii).

[25] *See* Cboe Options Rule 24.6, Interpretations and Policies .01 (options with Quarterly Index Expirations), .03 (Cboe S&P 500 AM/PM Basis options), .04 (P.M.-settled SPX options with third Friday-of-the-month expiration and P.M.-settled XSP options), and .05 (MSCI EAFE Index options).

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2018–066 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–2018–066. 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–2018–066, and should be submitted on or before November 20, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018–23624 Filed 10–29–18; 8:45 am]

**BILLING CODE 8011–01–P**

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–84477; File No. SR–Phlx–2018–62]**

## Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delete Current Rules on Arbitration

October 24, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 9, 2018, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to delete the current rules on arbitration (''Current Arbitration Rules''), under Rule 950, and incorporate by reference The Nasdaq Stock Market LLC's (''Nasdaq'') rules on arbitration at General 6 (''Proposed Arbitration Rules''), into General 6 of the Exchange's rulebook's (''Rulebook'') shell structure.[3]

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the 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 delete the rules on arbitration, currently under Rule 950, and incorporate by reference the Nasdaq rules on arbitration at General 6 of Nasdaq's rulebook into General 6 of the Exchange's Rulebook.

The Exchange adopted the Current Arbitration Rules to ensure a fair and efficient manner in which to handle any dispute, claim or controversy arising out of, or in connection with, the business of any Member of the Exchange. To help administer the process of dispute resolution, the Exchange and FINRA are parties to a Regulatory Contract, pursuant to which FINRA has agreed to perform certain functions and provide access to certain services, including: Member regulation and registration; non-real time market surveillance; examinations and investigations; and dispute resolution. FINRA currently operates the largest securities dispute resolution forum in the United States,[4] and has given the Exchange access to these services. Under the Current Arbitration Rules, Members and associated persons of a Member are subject to the FINRA Code of Arbitration Procedure.

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[26] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Recently, the Exchange added a shell structure to its Rulebook with the purpose of improving efficiency and readability and to align its rules closer to those of its five sister exchanges, The Nasdaq Stock Market LLC; Nasdaq BX, Inc.; Nasdaq ISE, LLC; Nasdaq GEMX, LLC; and Nasdaq MRX, LLC (''Affiliated Exchanges''). The shell structure currently contains eight (8) Chapters which, once complete, will apply a common set of rules to the Affiliated Exchanges. *See* Securities Exchange Act Release No. 82169 (November 29, 2017), 82 FR 57508 (December 5, 2017) (SR–PHLX–2017–97).

[4] *http://www.finra.org/arbitration-and-mediation.*

Because the Affiliated Exchanges are also parties to similar Regulatory Contracts with FINRA that make their members and associated persons of such members subject to the FINRA Code of Arbitration Procedure, the Exchange believes it is pertinent that a common set of rules on arbitration be included in the General section of the Rulebook's shell. Nasdaq completed this process recently [5] and, pursuant to subsequent filings, the intention is to replace the existing arbitration rules for each of the Affiliated Exchanges by incorporating the Nasdaq rules on arbitration by reference.

Therefore, the Exchange will incorporate by reference the Proposed Arbitration Rules in ''General 6 Arbitration'' of the shell's ''General Equity and Options Rules'' section.

The relocation and harmonization of the arbitration rules is part of the Exchange's continued effort to promote efficiency and conformity of its processes with those of its Affiliated Exchanges.[6] The Exchange believes that the adoption and placement of the Proposed Arbitration Rules to their new location in the shell will facilitate the use of the Rulebook by Members of the Exchange who are members of other Affiliated Exchanges. Moreover, the proposed changes are of a conforming nature and will not amend the substance of the adopted rules other than to update the language to that of the Proposed Arbitration Rules, and to make conforming cross-reference changes.

PHLX will continue to file proposed rule changes to amend its General 6 Rules until such time as it receives an exemption from the Securities and Exchange Commission, pursuant to its authority under Section 36 of the Exchange Act of 1934 (''Act'') and Rule 0–12 [7] thereunder, from the Section 19(b) filing requirements to separately file a proposed rule change to amend General 6.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by promoting efficiency and structural conformity of the Exchange's processes with those of the Affiliated Exchanges and to make the Exchange's Rulebook easier to read and more accessible to its Members. The Exchange believes that the adoption and harmonization of the arbitration rules and cross-reference updates are of a non-substantive nature.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes do not impose a burden on competition because, as previously stated, they are (i) of a non-substantive nature, (ii) intended to harmonize the structure of the Exchange's rules with those of its Affiliated Exchanges, and (iii) intended to organize the Rulebook in a way that it will ease the Members' navigation and reading of the rules across the Affiliated Exchanges.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were either solicited or received.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [10] and subparagraph (f)(6) of Rule 19b–4 thereunder.[11]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2018–62 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2018–62. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–

[5] *See* Securities Exchange Act Release No. 83834 (August 13, 2018), 83 FR 41115 (August 17, 2018) (SR–NASDAQ–2018–067).

[6] *See* footnote 3.

[7] *See* 17 CFR 240.0–12; Securities Exchange Act Release No. 39624 (February 5, 1998), 63 FR 8101 (February 18, 1998).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

2018–62 and should be submitted on or before November 20, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2018–23621 Filed 10–29–18; 8:45 am]

**BILLING CODE 8011–01–P**

[12] 17 CFR 200.30–3(a)(12).

## SMALL BUSINESS ADMINISTRATION

**[Disaster Declaration # 15780 and # 15781; FLORIDA Disaster Number FL–00141]**

### Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Florida

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Florida (FEMA–4399–DR), dated 10/23/2018.

*Incident:* Hurricane Michael.

*Incident Period:* 10/07/2018 through 10/19/2018.

**DATES:** Issued on 10/23/2018.

*Physical Loan Application Deadline Date:* 12/24/2018.

*Economic Injury (EIDL) Loan Application Deadline Date:* 07/23/2019.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that as a result of the President's major disaster declaration on 10/23/2018, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

*Primary Counties:* Bay, Calhoun, Gadsden, Gulf, Jackson, Liberty.

The Interest Rates are:

| | Percent |
|---|---|
| *For Physical Damage:* | |
| Non-Profit Organizations with Credit Available Elsewhere | 2.500 |
| Non-Profit Organizations without Credit Available Elsewhere | 2.500 |
| *For Economic Injury:* | |
| Non-Profit Organizations without Credit Available Elsewhere. | 2.500 |

The number assigned to this disaster for physical damage is 157808 and for economic injury is 157810.

(Catalog of Federal Domestic Assistance Number 59008)

**Rafaela Monchek,**

*Acting Associate Administrator for Disaster Assistance.*

[FR Doc. 2018–23626 Filed 10–29–18; 8:45 am]

**BILLING CODE 8025–01–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2018–0159]**

### Agency Information Collection Activities; Revision of an Approved Information Collection Request: Commercial Driver Licensing and Test Standards

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for review and approval. FMCSA requests approval to revise and renew an ICR titled, ''Commercial Driver Licensing and Test Standards,'' due to, in part, a decrease in the number of commercial driver's license records and the addition of one information collection item: ''Driver completion of knowledge and skills tests.'' This ICR is needed to ensure that drivers, motor carriers and the States are complying with notification and recordkeeping requirements for information related to testing, licensing, violations, convictions and disqualifications and that the information is accurate, complete and transmitted and recorded within certain time periods as required by the Commercial Motor Vehicle Safety Act of 1986 (CMVSA), as amended.

**DATES:** Please send your comments by November 29, 2018. OMB must receive your comments by this date in order to act quickly on the ICR.

**ADDRESSES:** All comments should reference Federal Docket Management System (FDMS) Docket Number FMCSA–2018–0159. 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. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/Federal Motor Carrier Safety Administration, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Mr. Selden Fritschner, Senior Transportation Specialist, Office of Safety Programs, Commercial Driver's License Division (MC–ESL), Department of Transportation, Federal Motor Carrier Safety Administration, 6th Floor, West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Telephone: 202–366–0677; Email Address: *selden.fritschner@dot.gov.* Office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

**SUPPLEMENTARY INFORMATION:**

*Title:* Commercial Driver Licensing and Test Standards.

*OMB Control Number:* 2126–0011.

*Type of Request:* Revision of a currently-approved information collection.

*Respondents:* Drivers with a commercial learner's permit (CLP) or commercial driver's license (CDL) and State driver licensing agencies.

*Estimated Number of Respondents:* 7,364,972 driver respondents and 4,746 State respondents.

*Estimated Time per Response:* Varies.

*Expiration Date:* October 31, 2018.

*Frequency of Response:* Varies.

*Estimated Total Annual Burden:* 2,825,503 hours, which is the total of four tasks for CDL drivers (2,403,248 hours), added to a total of eight tasks for State driver licensing agency CDL activities (422,255 hours).

Information collection tasks and associated burden hours are as follows:

IC–1.1 Driver Notification of Convictions/Disqualifications to Employer: 473,577 hours

IC–1.2 Driver Providing Previous Employment History to New Employer: 297,758 hours
IC–1.3 Driver Completion of the CDL Application Form: 40,719 hours
IC–1.4 Driver Completion of Knowledge and Skills Tests: 1,591,194 hours
IC–2.1 State Recording of Medical Examiner's Certificate Information: 80,344 hours
IC–2.2 State Recording of the Self Certification of Commercial Motor Vehicle (CMV) Operation: 3,018 hours
IC–2.3 State Verification of Medical Certification Status: 3,180 hours
IC–2.4 Annual State Certification of Compliance: 1,632 hours
IC–2.5 State Preparing for and Participating in Annual Program Review: 10,200 hours
IC–2.6 CDLIS/PDPS/State Recordkeeping: 214,548 hours
IC–2.7 Knowledge and Skills Test Recordkeeping: 82,034 hours
IC–2.8 Knowledge and Skills Test Examiner Certification: 27,299 hours

*Background:* The licensed drivers in the United States deserve reasonable assurance that their fellow motorists are properly qualified to drive the vehicles they operate. Before the Commercial Motor Vehicle Safety Act of 1986 (CMVSA or the Act) Public Law 99–570, Title XII, 100 Stat. 3207, codified at 49 U.S.C. chapter 313) was signed by the President on October 27, 1986, 18 States and the District of Columbia authorized any person licensed to drive an automobile to also legally drive a large truck or bus. No special training or special license was required to drive these vehicles, even though it was widely recognized that operation of certain types of vehicles called for special skills, knowledge and training. Even in the 32 States that had a classified driver licensing system in place, only 12 of these States required an applicant to take a skills test in a representative vehicle. Equally serious was the problem of drivers possessing multiple driver licenses. By spreading their convictions among several States, CMV drivers could avoid punishment for their infringements, and stay behind the wheel.

For a detailed history of regulatory developments in 49 CFR parts 383 and 384 to implement the mandates in the CMVSA, see the supporting statement in the docket for this matter.''

*Public Comments Invited:* You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FMCSA to perform its functions; (2) the accuracy of the estimated burden; (3) ways for the FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority delegated in 49 CFR 1.87 on: October 24, 2018

**G. Kelly Regal,**

*Associate Administrator for Office of Research and Information Technology.*

[FR Doc. 2018–23707 Filed 10–29–18; 8:45 am]

**BILLING CODE 4910–EX–P**

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## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

**[Docket No. FMCSA–2018–0014]**

### Qualification of Drivers; Exemption Applications; Vision

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of final disposition.

**SUMMARY:** FMCSA announces its decision to exempt 13 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. They are unable to meet the vision requirement in one eye for various reasons. The exemptions enable these individuals to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

**DATES:** The exemptions were applicable on August 17, 2018. The exemptions expire on August 17, 2020.

**FOR FURTHER INFORMATION CONTACT:** Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

**SUPPLEMENTARY INFORMATION:**

## I. Public Participation

### *A. Viewing Documents and Comments*

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2018–0014, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

### *B. 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, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

## II. Background

On July 17, 2018, FMCSA published a notice announcing receipt of applications from 13 individuals requesting an exemption from vision requirement in 49 CFR 391.41(b)(10) and requested comments from the public (83 FR 33292). The public comment period ended on August 16, 2018, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting the exemptions to these individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in 49 CFR 391.41(b)(10) states that a person is physically qualified to driver a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

## III. Discussion of Comments

FMCSA received no comments in this proceeding.

## IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for up to five years from the vision standard in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. The exemption allows applicants to operate CMVs in

interstate commerce. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The Agency's decision regarding these exemption applications is based on medical reports about the applicants' vision as well as their driving records and experience driving with the vision deficiency. The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the July 17, 2018, **Federal Register** notice (83 FR 33292) and will not be repeated in this notice.

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their limitation and demonstrated their ability to drive safely. The 13 exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including amblyopia, complete loss of vision, corneal scar, irregularly shaped pupil, macular myelinated nerve fibers, macular scar, optic nerve damage, posterior staphyloma, prosthetic eye, and retinal detachment. In most cases, their eye conditions were not recently developed. Nine of the applicants were either born with their vision impairments or have had them since childhood. The four individuals that sustained their vision conditions as adults have had it for a range of 6 to 18 years. Although each applicant has one eye which does not meet the vision requirement in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV.

Doctors' opinions are supported by the applicants' possession of a valid license to operate a CMV. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV, with their limited vision in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions.

The applicants in this notice have driven CMVs with their limited vision in careers ranging for 4 to 78 years. In the past three years, no drivers were involved in crashes, and one driver was convicted of a moving violation in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

Consequently, FMCSA finds that in each case exempting these applicants from the vision requirement in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption.

## V. Conditions and Requirements

The terms and conditions of the exemption are provided to the applicants in the exemption document and includes the following: (1) Each driver must be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the standard in 49 CFR 391.41(b)(10) and (b) by a certified Medical Examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) each driver must provide a copy of the ophthalmologist's or optometrist's report to the Medical Examiner at the time of the annual medical examination; and (3) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

## VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

## VII. Conclusion

Based upon its evaluation of the 13 exemption applications, FMCSA exempts the following drivers from the vision requirement, 49 CFR 391.41(b)(10), subject to the requirements cited above:

Ronald D. Blakely (MI)
Homero Dominguez (TX)
Larry L. George (LA)
Jason C. Hetrick (PA)
Michael A. Hildebrand (PA)
Junior M. Isenberg (KY)
David G. Livingston (VT)
Joseph P. Markley (PA)
Derek L. Redford (ID)
David Tavarez (NJ)
William B. Van Drielen (NV)
Willie R. White, Jr. (NV)
Curtis C. Williams (MO)

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for two years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

Issued on: October 24, 2018.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2018–23706 Filed 10–29–18; 8:45 am]

BILLING CODE 4910–EX–P

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## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

**[Docket No. FRA–2018–0008–N–10]**

### Proposed Agency Information Collection Activities; Comment Request

**AGENCY:** Federal Railroad Administration (FRA), Department of Transportation (DOT).

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** Under the Paperwork Reduction Act of 1995 (PRA), this notice announces that FRA is forwarding the Information Collection Requests (ICRs) abstracted below to the Office of Management and Budget (OMB) for review and comment. The ICRs describe the information collections and their expected burden. On August 1, 2018, FRA published a notice providing a 60-day period for public comment on the ICRs.

**DATES:** Interested persons are invited to submit comments on or before November 29, 2018.

**ADDRESSES:** Submit written comments on the ICRs to the Office of Information

and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: FRA Desk Officer. Comments may also be sent via email to OMB at the following address: *oira_submissions@omb.eop.gov.*

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W33–497, Washington, DC 20590 (telephone: (202) 493–6292); or Ms. Kim Toone, Information Collection Clearance Officer, Office of Administration, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W34–212, Washington, DC 20590 (telephone: (202) 493–6132).

**SUPPLEMENTARY INFORMATION:** The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. On August 1, 2018, FRA published a 60-day notice in the **Federal Register** soliciting comment on the ICRs for which it is now seeking OMB approval. *See* 83 FR 37606. FRA received no comments in response to this notice.

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect.

*Comments are invited on the following ICRs regarding:* (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the information will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology.

The summaries below describe the ICRs that FRA will submit for OMB clearance as the PRA requires:

*Title:* Railroad Locomotive Safety Standards and Event Recorders.

*OMB Control Number:* 2130–0004.

*Abstract:* The Locomotive Safety Standards at 49 CFR part 229 require railroads to inspect, repair, and maintain locomotives, including their event recorders, to ensure they are safe and free of defects. Crashworthy locomotive event recorders provide FRA with verifiable factual information about how trains are operated. These devices are used by FRA and State inspectors for part 229 rule enforcement. The information garnered from crashworthy event recorders is used by railroads to monitor railroad operations and by railroad employees (locomotive engineers, train crews, dispatchers) to improve train handling, and promote the safe and efficient operation of trains throughout the country, based on a surer knowledge of different control inputs.

*Type of Request:* Extension with change of a current information collection.

*Affected Public:* Businesses (railroads).

*Form(s):* FRA F 6180.49A.

*Respondent Universe:* 741 Railroads.

*Frequency of Submission:* On occasion.

*Total Estimated Annual Responses:* 7,509,648.

*Total Estimated Annual Burden:* 3,815,751 hours.

*Title:* Railroad Signal System Requirements.

*OMB Control Number:* 2130–0006.

*Abstract:* The regulations pertaining to railroad signal systems are contained in 49 CFR parts 233 (Signal System Reporting Requirements), 235 (Instructions Governing Applications for Approval of a Discontinuance or Material Modification of a Signal System), and 236 (Rules, Standards, and Instructions Governing the Installation, Inspection, Maintenance, and Repair of Signal and Train Control Systems, Devices, and Appliances). Section 233.5 provides that each railroad must report to FRA within 24 hours after learning of an accident or incident arising from signal failure (*e.g.,* failure of a signal appliance, device, method or system to function or indicate as required by 49 CFR part 236 that results in a more favorable aspect than intended) or other condition hazardous to the movement of a train. Section 233.7 provides that each railroad must report signal failures within 15 days in accordance with the instructions printed on Form FRA F 6180.14.

Title 49 CFR part 235 sets forth the specific conditions under which FRA will approve the modification or discontinuance of railroad signal systems. These regulations also describe the process that should be followed by a railroad to seek such an approval. The application process prescribed under 49 CFR part 235 enables FRA to obtain the necessary information to make logical and informed decisions concerning railroad requests to modify or discontinue signaling systems. Section 235.5 requires railroads to apply for FRA approval to discontinue or materially modify railroad signal systems. However, section 235.7 cites signal system changes that do not require FRA approval such as removal of an interlocking where a drawbridge has been permanently closed by the formal approval of another governmental agency. Section 235.8 allows railroads to seek relief from the requirements in 49 CFR part 236. Sections 235.10, 235.12, and 235.13 explain where the application must be submitted, what information must be included, what the format should be, and who is authorized to sign the application. FRA provides public notice concerning applications for relief and allows individuals and organizations to protest the granting of an application for relief. Section 235.20 describes the protest process, including essential information that must accompany the protest, the address for filing the protest, the time limit for filing the protest, and the requirement that a person requesting a public hearing explain why written statements cannot be used to explain his or her position.

Title 49 CFR part 236 contains FRA's signal system requirements. Section 236.110 requires that the results of signal system tests required under §§ 236.102 through 236.109; 236.376 through 236.387; 236.576 and 236.577; and 236.586 through 236.589 be recorded on pre-printed forms provided by the railroad or by electronic means, subject to FRA approval. These forms show the name of the railroad, place and date of the test conducted, type of equipment tested, and results of the test. They also describe any repairs, replacements, and adjustments performed on the equipment that has been tested, and the condition in which the equipment was left. This section

also requires that the employee conducting the test must sign the form and that the record be retained at the office of the supervisory official. Test results made in compliance with § 236.587 must be retained for 92 days. The results of all other tests required under §§ 236.102 through 109; 236.376 through 236.387; 236.576 and 236.577; and 236.586 through 236.589, including results of periodic tests, must be retained until the next record is filed, but no less than one year. Additionally, § 236.587 requires each railroad to make a departure test of the cab signal, automatic train stop, or train control devices on locomotives prior to a locomotive entering equipped territory. This section further requires that whoever performs the departure test must certify in writing that the test was properly performed. The certification and test results must be posted in the locomotive cab with a copy of the certification and test results retained at the office of the supervisory official. However, if it is impractical to leave a copy of the certification and test results at the location where the test is conducted, then the test results must be transmitted to either the dispatcher or another designated official who must keep a written record of the test results and the name of the person performing the test. All records prepared under this section are required to be retained for 92 days. Finally, § 236.590 requires railroads to clean and inspect the pneumatic apparatus of automatic train stop, train control, or cab signal devices on locomotives as required by § 229.29(a).

*Type of Request:* Extension with change of a currently approved information collection.

*Affected Public:* Businesses.

*Form(s):* FRA F 6180.14.

*Respondent Universe:* 741 Railroads.

*Frequency of Submission:* On occasion.

*Total Estimated Annual Responses:* 1,673,437.

*Total Estimated Annual Burden:* 444,820 hours.

*Title:* Inspection Brake System Safety Standards for Freight and Other Non-Passenger Trains and Equipment (Power Brakes).

*OMB Control Number:* 2130–0008.

*Abstract:* Recognizing the importance of upgrading rail technologies, Congress in 1980 passed the Rock Island Railroad Transition and Employee Assistance Act (the ''Rock Island Act''), which, inter alia, provides statutory relief for the implementation of new technologies. More specifically, when certain statutory requirements preclude the development or implementation of more efficient railroad transportation equipment or other transportation innovations, the applicable section of the Rock Island Act, currently codified at 49 U.S.C. 20306, provides the Secretary of Transportation with the authority to grant an exemption to those requirements based on evidence received and findings developed at a hearing. In accordance with that statute, FRA held a public hearing and invoked its discretionary authority under 49 U.S.C. 20306 to provide a limited exemption from 49 U.S.C. 20303 for freight trains and freight cars operating with electronically controlled pneumatic (ECP) brake systems. In doing so, FRA revised the regulations governing freight power brakes and equipment in October 2008 by adding a new subpart G. The revisions are designed to provide for and encourage the safe implementation and use of ECP brake system technologies. These revisions contain specific requirements on the design, interoperability, training, inspection, testing, handling of defective equipment, and periodic maintenance related to ECP brake systems. The final rule also provides flexibility to facilitate the voluntary adoption of this advanced brake system technology. The collection of information is used by FRA to monitor and enforce regulatory requirements related to power brakes on freight cars, including the requirements related to ECP brake systems. The collection of information is also used by locomotive engineers and road crews to verify that the terminal air brake test has been performed in a satisfactory manner.

*Type of Request:* Extension with change of a currently approved information collection.

*Affected Public:* Businesses.

*Form(s):* N/A.

*Respondent Universe:* 741 Railroads.

*Frequency of Submission:* On occasion.

*Total Estimated Annual Responses:* 30,518,808.

*Total Estimated Annual Burden:* 1,045,478 hours.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

**Authority:** 44 U.S.C. 3501–3520.

**Juan D. Reyes III,**

*Chief Counsel.*

[FR Doc. 2018–23586 Filed 10–29–18; 8:45 am]

BILLING CODE 4910–06–P

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. MARAD–2018–0158]**

### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel YEMAYA; Invitation for Public Comments

**AGENCY:** Maritime Administration, DOT.

**ACTION:** Notice.

**SUMMARY:** The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before November 29, 2018.

**ADDRESSES:** You may submit comments identified by DOT Docket Number MARAD–2018–0158 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–2018–0158 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0158, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

*Note:* If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

*Instructions:* All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

**FOR FURTHER INFORMATION CONTACT:** Bianca Carr, U.S. Department of Transportation, Maritime

Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel YEMAYA is:

—*Intended Commercial Use of Vessel:* ''Bareboat charters''

—*Geographic Region Including Base of Operations:* ''Michigan, Illinois'' (Base of Operations: Holland, MI)

—*Vessel Length and Type:* 60′ Arduman motor with twin diesel Caterpillar engines

The complete application is available for review identified in the DOT docket as MARAD–2018–0158 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

**Public Participation**

*How do I submit comments?*

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

*Where do I go to read public comments, and find supporting information?*

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2018–0158 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

*Will my comments be made available to the public?*

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

*May I submit comments confidentially?*

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

**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,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* 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.

**Authority:** 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121

* * * * *

Dated: October 25, 2018.

By Order of the Maritime Administrator.

**T. Mitchell Hudson, Jr.,**

*Secretary, Maritime Administration.*

[FR Doc. 2018–23650 Filed 10–29–18; 8:45 am]

**BILLING CODE 4910–81–P**

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## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. MARAD–2018–0161]**

### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel Y KNOT; Invitation for Public Comments

**AGENCY:** Maritime Administration, DOT.

**ACTION:** Notice.

**SUMMARY:** The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before November 29, 2018.

**ADDRESSES:** You may submit comments identified by DOT Docket Number MARAD–2018–0161 by any one of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0161 and follow the instructions for submitting comments.

• *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0161, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

*Note:* If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

*Instructions:* All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

**FOR FURTHER INFORMATION CONTACT:** Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel Y KNOT is:

—*Intended Commercial Use of Vessel:* Carrying small groups of passengers for hire under private charter

—*Geographic Region Including Base of Operations:* ''Florida, New York (excluding New York Harbor)'' (Base of Operations: Miami, Florida.)

—*Vessel Length and Type:* 68' Leopard motor vessel

The complete application is available for review identified in the DOT docket

as MARAD–2018–0161 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

**Public Participation**

*How do I submit comments?*

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

*Where do I go to read public comments, and find supporting information?*

Go to the docket online at *http://www.regulations.gov.* keyword search MARAD–2018–0161 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

*Will my comments be made available to the public?*

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

*May I submit comments confidentially?*

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

**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,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* 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.

**Authority:** 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

* * * * *

Dated: October 25, 2018.

By Order of the Maritime Administrator.

**T. Mitchell Hudson, Jr.,**

*Secretary, Maritime Administration.*

[FR Doc. 2018–23655 Filed 10–29–18; 8:45 am]

BILLING CODE 4910–81–P

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. MARAD–2018–0162]**

### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel ONE LOVE; Invitation for Public Comments

**AGENCY:** Maritime Administration, DOT.

**ACTION:** Notice.

**SUMMARY:** The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before November 29, 2018.

**ADDRESSES:** You may submit comments identified by DOT Docket Number MARAD–2018–0162 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0162 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0162, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

*Note:* If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

*Instructions:* All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

**FOR FURTHER INFORMATION CONTACT:** Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel ONE LOVE is:

—*Intended Commercial Use of Vessel:* ''Charter Boat''

—*Geographic Region Including Base of Operations:* ''Florida'' (Base of Operations: Key Largo, Florida)

—*Vessel Length and Type:* 40′ fixed keel catamaran sailing vessel

The complete application is available for review identified in the DOT docket as MARAD–2018–0162 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of

MARAD's regulations at 46 CFR part 388.

**Public Participation**

*How do I submit comments?*

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

*Where do I go to read public comments, and find supporting information?*

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0162 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

*Will my comments be made available to the public?*

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

*May I submit comments confidentially?*

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

**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,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* 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.

**Authority:** 49 CFR 1.93(a), 46 U.S.C. § 55103, 46 U.S.C. § 12121.

* * * * *

Dated: October 25, 2018.

By Order of the Maritime Administrator.

**T. Mitchell Hudson, Jr.,**

*Secretary, Maritime Administration.*

[FR Doc. 2018–23656 Filed 10–29–18; 8:45 am]

**BILLING CODE 4910–81–P**

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## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. MARAD–2018–0160]**

### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MACONDO; Invitation for Public Comments

**AGENCY:** Maritime Administration, DOT.

**ACTION:** Notice.

**SUMMARY:** The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before November 29, 2018.

**ADDRESSES:** You may submit comments identified by DOT Docket Number MARAD–2018–0160 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0160 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0160, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

*Note:* If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

*Instructions:* All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

**FOR FURTHER INFORMATION CONTACT:** Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel MACONDO is:

—*Intended Commercial Use of Vessel:* Vessel will be used for recreational sailing charters including sunset cruises, day sails, and overnight excursions upon the waters of Marina del Rey and Santa Monica Bay from Paradise Cove to Santa Catalina Island, California. The majority of the time the boat operation will be within 10 nautical miles of Marina del Rey. The area of operation is Santa Monica Bay and on occasion, the boat would travel to Santa Catalina Island.

—Geographic Region Including Base of Operations: ''California'' (Base of Operations: Marina del Rey, CA)

—*Vessel Length and Type:* 47.6′ fixed-keel, single mast, sloop rig sailboat

The complete application is available for review identified in the DOT docket as MARAD–2018–0160 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

**Public Participation**

*How do I submit comments?*

Please submit your comments, including the attachments, following the

instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

*Where do I go to read public comments, and find supporting information?*

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2018–0160 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

*Will my comments be made available to the public?*

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

*May I submit comments confidentially?*

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

**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,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* 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.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: October 25, 2018.

By Order of the Maritime Administrator.

**T. Mitchell Hudson, Jr.,**

*Secretary, Maritime Administration.*

[FR Doc. 2018–23654 Filed 10–29–18; 8:45 am]

BILLING CODE 4910–81–P

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

**[Docket No. MARAD–2018–0159]**

### Requested Administrative Waiver of the Coastwise Trade Laws: Vessel SHANGHAI MAC; Invitation for Public Comments

**AGENCY:** Maritime Administration, DOT.

**ACTION:** Notice.

**SUMMARY:** The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

**DATES:** Submit comments on or before November 29, 2018.

**ADDRESSES:** You may submit comments identified by DOT Docket Number MARAD–2018–0159 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0159 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0159, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

*Note:* If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

*Instructions:* All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

**FOR FURTHER INFORMATION CONTACT:** Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

**SUPPLEMENTARY INFORMATION:** As described by the applicant the intended service of the vessel SHANGHAI MAC is:

—*Intended Commercial Use of Vessel:* ''Day charter cruises along the Napa River.''

—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: Vallejo Marina in Vallejo, CA)

—*Vessel Length and Type:* 70′6″ Azimut Motor boat

The complete application is available for review identified in the DOT docket as MARAD–2018–0159 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

**Public Participation**

*How do I submit comments?*

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

*Where do I go to read public comments, and find supporting information?*

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0159 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

*Will my comments be made available to the public?*

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

*May I submit comments confidentially?*

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

**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,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* 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.

(Authority: 49 CFR 1.93(a), 46 U.S.C. § 55103, 46 U.S.C. § 12121)

* * * * *

Dated: October 25, 2018.

By Order of the Maritime Administrator.

**T. Mitchell Hudson, Jr.,**

*Secretary, Maritime Administration.*

[FR Doc. 2018–23651 Filed 10–29–18; 8:45 am]

**BILLING CODE 4910–81–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 FURTHER INFORMATION CONTACT:** OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410.

**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 October 25, 2018, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons and the following vessels subject to U.S. jurisdiction are blocked pursuant to the relevant sanctions authority listed below.

*Individual*

1. TAN, Wee Beng, 51 Siang Kuang Avenue, Singapore; DOB 14 Feb 1977; Gender Male; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Director of Wee Tiong (S) Pte Ltd; Managing Director of WT Marine Pte Ltd (individual) [DPRK].

Designated pursuant to Section 1(a)(ii)(D) of Executive Order 13551 of August 30, 2010, ''Blocking Property of Certain Persons With Respect to North Korea'' (E.O. 13551) for having directly or indirectly, engaged in money laundering, the counterfeiting of goods or currency, bulk cash smuggling, narcotics trafficking, or other illicit economic activity that involves or supports the Government of North Korea or any senior official thereof.

*Entities*

1. WEE TIONG (S) PTE LTD (a.k.a. WEE TIONG S PTE LTD), 1813 Geylang Bahru, #01–01 Kallang Distripark 339715, Singapore; 64D Kallang Pudding Road, #02–00, Wee Tiong Building 349323, Singapore; 02–00 Wee Tiong Building, 64D, Kallang Pudding Road 349323, Singapore; 1805 Geylang Bahru #01–03 339711, Singapore; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Registration Number 199308567K [DPRK].

Designated pursuant to Section 1(a)(ii)(D) E.O. 13551 for having directly or indirectly, engaged in money laundering, the counterfeiting of goods or currency, bulk cash smuggling, narcotics trafficking, or other illicit economic activity that involves or supports the Government of North Korea or any senior official thereof.

2. WT MARINE PTE LTD, #11–09 Parkway Parade 449269, Singapore; 64D Kallang Pudding Road, #09–00 Wee Tiong Building 349323, Singapore; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Registration Number 201616714Z [DPRK].

Designated pursuant to Section 1(a)(ii)(D) of E.O. 13551 for having directly or indirectly, engaged in money laundering, the counterfeiting of goods or currency, bulk cash smuggling, narcotics trafficking, or other illicit economic activity that involves or supports the Government of North Korea or any senior official thereof.

*Vessels*

1. NYMEX STAR Singapore flag; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Vessel Registration Identification IMO 9078191 (vessel) [DPRK] (Linked To: WT MARINE PTE LTD).

Identified pursuant to E.O. 13551 as property in which WT MARINE PTE LTD, an entity whose property and interests in property are blocked pursuant to E.O. 13551, has an interest.

2. JW JEWEL Singapore flag; Secondary sanctions risk: North Korea Sanctions Regulations, sections 510.201 and 510.210; Vessel Registration Identification IMO 9402964 (vessel) [DPRK] (Linked To: WT MARINE PTE LTD).

Identified pursuant to E.O. 13551 as property in which WT MARINE PTE LTD, an entity whose property and interests in property are blocked pursuant to E.O. 13551, has an interest.

Additionally, on October 25, 2018, OFAC updated the entries on the Specially Designated Nationals and Blocked Persons List for the following individuals, whose property and interests in property are subject to U.S. jurisdiction and who continue to be

blocked under the relevant sanctions authorities listed below.

*Individuals*

1. OWHADI, Mohammad Ebrahim (a.k.a. OWHADI, Jalal; a.k.a. TAHERI, Jalal; a.k.a. VAHEDI, Jalal), Iran; DOB 1963; Gender Male (individual) [SDGT] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)–QODS FORCE; Linked To: TALIBAN).

1. OWHADI, Mohammad Ebrahim (a.k.a. OWHADI, Jalal; a.k.a. TAHERI, Jalal; a.k.a. VAHEDI, Jalal), Iran; DOB 1963; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male (individual) [SDGT] [IRGC] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)–QODS FORCE; Linked To: TALIBAN).

Designated on October 23, 2018 pursuant to section 1(c) of E.O. 13224 for acting for or on behalf of the ISLAMIC REVOLUTIONARY GUARD CORPS–QODS FORCE (IRGC–QF), a person determined to be subject to E.O. 13224, and 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, the TALIBAN, a person determined to be subject to E.O. 13224.

2. RAZAVI, Esma'il (a.k.a. MOHAJERI, Mostafa), Iran; DOB 1959; Gender Male (individual) [SDGT] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)–QODS FORCE; Linked To: TALIBAN).

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2. RAZAVI, Esma'il (a.k.a. MOHAJERI, Mostafa), Iran; DOB 1959; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male (individual) [SDGT] [IRGC] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)–QODS FORCE; Linked To: TALIBAN).

Designated on October 23, 2018 pursuant to section 1(c) of E.O. 13224 for acting for or on behalf of the IRGC–QF, a person determined to be subject to E.O. 13224, and 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, the TALIBAN, a person determined to be subject to E.O. 13224.

Dated: October 25, 2018.

**Andrea M. Gacki,**

*Director, Office of Foreign Assets Control.*

[FR Doc. 2018–23659 Filed 10–29–18; 8:45 am]

BILLING CODE 4810–AL–P

## DEPARTMENT OF THE TREASURY

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple IRS Information Collection Requests

**AGENCY:** Departmental Offices, U.S. Department of the Treasury.

**ACTION:** Notice.

**SUMMARY:** The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

**DATES:** Comments should be received on or before November 29, 2018 to be assured of consideration.

**ADDRESSES:** Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW, Suite 8100, Washington, DC 20220, or email at *PRA@treasury.gov.*

**FOR FURTHER INFORMATION CONTACT:** Copies of the submissions may be obtained from Jennifer Leonard by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov.*

**SUPPLEMENTARY INFORMATION:**

### Internal Revenue Service (IRS)

*Title:* FI–27–89 (Temporary and Final) Real Estate Mortgage Investment Conduits; Reporting Requirements and Other Administrative Matters; FI–61–91 (Final) Allocation of Allocable Investment.

*OMB Control Number:* 1545–1018.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* These previously approved regulations prescribe the manner in which an entity elects to be taxed as a real estate mortgage investment conduit (REMIC) and the filing requirements for REMICs and certain brokers.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 655.

*Frequency of Response:* Quarterly.

*Estimated Total Number of Annual Responses:* 9,725.

*Estimated Time per Response:* 6 minutes.

*Estimated Total Annual Burden Hours:* 978.

*Title:* Form 8801—Credit for Prior Year Minimum Tax—Individuals, Estates and Trusts.

*OMB Control Number:* 1545–1073.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Form 8801 is used by individuals, estates, and trusts to compute the minimum tax credit, if any, available from a tax year beginning after 1986 to be used in the current year or to be carried forward for use in a future year.

*Form:* 8801.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 38,744.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 12,914.

*Estimated Time per Response:* 7.06 hours per response.

*Estimated Total Annual Burden Hours:* 91,173.

*Title:* Qualified Separate Lines of Business.

*OMB Control Number:* 1545–1221.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* The affected public includes employers who maintain qualified employee retirement plans. Where applicable, the employer must furnish notice to the IRS that the employer treats itself as operating qualified separate lines of business and some may request an IRS determination that such lines satisfy administrative scrutiny.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 125.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 125.

*Estimated Time per Response:* 3.55 hours per response.

*Estimated Total Annual Burden Hours:* 444.

*Title:* TD 8395—Special Valuation Rules.

*OMB Control Number:* 1545–1241.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Section 2701 of the Internal Revenue Code allows various elections by family members who make gifts of common stock or partnership interests and retain senior interest. The elections affect the value of the gifted interests and the retained interests. This document contains final regulations relating to chapter 14 of the Internal Revenue Code as enacted in the Omnibus Budget Reconciliation Act of 1990, Public Law 101–508, 104 Stat. 1388. These previously approved regulations provide special valuation rules for purposes of Federal estate and gift taxes imposed under chapter 1 and 12 of the Code. In addition, these regulations provide rules involving lapsing rights and other transactions that are treated as completed transfers under chapter 14.

*Form:* None.

*Affected Public:* Individuals or Households.

*Estimated Number of Respondents:* 1,200.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 1,200.

*Estimated Time per Response:* .41 hours per response.

*Estimated Total Annual Burden Hours:* 496.

*Title:* TD 8513—Bad Debt Reserves of Banks.

*OMB Control Number:* 1545–1290.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Section 585(c) of the Internal Revenue Code requires large banks to change from the reserve method of accounting to the specific charge off method of accounting for bad debts. The information required by section 1.585–8 of the regulations identifies any election made or revoked by the taxpayer in accordance with section 585(c).

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 2,500.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 2,500.

*Estimated Time per Response:* .25 hours per response.

*Estimated Total Annual Burden Hours:* 625.

*Title:* TD 8725—Miscellaneous Sections Affected by the Taxpayer Bill of Rights 2 and the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

*OMB Control Number:* 1545–1356.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* This document contains previously approved final regulations relating to joint returns, property exempt from levy, interest, penalties, offers in compromise, and the awarding of costs and certain fees. The regulations reflect changes to the law made by the Taxpayer Bill of Rights 2 and a conforming amendment made by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. The regulations affect taxpayers with respect to filing of returns, interest, penalties, court costs, and payment, deposit, and collection of taxes.

*Form:* None.

*Affected Public:* Individuals or Households.

*Estimated Number of Respondents:* 38.

*Frequency of Response:* On Occasion.

*Estimated Total Number of Annual Responses:* 38.

*Estimated Time per Response:* 2.26 hours per response.

*Estimated Total Annual Burden Hours:* 86.

*Title:* Qualified Electric Vehicle Credit.

*OMB Control Number:* 1545–1374.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Form 8834 is used to claim any qualified electric vehicle passive activity credit allowed for the current tax. The data on Form 8834 will be used to determine that the credit is allowable and that it has been properly computed.

*Form:* 8834.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 3,136.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 3,136.

*Estimated Time per Response:* 4.79 hours per response.

*Estimated Total Annual Burden Hours:* 15,022.

*Title:* TD 8549 (Final) Preparer Penalties—Manual Signature Requirement.

*OMB Control Number:* 1545–1385.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* The reporting requirements affect return preparers of fiduciary returns. They will be required to submit a list of the names and identifying numbers of all fiduciary returns which are being filed with a facsimile signature of the returns preparer.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 20,000.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 20,000.

*Estimated Time per Response:* 1.2 hours per response.

*Estimated Total Annual Burden Hours:* 24,000.

*Title:* Third-Party Disclosure Requirements in the IRS Regulations.

*OMB Control Number:* 1545–1466.

*Type of Review:* Revision of a currently approved collection.

*Description:* Taxpayers must obtain third-party certification or documentation to avail themselves of certain credits, deductions or other benefits permitted by the Internal Revenue Code. Taxpayers will use these documents or information to support claims for certain credits, deductions or tax benefits on their returns. The Service may review these documents or information during any examination of taxpayers' returns to verify the taxpayers' entitlement to the claimed credits, deductions or tax benefits. This submission contains third-party disclosure regulations subject to the Paperwork Reduction Act of 1995.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 245,073,905.

*Frequency of Response:* .53342215 responses annually.

*Estimated Total Number of Annual Responses:* 130,727, 849.

*Estimated Time per Response:* .26 hours per response.

*Estimated Total Annual Burden Hours:* 33,931,750.

*Title:* Electronic Federal Tax Payment System (EFTPS).

*OMB Control Number:* 1545–1467.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Enrollment is vital to the implementation of the Electronic Federal Tax Payment System (EFTPS). EFTPS is an electronic remittance processing system that the Service will use to accept electronically transmitted federal tax payments. This system is a necessary outgrowth of advanced information and communication technologies.

*Forms:* 9783, 9779, 14781, 9787, and 9789.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 4,350,000.
*Frequency of Response:* On occasion.
*Estimated Total Number of Annual Responses:* 4,350,000.
*Estimated Time per Response:* .17 hours per response.
*Estimated Total Annual Burden Hours:* 755,192.

*Title:* Distributions from an Archer MSA or Medicare + Choice MSA.
*OMB Control Number:* 1545–1517.
*Type of Review:* Extension without change from a currently approved collection.
*Description:* This form is used to report distributions from a medical savings account as set forth in section 220(h).
*Form:* 1099–SA.
*Affected Public:* Businesses or other for-profits.
*Estimated Number of Respondents:* 10,336.
*Frequency of Response:* 2.4999 responses per respondent.
*Estimated Total Number of Annual Responses:* 25,839.
*Estimated Time per Response:* .14 hours per response.
*Estimated Total Annual Burden Hours:* 3,618.

*Title:* HSA, Archer MSA, or Medicare Advantage MSA Information.
*OMB Control Number:* 1545–1518.
*Type of Review:* Extension without change of a currently approved collection.
*Description:* Section 220(h) requires trustees to report to the IRS and medical savings account holders the contributions and year-end fair market value of any contributions made to a medical savings account (MSA). Congress requires Treasury to report to them the total contributions made to an MSA for the current tax year. Section 1201 of the Medicare prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) created new Code section 223. Section 223(h) requires the reporting of contributions to and the year-end fair market value of health savings accounts for tax years beginning after December 31, 2003.
*Form:* 5498–SA.
*Affected Public:* Businesses or other for-profits.
*Estimated Number of Respondents:* 9.167.
*Frequency of Response:* Annually.
*Estimated Total Number of Annual Responses:* 9,167.
*Estimated Time per Response:* .17 hours per response.
*Estimated Total Annual Burden Hours:* 1,559.

*Title:* Low-Income Taxpayer Clinic Grant Application Package and Guidelines; Grant website.
*OMB Control Number:* 1545–1648.
*Type of Review:* Extension without change of a currently approved collection.
*Description:* Publication 3319 is the grant application and program requirements for our external customers, non-profits, legal aid societies, universities, law schools, and will be used by anyone in the US and territories to apply for a low income taxpayer grant. There is a website, which collects the information.
*Form:* None.
*Affected Public:* Not-for-profit-institutions.
*Estimated Number of Respondents:* 310.
*Frequency of Response:* Annually.
*Estimated Total Number of Annual Responses:* 310.
*Estimated Time per Response:* 29.03 hours per response.
*Estimated Total Annual Burden Hours:* 9,000.

*Title:* REG–209709–94 (Final-TD 8865) Amortization of Intangible Property.
*OMB Control Number:* 1545–1671.
*Type of Review:* Extension without change of a currently approved collection.
*Description:* The collection of information in this previously approved regulation is in § 1.197–2(h)(9). This information is required in order to provide guidance on the time and manner of making the election under section 197(f)(9)(B). Under this election, the seller of a section 197 intangible may pay a tax on the sale in order to avoid the application of the antichurning rules of section 197(f)(9) to the purchaser. This information will be used to confirm the parties to the transaction, calculate any additional tax due, and notify the purchaser of the seller's election. The likely respondents are business or other for-profit institutions.
*Form:* None.
*Affected Public:* Businesses or other for-profits.
*Estimated Number of Respondents:* 500.
*Frequency of Response:* Annually.
*Estimated Total Number of Annual Responses:* 500.
*Estimated Time per Response:* 3 hours per response.
*Estimated Total Annual Burden Hours:* 1,500.

*Title:* TD 9584—Guidance on Reporting Interest Paid to Nonresident Aliens.
*OMB Control Number:* 1545–1725.
*Type of Review:* Extension without change of a currently approved collection.
*Description:* This document contains previously approved final regulations that provide guidance on the reporting requirements for interest on deposits maintained at the U.S. office of certain financial institutions and paid to nonresident alien individuals. These regulations affect persons making payments of interest with respect to such a deposit.
*Form:* None.
*Affected Public:* Businesses or other for-profit.
*Estimated Number of Respondents:* 2,000.
*Frequency of Response:* Annually.
*Estimated Total Number of Annual Responses:* 2,000.
*Estimated Time per Response:* .25 hours per response.
*Estimated Total Annual Burden Hours:* 500.

*Title:* Form 8802—Application for United States Residency Certification.
*OMB Control Number:* 1545–1817.
*Type of Review:* Extension without change of a currently approved collection.
*Description:* All requests for U.S. residency certification must be received on Form 8802, Application for United States Residency Certification. This application must be sent to the Philadelphia Service Center. As proof of residency in the United States and of entitlement to the benefits of a tax treaty, U.S. treaty partner countries require a U.S. Government certification that you are a U.S. citizen, U.S. Corporation, U.S. partnership, or resident of the United States for purposes of taxation.
*Form:* 8802.
*Affected Public:* Businesses or other for-profits.
*Estimated Number of Respondents:* 1,000,000.
*Frequency of Response:* On occasion.
*Estimated Total Number of Annual Responses:* 130,132.
*Estimated Time per Response:* 3.63 hours per response.
*Estimated Total Annual Burden Hours:* 472,380.

*Title:* TD 9157 (Final) Guidance Regarding the Treatment of Certain Contingent Payment Debt Instruments w/one or more Payments that are Denominated in, or Determined by Reference to, a Nonfunctional Currency.
*OMB Control Number:* 1545–1831.
*Type of Review:* Extension without change of a currently approved collection.
*Description:* This document contains previously approved final regulations regarding the treatment of contingent payment debt instruments for which

one or more payments are denominated in, or determined by reference to, a currency other than the taxpayer's functional currency. These regulations are necessary because current regulations do not provide guidance concerning the tax treatment of such instruments. The regulations affect issuers and holders of such instruments including investment banks and others who hold these debt instruments for investments.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 100.

*Frequency of Response:* On occasion.

*Estimated Total Number of Annual Responses:* 250.

*Estimated Time per Response:* .4 hours per response.

*Estimated Total Annual Burden Hours:* 100.

*Title:* Application for Registration (For Certain Excise Tax Activities) and Questionnaires.

*OMB Control Number:* 1545–1835.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Form 637 is used to apply for excise tax registration for activities under sections 4101, 4222, and 4682. This includes, but is not limited to, pipeline operator or vessel operator: Activity Letter, Enterers, position holders, refiners, and terminal operators, Blenders, Producers or importers of alcohol, agri-biodiesel, and biodiesel (including renewable diesel), Producers of second generation biofuel. The information will be used to make an informed decision on whether the applicant/registrant qualifies for registration. Form 637 Questionnaires will be used to collect information about persons who are attempting to register or are registered with the Internal Revenue Service (IRS) in accordance with Internal Revenue Code (IRC) § 4101, 4222, or Notice 2005–04. The information will be used to make an informed decision on whether the applicant/registrant qualifies for registration.

*Form:* 637.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 4,840.

*Frequency of Response:* On occasion.

*Estimated Total Number of Annual Responses:* 4,840.

*Estimated Time per Response:* 6.3 hours per response.

*Estimated Total Annual Burden Hours:* 30,499.

*Title:* Qualified Severance of a Trust for Generation-Skipping Transfer (GST) Tax Purposes.

*OMB Control Number:* 1545–1902.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* This previously approved Regulation requires taxpayers to report a qualified severance by filing a Form 706–GS(T), or such other form that may be published by the Internal Revenue Service in the future that is specifically designated to be utilized to report qualified severance's. Where Form 706–GS(T) is used, the filer should attach a Notice of Qualified Severance to the return that clearly identifies the trust that is being severed and the new trusts created as a result of the severance. The Notice must also provide the inclusion ratio of the trust that was severed and the inclusion ratios of the new trusts resulting from the severance. The information collected will be used by the IRS to identify the trusts being severed and the new trusts created upon severance. The collection of information is required in order to have a qualified severance. If there was no reporting requirement, the IRS would be unable to achieve its objectives.

*Form:* None.

*Affected Public:* Individuals or Households.

*Estimated Number of Respondents:* 350.

*Frequency of Response:* On occasion.

*Estimated Total Number of Annual Responses:* 650.

*Estimated Time per Response:* 2.08 hours per response.

*Estimated Total Annual Burden Hours:* 1,352.

*Title:* Form 8858—Information Return of U.S. Persons With Respect To Foreign Disregarded Entities; and Transactions Between Foreign Disregarded Entity of a Foreign Tax Owner and the Filer.

*OMB Control Number:* 1545–1910.

*Type of Review:* Revision of a currently approved collection.

*Description:* Form 8858 and Schedule M (Form 8858) are used by certain U.S. persons that own a foreign disregarded entity (FDE) directly or, in certain circumstances, indirectly or constructively. The form and schedules are used to satisfy the reporting requirements of sections 6011, 6012, 6031, and 6038, and related regulations.

*Forms:* 8858, Ach M (F. 8858).

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 28,000.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 20,000.

*Estimated Time per Response:* 32.78 hours per response.

*Estimated Total Annual Burden Hours:* 917,800.

*Title:* Application for Automatic Extension of Time To File Form 709 and/or Payment of Gift/Generation-Skipping Transfer Tax.

*OMB Control Number:* 1545–1913.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Form 8892 was created to serve a dual purpose. First, the form enables taxpayers to request an extension of time to File 709, when they are not filing an individual income tax extension. Second, it serves as a payment voucher for taxpayers, who are filing an individual income tax extension (by Form 4868) and will have a gift tax balance due on Form 709.

*Form:* 8892.

*Affected Public:* Individuals or Households.

*Estimated Number of Respondents:* 10,000.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 10,000.

*Estimated Time per Response:* .72 hours per response.

*Estimated Total Annual Burden Hours:* 7,200.

*Title:* Form 8896—Low Sulfur Diesel Fuel Production Credit.

*OMB Control Number:* 1545–1914.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Internal Revenue Code section 45H allows small business refiners a 5 cent/gallon credit for the production of low sulfur diesel fuel. Form 8896 is used to claim the credit.

*Form:* 8896.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 66.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 66.

*Estimated Time per Response:* 3.93 hours per response.

*Estimated Total Annual Burden Hours:* 260.

*Title:* 26 U.S. Code § 475—Mark to market accounting method for dealers in securities.

*OMB Control Number:* 1545–1945.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Section 475 was added by section 13223(a) of the Revenue

Reconciliation Act of 1993, Public Law 103–66, 107 Stat.481, and is effective for all taxable years ending on or after December 31, 1993. The statutory requirements under 26 U.S.C. 475 are codified under 26 CFR part 1, sections 1.475 et al. Information collection requirements under § 1.475(a)–4 sets forth an elective safe harbor that permits dealers in securities and dealers in commodities to elect to use the values of positions reported on certain financial statements as the fair market values of those positions for purposes of section 475 of the Internal Revenue Code (Code). This safe harbor is intended to reduce the compliance burden on taxpayers and to improve the administrability of the valuation requirement of section 475. The recordkeeping requirement under section 1.475(b)–4 are required to determine whether exemption from mark- to-market treatment is properly claimed, and will be used to make that determination upon audit of taxpayer's books and records. The information under section 1.475(c)–1(a)(3)(iii), is necessary to determine whether a consolidated group has elected to disregard inter-member transactions in determining a member's status as a dealer in securities.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 15,708.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 15,708.

*Estimated Time per Response:* 3.32 hours per response.

*Estimated Total Annual Burden Hours:* 52,182.

*Title:* Contributions of Motor Vehicles, Boats, and Airplanes.

*OMB Control Number:* 1545–1959.

*Type of Review:* Revision of a currently approved collection.

*Description:* Section 884 of the American Jobs Creation Act of 1004 (Pub. L. 108–357) added paragraph 12 to section 170(f) for contributions of used motor vehicles, boats, and airplanes. Section 170(f)(12) requires that a donee organization provide an acknowledgement to the donor of this type of property and is required to file the same information to the Internal Revenue Service. Form 1098–C may be used as the acknowledgement and it, or an acceptable substitute, must be filed with the IRS.

*Form:* 1098–C.

*Affected Public:* Not-for-profit institutions.

*Estimated Number of Respondents:* 106,200.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 106,200.

*Estimated Time per Response:* .31 hours per response.

*Estimated Total Annual Burden Hours:* 32,922.

*Title:* Form 3949–A—Information Referral.

*OMB Control Number:* 1545–1960.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* This application is voluntary and the information requested helps us determine if there has been a violation of Income Tax Law. We need the taxpayer identification numbers-Social Security Number (SSN) or Employer Identification Number (EIN) in order to fully process your application. Failure to provide this information may lead to suspension of processing this application.

*Form:* 3949–A.

*Affected Public:* Individuals or Households.

*Estimated Number of Respondents:* 215,000.

*Frequency of Response:* On occasion.

*Estimated Total Number of Annual Responses:* 215,000.

*Estimated Time per Response:* .25 hours per response.

*Estimated Total Annual Burden Hours:* 53,750.

*Title:* Form 8899—Notice of Income from Donated Intellectual Property.

*OMB Control Number:* 1545–1962.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Form 8899 is filed by charitable organizations receiving donations of intellectual property if the donor provides a timely notice. The initial deduction is limited to the donor's basis, additional deductions are allowed to the extent of income from the property, reducing excessive deductions.

*Form:* 8899.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 1,000.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 1,000.

*Estimated Time per Response:* 5.43 hours per response.

*Estimated Total Annual Burden Hours:* 5,430.

*Title:* REG–146459–05—TD 9324 (Final) Designated Roth Contributions Under Section 402A.

*OMB Control Number:* 1545–1992.

*Type of Review:* Revision of a currently approved collection.

*Description:* The previously approved final regulations set forth the rules for taxation of distributions from Designated Roth Accounts which are a part of a 401(k) plan or 403(b) plan.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 397,000.

*Frequency of Response:* On occasion.

*Estimated Total Number of Annual Responses:* 397,000.

*Estimated Time per Response:* 2.26 hours per response.

*Estimated Total Annual Burden Hours:* 898,000.

*Title:* Revenue Procedures 2008–60; 2012–27: Election Involving the Repeal of the Bonding Requirement and Notification of Increase of Tax under § 42(j)(6).

*OMB Control Number:* 1545–2120.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* This revenue procedure affects taxpayers who are maintaining a surety bond or a Treasury Direct Account (TDA) to satisfy the low-income housing tax credit recapture exception in § 42(j)(6) of the Internal Revenue Code, as in effect on or before July 30, 2008. This revenue procedure provides the procedures for taxpayers to follow when making the election under section 3004(i)(2)(B)(ii) of the Housing Assistance Tax Act of 2008 (Pub. L. 110–289) to no longer maintain a surety bond or a TDA to avoid recapture.

*Form:* None.

*Affected Public:* Individuals or Households.

*Estimated Number of Respondents:* 7800.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 7,800.

*Estimated Time per Response:* 1 hour per response.

*Estimated Total Annual Burden Hours:* 7,800.

*Title:* Form 8928—Return of Certain Excise Taxes Under Chapter 43 & TD 9457-Employer Comparable Contributions to HSAs and Requirement for filing excise taxes under sections 4980B, 4980D, 4980E and 4980G.

*OMB Control Number:* 1545–2146.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Form 8928 is used by employers, group health plans, HMOs, and third party administrators to report and pay excise taxes due for failures under sections 4980B, 4980D, 4980E, and 4980G. The information results

from the requirement from TD 9457 to file a return for the payment of the excise taxes under section 4980B, 4980D, 4980E, and 4980G of the code.

*Form:* 8928.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 100.

*Frequency of Response:* On occasion.

*Estimated Total Number of Annual Responses:* 100.

*Estimated Time per Response:* 23.48 hours per response.

*Estimated Total Annual Burden Hours:* 2,348.

*Title:* TD 9544 (REG–112805–10)—Branded Prescription Drugs.

*OMB Control Number:* 1545–2209.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111–148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111–152 (124 Stat. 1029 (2010)) imposes an annual fee on manufacturers and importers of branded prescription drugs that have gross receipts of over $5 million from the sales of these drugs to certain government programs (covered entity/covered entities). The previously approved final regulations supersede temporary regulations and describe how the IRS will administer the branded prescription drug fee. Section 51.7T(b) of the temporary regulations provides that the IRS will send each covered entity notification of its preliminary fee calculation by May 15 of the fee year. If a covered entity chooses to dispute the IRS' preliminary fee calculation, the covered entity must follow the procedures for submitting an error report that are established in § 51.8T.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 45.

*Frequency of Response:* On occasion.

*Estimated Total Number of Annual Responses:* 45.

*Estimated Time per Response:* 40 hours per response.

*Estimated Total Annual Burden Hours:* 1,800.

*Title:* Form 8952—Application for Voluntary Classification Settlement Program.

*OMB Control Number:* 1545–2215.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Form 8952 was created by the IRS in conjunction with a new program developed to permit taxpayers to voluntarily reclassify workers as employees for federal employment tax purposes and obtain similar relief to that obtained in the current Classification Settlement Program. To participate in the program, taxpayers must meet certain eligibility requirements, apply to participate in VCSP, and enter into closing agreements with the IRS.

*Form:* 8952.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 1,700.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 1,700.

*Estimated Time per Response:* 9.85 hours per response.

*Estimated Total Annual Burden Hours:* 16,745.

*Title:* Form 1098–MA—Mortgage Assistance Payments.

*OMB Control Number:* 1545–2221.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* This form is a statement reported to the IRS and to taxpayers. It will be filed and furnished by State Housing Finance Agencies (HFAs) and the Department of Housing and Urban Development (HUD) to report the total amounts of mortgage assistance payments and homeowner mortgage payments made to mortgage servicers. The requirement for the statement are authorized by Notice 2011–14, supported by Public Law 111–203, sec. 1496, and Public Law 110–343, Division A, sec. 109.

*Form:* 1098–MA.

*Affected Public:* State, Local, and Tribal Governments.

*Estimated Number of Respondents:* 52.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 60,000.

*Estimated Time per Response:* 2.84 hours per response.

*Estimated Total Annual Burden Hours:* 170,400.

**Authority:** 44 U.S.C. 3501 *et seq.*

Dated: October 25, 2018.

**Spencer W. Clark,**

*Treasury PRA Clearance Officer.*

[FR Doc. 2018–23644 Filed 10–29–18; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF THE TREASURY

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Fiscal Service Information Collection Requests

**AGENCY:** Departmental Offices, U.S. Department of the Treasury.

**ACTION:** Notice.

**SUMMARY:** The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

**DATES:** Comments should be received on or before November 29, 2018 to be assured of consideration.

**ADDRESSES:** Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW, Suite 8100, Washington, DC 20220, or email at *PRA@treasury.gov.*

**FOR FURTHER INFORMATION CONTACT:** Copies of the submissions may be obtained from Jennifer Quintana by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov.*

**SUPPLEMENTARY INFORMATION:**

**Bureau of the Fiscal Service (FS)**

*1. Title:* Annual Letters—Certificate of Authority (A) and Admitted Reinsurer (B).

*OMB Control Number:* 1530–0014.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Annual letters sent to insurance companies providing surety bonds to protect the U.S. or companies providing reinsurance to the U.S. Information needed for renewal of certified companies and their underwriting limitations, and of admitted reinsurers.

*Form:* Annual Letter A, Annual Letter B.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 341.

*Frequency of Response:* Annually.

*Estimated Total Number of Annual Responses:* 341.

*Estimated Time per Response:* 18.75 hours.

*Estimated Total Annual Burden Hours:* 6,394.

*2. Title:* Request for Payment of Federal Benefit by Check and EFT Waiver Form.

*OMB Control Number:* 1530–0019.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* 31 CFR part 208 requires that all Federal non-tax payments be made by electronic funds transfer (EFT). This form is used to collect information from individuals requesting a waiver from the EFT requirement because of a mental impairment and/or who live in a remote geographic location that does not support the use of EFT. These individuals may continue to receive payment by check. However, 31 CFR part 208 requires individuals requesting one of these waiver conditions to submit a written justification.

*Form:* FS Form 1201W, FS Form 1201W (SP), FS Form 1201W–DFAS.

*Affected Public:* Individuals and households.

*Estimated Number of Respondents:* 3,250.

*Frequency of Response:* Once.

*Estimated Total Number of Annual Responses:* 3,250.

*Estimated Time per Response:* 20 minutes.

*Estimated Total Annual Burden Hours:* 1,083.

*3. Title:* Claim for Lost, Stolen or Destroyed U.S. Savings Bonds and Supplemental Statement for U.S. Securities.

*OMB Control Number:* 1530–0021.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* The information is necessary to apply for relief on account of the loss, theft, or destruction of United States Savings Bonds or the non-receipt of United States Securities.

*Form:* FS Form 1048, FS Form 2243.

*Affected Public:* Individuals and households.

*Estimated Number of Respondents:* 72,000.

*Frequency of Response:* On occasion.

*Estimated Total Number of Annual Responses:* 72,000.

*Estimated Time per Response:* 17 minutes.

*Estimated Total Annual Burden Hours:* 20,352.

*4. Title:* Request by Fiduciary for Reissue of United States Savings Bonds.

*OMB Control Number:* 1530–0035.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* One or more fiduciaries (individual or corporate) must use this form to establish entitlement and request distribution of United States Treasury Securities and/or related payments to the person lawfully entitled due to termination of a trust, distribution of an estate, attainment of majority, restoration to competency, or other reason.

*Form:* FS Form 1455.

*Affected Public:* Individuals and households.

*Estimated Number of Respondents:* 17,700.

*Frequency of Response:* On occasion.

*Estimated Total Number of Annual Responses:* 17,700.

*Estimated Time per Response:* 30 minutes.

*Estimated Total Annual Burden Hours:* 8,850.

**Authority:** 44 U.S.C. 3501 et seq.

Dated: October 25, 2018.

**Spencer W. Clark,**

*Treasury PRA Clearance Officer.*

[FR Doc. 2018–23646 Filed 10–29–18; 8:45 am]

BILLING CODE 4810–AS–P

## DEPARTMENT OF THE TREASURY

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Financial Crimes Enforcement Network Information Collection Requests

**AGENCY:** Departmental Offices, U.S. Department of the Treasury.

**ACTION:** Notice.

**SUMMARY:** The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

**DATES:** Comments should be received on or before November 29, 2018 to be assured of consideration.

**ADDRESSES:** Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW, Suite 8100, Washington, DC 20220, or email at *PRA@treasury.gov.*

**FOR FURTHER INFORMATION CONTACT:** Copies of the submissions may be obtained from Jennifer Quintana by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov.*

**SUPPLEMENTARY INFORMATION:**

### Financial Crimes Enforcement Network (FinCEN)

*1. Title:* Suspicious Activity Report by Securities and Futures Industries.

*OMB Control Number:* 1506–0019.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Treasury requires certain securities broker-dealers, futures commission merchants and introducing brokers in commodities to file suspicious activity reports. This renewal pertains to OMB approval of the information collection requirement per se imposed upon brokers or dealers in securities and futures commission merchants and introducing brokers in commodities. OMB approval of the allocated burden hours associated with these requirements (31 CFR 1023.320 and 1026.320), stemming from the submission and record maintenance of the BSARs themselves, is reflected in the burden for the BSAR as approved under OMB Control No. 1506–0065. This splitting in the coverage of the OMB numbers is a result of FinCEN's streamlining of SAR reporting into one a single, unified format. Although the means of reporting was consolidated into a single reporting format covering multiple industry sectors under OMB Control No. 1506–0065, the reporting requirements themselves are still contained in separate rules covered by various OMB control numbers. Consequently, the burden listed in this renewal under control number 1506–0019 is estimated at one response and one hour in order to avoid double-counting the same burdens that have already been included in the estimate under control number 1506–0065.

*Form:* FinCEN Form 111.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 1.

*Frequency of Response:* On Occasion.

*Estimated Total Number of Annual Responses:* 1.

*Estimated Time per Response:* 1 hour.

*Estimated Total Annual Burden Hours:* 1 hour.

*2. Title:* Anti-Money Laundering programs for money services business, mutual funds, operators of credit card systems, and Providers of Prepaid Access.

*OMB Control Number:* 1506–0020.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Money services businesses, mutual funds, and operators of credit card systems, and providers of prepaid access are required to develop and implement written anti-money laundering program. A copy of the program must be maintained for five years. See 31 CFR 103.125, 103.130, and 103.135.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 327,106.

*Frequency of Response:* On Occasion.

*Estimated Total Number of Annual Responses:* 2,910,406.

*Estimated Time per Response:* 9 minutes.

*Estimated Total Annual Burden Hours:* 413,216.

*3. Title:* Correspondent Accounts for Foreign Shell Banks; Record keeping and Termination of Correspondent Accounts.

*OMB Control Number:* 1506–0043.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* These rules prohibit domestic financial institutions from maintaining correspondent accounts with foreign shell banks and require such institutions to maintain records of the owners, and agents, for service of legal process of foreign banks.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 2,000.

*Frequency of Response:* On Occasion.

*Estimated Total Number of Annual Responses:* 27,000.

*Estimated Time per Response:* 11.33 hours.

*Estimated Total Annual Burden Hours:* 306,000.

**Authority:** 44 U.S.C. 3501 et seq.

Dated: October 25, 2018.

**Spencer W. Clark,**

*Treasury PRA Clearance Officer.*

[FR Doc. 2018–23645 Filed 10–29–18; 8:45 am]

BILLING CODE 4810–02–P

## DEPARTMENT OF THE TREASURY

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Departmental Offices Information Collection Requests

**AGENCY:** Departmental Offices, U.S. Department of the Treasury.

**ACTION:** Notice.

**SUMMARY:** The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

**DATES:** Comments should be received on or before November 29, 2018 to be assured of consideration.

**ADDRESSES:** Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW, Suite 8100, Washington, DC 20220, or email at *PRA@treasury.gov.*

**FOR FURTHER INFORMATION CONTACT:** Copies of the submissions may be obtained from Jennifer Quintana by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov.*

**SUPPLEMENTARY INFORMATION:**

### Departmental Offices (DO)

*1. Title:* Solicitation of Proposal Information for Award of Public Contracts.

*OMB Control Number:* 1505–0081.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* Information requested of offerors is specific to each procurement solicitation, and is required for Treasury to properly evaluate the capabilities and experience of potential contractors who desire to provide the supplies or services to be acquired. Evaluation will be used to determine which proposal most benefit the Government.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 23,781.

*Frequency of Response:* On occasion.

*Estimated Total Number of Annual Responses:* 23,781.

*Estimated Time per Response:* 9 hours.

*Estimated Total Annual Burden Hours:* 214,029.

*2. Title:* Treasury International Capital (TIC) Form D: Report of Holdings of, and Transactions in, Financial Derivatives Contracts with Foreign Residents.

*OMB Control Number:* 1505–0199.

*Type of Review:* Revision of a currently approved collection.

*Description:* Form D is required by law and is designed to collect timely information on International portfolio capital movements, including U.S. residents' holdings of, and transactions in, financial derivatives contracts with foreign residents. The information is used in the computation of the U.S. balance of payments accounts and international investments position, as well as in the formulation of U.S. International financial and monetary policies.

*Form:* TIC Form D.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 35.

*Frequency of Response:* Quarterly.

*Estimated Total Number of Annual Responses:* 140.

*Estimated Time per Response:* 30 hours.

*Estimated Total Annual Burden Hours:* 4,200.

*3. Title:* Determinations Regarding Certain Nonbank Financial Companies.

*OMB Control Number:* 1505–0244.

*Type of Review:* Extension without change of a currently approved collection.

*Description:* The information collected in § 1310.20 from state regulatory agencies will be used generally by FSOC to carry out its duties under Title I of the Dodd-Frank Act. The collections of information in §§ 1310.21 and 1310.22 provide an opportunity to request a hearing or submit written materials to the Council concerning whether, in the company's view, material financial distress at the company, or the nature, scope, size, scale, concentration, interconnectedness, or mix of the activities of the company, could pose a threat to the financial stability of the United States.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Number of Respondents:* 1.

*Frequency of Response:* On occasion.

*Estimated Total Number of Annual Responses:* 1.

*Estimated Time per Response:* 20 hours.

*Estimated Total Annual Burden Hours:* 20.

**Authority:** 44 U.S.C. 3501 et seq.

Dated: October 24, 2018.

**Spencer W. Clark,**

*Treasury PRA Clearance Officer.*

[FR Doc. 2018–23610 Filed 10–29–18; 8:45 am]

BILLING CODE 4810–25–P

## DEPARTMENT OF VETERANS AFFAIRS

### Annual Pay Ranges for Physicians, Dentists, and Podiatrists of the Veterans Health Administration (VHA)

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Notice; correction.

**SUMMARY:** The Department of Veterans Affairs (VA) is correcting a Notice that published in the **Federal Register** on September 12, 2018 which provides information that podiatrists be paid from the Veterans Health Administration (VHA) physician and dentist pay system.

**DATES:** Annual pay ranges are applicable November 25, 2018.

**FOR FURTHER INFORMATION CONTACT:** Farine Cohen, Program Analyst, Policy and Programs, VHA Workforce Management and Consulting Office (10A2A), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–7179. This is not a toll-free number.

**SUPPLEMENTARY INFORMATION:** On September 12, 2018, at 83 FR 46258, VA published a Notice that provides information and gives notices of annual pay ranges for VHA podiatrists as prescribed by the Secretary for Department-wide applicability. The pay table placement and annual salary rates of podiatrists is intended to enhance the flexibility of the Department to recruit, develop, and retain the most highly-qualified podiatrists to serve our Nation's Veterans and maintain a standard of excellence in the VA health care system.

### Correction

In FR Doc. 20018–19847, appearing on page 46259 in the **Federal Register** of 83 FR 46258, the following correction is made:

1. On page 46259, in the Pay Table 1—Clinical Specialty, the minimum TIER 1 dollar amount should be corrected to read as $103,395 vs. $100,967.

Dated: October 24, 2018.

**Jeffrey M. Martin,**

*Assistant Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.*

[FR Doc. 2018–23670 Filed 10–29–18; 8:45 am]

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