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FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

5 CFR Part 1650

Section 1650.32(b) is amended by revising the introductory text and paragraph (b) introductory text and paragraph (b) introductory text as follows:

Hardship Withdrawals for Expenses Related to Natural Disasters

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Final rule.

SUMMARY: The Federal Retirement Thrift Investment Board ("FRTIB") is amending its regulations to allow participants to take hardship withdrawals for expenses related to natural disasters.

DATES: This rule is effective October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Jessica Bradford, (202) 864-8699.

SUPPLEMENTARY INFORMATION: The FRTIB administers the Thrift Savings Plan (TSP), which was established by the Federal Employees’ Retirement System Act of 1986 (FERSA), Public Law 99-335, 100 Stat. 514. The TSP provisions of FERSA are codified, as amended, largely at 5 U.S.C. 8351 and 8401–79. The TSP is a tax-deferred retirement savings plan for federal civilian employees and members of the uniformed services. The TSP is similar to cash or deferred arrangements established for private-sector employees under section 401(k) of the Internal Revenue Code (26 U.S.C. 401(k)).

On February 14, 2020, the FRTIB published a proposed rule with request for comments in the Federal Register (85 FR 8482), and for reasons described below, is publishing the proposed rule as final without change.

The proposed rule amended 5 CFR 1650.32(b) to add to its list of authorized hardship expenses, the expenses and losses (including loss of income) resulting from a natural disaster as declared by the Federal Emergency Management Agency ("FEMA") and designated for individual assistance in order to allow TSP participants to make financial hardship withdrawals for such natural disaster expenses and losses. The FRTIB received six comments. Three of the comments expressed approval of the proposed regulation and recommended no changes.

One commenter encouraged the FRTIB to expand other parts of the FRTIB’s hardship withdrawal program, such as permitting withdrawal of the full balance subject to certain minimum account values and increasing the current six-month wait period to 12 months between financial hardship requests. The proposed regulation sought comments exclusively on adding natural disaster expenses and losses to the TSP’s hardship withdrawal conditions, and, therefore, the FRTIB cannot further expand the withdrawal program beyond that purpose in the final regulation.

Another commenter asked whether a TSP participant may make a withdrawal under the natural disaster condition for expenses related to a family member’s death resulting from the natural disaster. The final regulation does not limit the expense to a specific type, such as property expenses or medical expenses. Rather, the regulation requires that the expense be “incurred by the participant on account of a disaster declared by the [FEMA]” and that the participant’s principal residence or principal place of employment at the time of the disaster be located in an area designated by the FEMA for individual assistance with respect to the disaster. Any expense that meets these requirements would be eligible for a hardship withdrawal.

For example, provided the participant’s principal residence at the time of the disaster was located in an area declared by the FEMA for individual assistance, if a TSP participant’s dependent or spouse died as a result of a natural disaster, and, as a result, the participant incurred funeral expenses relating to that dependent or spouse, then the expense would be eligible for a hardship withdrawal under 1650.32(b)(5).

Another commenter urged the FRTIB to treat pandemics such as COVID–19 as natural disasters under this regulation. Guided by legislation, the FRTIB has implemented other withdrawal options designed to afford relief for adverse financial consequences due to COVID–19. For more information about those options, please visit www.tsp.gov/covid-19/.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation will affect Federal employees, members of the uniformed services who participate in the Thrift Savings Plan, and their beneficiaries. The TSP is a Federal defined contribution retirement savings plan created FERSA and is administered by the Agency.

Paperwork Reduction Act

I certify that these regulations do not require additional reporting under the Paperwork Reduction Act.

Unfunded Mandates Reform Act of 1995

Pursuant to the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 602, 632, 653, 1501–1571, the effects of this regulation on state, local, and tribal governments and the private sector have been assessed. This regulation will not compel the expenditure in any one year of $100 million or more by state, local, and tribal governments, in the aggregate, or by the private sector. Therefore, a statement under 1532 is not required.

List of Subjects in 5 CFR Part 1650


Ravindra Deo,
Executive Director, Federal Retirement Thrift Investment Board.

For the reasons stated in the preamble, the FRTIB amends 5 CFR chapter VI as follows:

PART 1650—METHODS OF WITHDRAWING FUNDS FROM THE THRIFT SAVINGS PLAN

1. The authority citation for part 1650 continues to read as follows:

Authority: 5 U.S.C. 8351, 8432d, 8433, 8434, 8435, 8474(b)(5) and 8474(c)(1).

2. Amend §1650.32 by revising paragraph (b) introductory text and adding paragraph (b)(5) to read as follows:

§1650.32 Financial hardship withdrawals.

(b) To be eligible for a financial hardship withdrawal, a participant must...
have a financial need that results from at least one of the following five conditions:

* * * * *

(5) The participant has incurred expenses and losses (including loss of income) on account of a disaster declared by the Federal Emergency Management Agency (FEMA) under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, Public Law 100–707, provided that the participant’s principal residence or principal place of employment at the time of the disaster was located in an area designated by the FEMA for individual assistance with respect to the disaster.

* * * * *

[FR Doc. 2020–20762 Filed 9–30–20; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 301 and 319

[Docket No. APHIS–2016–0065]

RIN 0579–AE41

Deregulation of Pine Shoot Beetle

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are adopting as a final rule, without change, a proposal to amend our regulations to remove the domestic pine shoot beetle (PSB) quarantine and to eliminate the restrictions that apply to the importation of PSB host material from Canada. We have determined through analysis that the regulatory program is ineffective in slowing the spread of the pest and reducing damage, which has also been found to be minimal. This action will provide flexibility to the States as they manage PSB. It will also allow Federal resources spent on this program to be allocated elsewhere, and it will remove PSB-related interstate movement and importation restrictions on PSB-regulated articles.


FOR FURTHER INFORMATION CONTACT: Mr. Bill Wesela, National Policy Manager, PPQ, APHIS, 4700 River Road Unit 22, Riverdale, MD 20737–1236; (301) 851–2229; William.D.Wesela@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Pine shoot beetle (PSB, *Tomicus piniperda*) is a pest of pines in Africa, Asia, and Europe. Biologically, this species of bark beetle is considered to be a secondary pest of pine and not able to successfully attack healthy trees. PSB colonizes fresh timber and drying pine trees in early spring. Larvae feed within the galleries under the bark and emerge as adults from shoots after a hard frost. They then move to the base of the tree to reproduce.

PSB was first detected in the United States in a Christmas tree farm in Ohio in 1992. Based on an initial finding of potentially high economic losses in 1992, the Animal and Plant Health Inspection Service (APHIS) implemented a program to regulate at-risk pine commodities, including logs with bark, Christmas trees, and nursery stock in known infested areas.

The regulations in “Subpart G—Pine Shoot Beetle” (7 CFR 301.50 through 301.50–10, referred to below as the regulations) had restricted interstate movement of certain regulated articles (generally wood and wood products) from quarantined areas in order to prevent spread of PSB into non-infested areas of the United States.

Since APHIS initiated the PSB program in 1992, PSB has advanced at a slow rate, and damage to native pines, plantations, and the nursery trade had been minimal. In 2015, APHIS met with the National Plant Board, which represents plant protection divisions of State departments of agriculture, to reassess the relevance and need for the PSB regulatory program. This was due to the slow advancement and minimal damage of PSB and the limited resources allotted to the PSB program.

We prepared an analysis of regulatory options, “Pine Shoot Beetle, *Tomicus piniperda* (Linnaeus): Analysis of Regulatory Options” (February 2015), referred to below as the February 2015 analysis, to evaluate the PSB program in terms of its effectiveness and efficiency in slowing the spread and reducing losses. The analysis looked at timber losses and estimated compliance costs that Christmas tree growers incur in quarantined areas. Given the little PSB damage observed and the amount of resources allocated to manage the minimal risks associated with PSB, we determined it appropriate to deregulate PSB. While the possibility exists that PSB may spread at a faster rate and enter Southern States sooner in the absence of Federal regulations, we anticipated that PSB would be controlled within managed timber stands in the South.

Accordingly, in a proposed rule published in the Federal Register on September 23, 2019 (84 FR 49680–49681, Docket No. APHIS–2016–0065), we proposed to remove the domestic PSB quarantine and the restrictions that apply to importation of PSB host material from Canada. We solicited comments concerning our proposal for 60 days ending November 22, 2019.

We received 10 comments by the close of the comment period. They were from private citizens and one State forestry.

Of the commenters, six opposed deregulation and the proposed rule. The remaining four commenters urged caution in deregulation, raising concerns similar to those opposed. One of these latter commenters recognized the positive economic impacts of deregulation on the industry, yet still pressed PSB concerns.

Comments fell into seven distinct categories: Concern for natural forestland protection; support for the current regulations out of perception that they work; concern for the pine industry and economy; concerns for future impacts of PSB; concerns regarding reallocation of regulatory funding; requests for delay or phase-in of deregulation with monitoring and assessment before action; and requests that science direct regulation of PSB.

We have characterized the comments received below according to these topics.

Natural Forestland Protection

A majority of the 10 commenters wanted continued regulation to prevent PSB from infecting pine tree losses on “natural” and wild forests, as well as private lands. Some addressed vulnerability of pine to PSB impact on tree trunks. Two commenters expressed concern over what they considered the growth-stunting potential of PSB in harming shoots of pine trees. The commenters stated that this is significant in that shoots are means of photosynthesis, energy conversion, and thus growth, which could impact yields and incomes.

We acknowledge that PSB can inflict damage on pine trees and that it is a plant pest. Our February 2015 analysis did not state otherwise. The analysis also reviewed studies that showed adult PSB prefers to colonize freshly-cut stumps and slash. Nonetheless, the analysis concluded that pine-stand owners and the industry can and do...
cover trees, remove downed trees, and treat pine for PSB in a manner that is more cost-effective than ongoing Federal regulation. As detailed in our February 2015 analysis, estimation and comparison of pine timber damage along the leading edge of PSB distribution, both with and without a “slow-the-spread” regulatory effort, indicates regulatory cost will exceed any avoided losses. Compliance costs projected long into the future outweigh any possible benefits to pine producers. There is also no evidence that in attacking the shoots of pine, this beetle has broadly retarded maturity across pine timber stands and negatively impacted growth, vitality, and yields. While PSB does inflict damage on pine shoots, and especially on certain pine varieties, initial fears that the pest would devastate pine forests and their industry never came true.

Regulatory Efficacy

Several commenters either presumed regulation is preventing spread within or from quarantined areas, or mistakenly believed PSB numbers are declining under regulation.

We are making no changes in response to these comments. Our February 2015 analysis demonstrates that despite regulatory efforts that have spanned 28 years, PSB has spread from a single Christmas tree farm in one State (Ohio) in 1992 to 20 States. Fourteen States are presently under Federal quarantine in their entirety.

While regulation did not keep PSB from spreading, we still find PSB damage to native pines and pine plantations, as well as costs to the nursery trade in this broad area, to be minimal. Our February 2015 analysis for deregulation indicated the pest is now considered minor and readily within State and local ability to manage.

Pine Industry and Economy

Four of the commenters expressed concern for the pine economy as a result of PSB deregulation. One commenter questioned especially the impact on the Christmas tree industry from possible increased cosmetic damage on certain species of pine.

We find no evidence of such negative economic impacts to justify changing deregulation as proposed. Our February 2015 analysis demonstrated that despite PSB’s spread, damage has been minor. Additionally, as experience now long indicates, pine producers can and do take steps to control the disease irrespective of Federal regulation. States may also impose and enforce their own quarantines in the absence of Federal regulation.

Our analysis found nothing to suggest PSB is singularly destructive, nor did it find evidence of high level destructive or economic impact. So many more pests of far greater impact have prompted regulatory efforts since PSB’s first detection 28 years ago.

Future PSB Impacts

Half of the 10 commenters on PSB deregulation voiced concern for a range of possible negative future impacts. Two commenters suggested deregulation will result in high tree mortality in higher density forests (from higher stress on weakened, dying trees, even on healthy trees).

One commenter addressed deregulatory impact on pine tree forests in the Southeastern States. The commenter feared PSB spread following deregulation will have a negative economic impact there, where the warmer climate will allow two incubation periods per year, instead of one; where storms are more frequent and violent, downing trees to create PSB brooding conditions; and where pine stands are large and dense.

Two other commenters feared PSB spread to pinewood forests in the Western States. One acknowledged positive impacts on timber producers once they are freed from time-consuming, expensive regulatory compliance. However, the commenter feared possible negative impact on Western pine forests and urged “Early Detection and Rapid Response” funding.

We understand these concerns, but we are making no changes to PSB deregulation. The commenters concerned about establishment in high density forests and Southeastern pine tree forests incorrectly assume the PSB damage has been minimal to date because PSB has become established in areas that are not densely populated with pine or are not otherwise conducive to PSB establishment. However, thus far, even in pine-dense regions where PSB has become endemic, PSB damage to native pines, plantations, and nursery trade has been minimal. Estimated compliance costs for Christmas tree growers have far outweighed timber losses. Moreover, Federal regulatory requirements for PSB have largely consisted of certification, inspection, and permitting. These activities control the artificial spread of PSB but are not aimed at controlling it within an affected region. It is the pine industry’s own practices that control PSB within such an area. Pine producers apply cover spray on trees, destroy cell piles, remove stumps, and use trap logs to attract broods into piles that they then destroy.

With regard to westward movement, the nation’s Great Plains region (more than 1.12 million square miles of prairie, steppe and grasslands, with negligible quantities of pine), has provided and will continue to provide a natural barrier to PSB spread to the West. Western States are also free to fashion their own PSB regulation in the absence of Federal regulation and to promote the industry practices that pine producers already effectively employ in the Northeast and Central States.

Funding Concerns

Four of 10 commenters either asked that regulatory funds be preserved to protect pine production and the natural environment from PSB’s harm, or sought evidence that funding reallocation will be more beneficial. Commenters said regulation is worthwhile and should be prioritized. They stated costs to the public are worth controlling PSB populations.

Our February 2015 analysis found that costs to producers in complying with quarantines, paperwork, and recordkeeping to manage agreements, data collection, and review for reporting all outweigh any benefits. Both assessments that we conducted call for new strategies, which the States and producers may undertake from the success of localized approaches.

The pine industry is largely composed of small businesses and producers who can better safeguard pine resources, products, and their economy if they do not have to devote time and resources to meeting permit, certificate, and form compliance costs under quarantine. We have determined that removing the PSB quarantine will provide flexibility to the States as they and the pine community manage PSB in all regions.

Funding used for PSB, which has become less and less significant even as the pest spread despite regulation, will be reallocated to address worsening Japanese beetle problems nationally. APHIS’ Japanese beetle regulations control the movement of aircraft from regulated areas to southern and western areas where Japanese beetle is not located, but could become established, if introduced, and cause economic losses. However, increased package and product shipping across the United States has created another pathway for Japanese beetle movement into Southern and Western States. APHIS is working with a National Plant Board harmonization initiative to address this problem, and the reprogrammed funds will be used to help address this issue.
by increasing inspection and treatment for Japanese beetle.

Delay or Phase-in of Deregulation

Four of the comments counseled more cautious approaches to regulatory change and PSB control. Three sought delay or a phase-in of deregulation, with monitoring of impact on PSB losses and harm before entirely deregulating. One commenter suggested allocating funds for damage control at conclusion of a phase-out of regulations.

While we recognize the value of cautionary approaches protective of natural resources, we find no basis to continue regulation. Deregulating PSB is based on 28 years of experience showing PSB regulation has not deterred spread of the pest. Yet neither widespread destruction nor significant economic loss resulted. Our February 2015 analysis demonstrated that funding is being ineffectively used to deter PSB. Projected well into the future, the cost of regulation outweighs any avoided negative losses. It will cost producers more in compliance than they realize in any economic benefit. Prolonging this cost to largely small producers a few more years is neither justifiable, nor defensible. We must invite new strategies other than Federal regulation, recognizing local pine industry practices have been most effective at minimizing PSB damage. Moreover, continued regulation precludes our reprogramming the funds for PSB to Japanese beetle control, which, as discussed above, is needed to address an emerging pathway for the spread of Japanese beetle.

We will however, continue to support the Nature Conservancy’s “Don’t Move Firewood” campaign, which is credited with a broad education effort to enlist the public in curbing the spread of PSB and other pests of firewood. That effort will continue even after PSB deregulation. States are also free to attempt their own PSB regulation, and one State has already stated that it will. As the pine industry, processing, and trade have demonstrated where PSB spread across the Northern States regions, their treatments in the field and handling of harvested material, diminish PSB impact and loss. States and the industry need to help shift PSB strategies now away from national regulation as present funding addresses pressing Japanese beetle expansion.

Scientific Basis for Deregulation

Two commenters asserted that official studies have not been conducted to justify the cost of regulation. They said the public needs scientific studies conducted to determine current PSB populations and losses under regulation. They said careful analysis based on scientific findings could then form a basis for addressing permanent changes that will result from deregulation.

We acknowledge need for more research to address many domestic pests. However, APHIS Plant Protection and Quarantine, Center for Plant Health Science and Technology (now named Science and Technology), and the Plant Epidemiology and Risk Laboratory did conduct the February 2015 analysis of regulatory options for this deregulation. Our analysis drew on 46 citations to assess the physical and economic impact of PSB and to project possible impact of deregulation on other regions. We also consulted with the National Plant Board.

Therefore, for the reasons given, we are adopting the proposed rule as a final rule, without change.

Executive Orders 12866 and 13771 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the Regulations.gov website (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT or on the Regulations.gov website.

APHIS is amending the pine shoot beetle (PSB) regulations to remove all Federal PSB quarantine areas and all Federal regulatory requirements related to the import and movement of PSB and associated host material. Although PSB is now found throughout the Northeast and North Central United States, damage to native pines and pine plantations and costs to the nursery trade have been minimal. It is now considered a minor pest that can be readily controlled locally.

Establishments that may be affected are ones that grow, handle, or move regulated pine (Pinus spp.) products: bark products, Christmas trees, logs and firewood with bark attached, lumber with bark attached, stumps, raw pine materials for pine wreaths and garlands, and stumps. Potentially affected establishments include timber tract operations, forest product operations, logging companies, forest tree nurseries, and Christmas tree operations. The majority of these establishments are small entities. Regulated articles from PSB quarantined areas may be moved interstate if accompanied by a certificate or limit permit. Under the rule, affected establishments in the Federal PSB quarantine areas will no longer incur costs of complying with certification or permitting requirements. Businesses that operate under Federal PSB compliance agreements, of which there are about 100, are the establishments most likely to be shipping regulated articles interstate. With this rule, they will forgo the paperwork and recordkeeping costs of compliance. For affected entities that do not operate under compliance agreement, the costs of inspection are incurred by APHIS, unless they occur outside of normal working hours.

We estimate that a establishment with an active PSB compliance agreement spends 4 to 8 hours annually collecting data and ensuring adherence to the agreement. Based on this estimate, total annual cost savings from PSB deregulation for establishments with active compliance agreements could be between $12,480 and $59,600. In accordance with guidance on complying with Executive Order 13771, the single primary estimate of the cost savings of this rule is about $36,000, the mid-point estimate annualized in perpetuity using a 7 percent discount rate.

Besides yielding cost savings for entities with compliance agreements, sales volumes for at least some businesses could increase if their sales are constrained because of the Federal quarantine. Restrictions ultimately borne will depend on whether States decide to enforce their own PSB quarantine programs.

Internationally, the deregulation is unlikely to affect exports of pine products. In 2018, the United States exported about $240 million of pine logs and timber, of which $75 million were Christmas trees and other plants used for ornamental purposes. However, these exports are required to be treated otherwise for pine wood nematode under a systems approach and accompanied by a phytosanitary certificate as proof that the trees meet the importing countries’ requirements, as documented in International Standards for Phytosanitary Measures No. 12.

Longer term, any delay in PSB spread attributable to the quarantine
regulations will end with promulgation of the rule. It is possible that without the PSB program, human-assisted dispersal of PSB would have occurred more rapidly and extended to areas that are not yet infested; the impact of the rule on pine populations in natural and urban environments within and outside currently quarantined areas—and on businesses that grow, use, or process pine products—is indeterminate. Still, PSB has caused negligible direct damage despite having spread widely, and compliance costs that will no longer be incurred under the rule are minimal.

Based on this information, the APHIS Administrator has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

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

Executive Order 12988

This final rule has been reviewed under Executive Order 12988. Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Congressional Review Act

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

Paperwork Reduction Act

This final rule contains no reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

List of Subjects

7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we are amending 7 CFR parts 301 and 319 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for part 301 continues to read as follows:


Section 301.75–15 issued under Sec. 204, Title II, Public Law 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 issued under Sec. 203, Title II, Public Law 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

Subpart G [Removed and Reserved]

2. Subpart G, consisting of §§ 301.50 through 301.50–10, is removed and reserved.

PART 319—FOREIGN QUARANTINE NOTICES

3. The authority citation for part 319 continues to read as follows:


§ 319.40–3 [Amended]

4. Section 319.40–3 is amended by:

a. In paragraph (a)(1)(i)(A), removing "", and"; and adding "" and" in its place;

b. Removing paragraph (a)(1)(i)(B); and


§ 319.40–5 [Amended]

5. Section 319.40–5 is amended by removing and reserving paragraph (m).

Done in Washington, DC, this 24th day of September 2020.

Michael Watson,
Acting Administrator, Animal and Plant Health Inspection Service.
[FR Doc. 2020–21800 Filed 9–30–20; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 32

[Docket ID OCC–2018–0041]

RIN 1557–AE21

Supplemental Lending Limits Program: Technical Correction

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Correcting amendment.

SUMMARY: On July 14, 2020, the Office of the Comptroller of the Currency (OCC) published in the Federal Register a final rule that, among other revisions, made technical changes to the OCC’s supplemental lending limits rule. This correcting amendment makes a correction to those regulations by reinstating two paragraphs to the lending limits rules that were inadvertently deleted.

DATES: This rule is effective on October 1, 2020.


SUPPLEMENTARY INFORMATION:

I. Background and Description of Correcting Amendment

On July 14, 2020, the OCC published in the Federal Register a final rule that made technical changes to the OCC’s supplemental lending limits rules, among other revisions. Specifically, the terms “small business loans” and “small farm loans or extensions of credit” were replaced with the terms “loans to small businesses” and “loans or extensions of credit to small farms,” respectively, to conform with the Call Report instructions. These technical changes were made to the supplemental lending limits rules in §§ 32.7(a)(1), 32.7(a)(2), and 32.7(d). However, §§ 32.7(a)(4) and (a)(5) were inadvertently deleted by the final rule. This correcting amendment reinstates §§ 32.7(a)(4) and (a)(5).

II. Administrative Law Matters

A. Administrative Procedure Act

The OCC is issuing this correcting amendment without prior notice and the opportunity for public comment and the delayed effective date ordinarily prescribed by the Administrative Procedure Act (APA). Pursuant to section 553(b)(B) of the APA, general notice and the opportunity for public comment are not required with respect to a rulemaking when an “agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.”

The OCC finds that public notice and comment are unnecessary because this correcting amendment makes a technical change to correct an erroneous removal of two paragraphs in the

1 85 FR 42630.

2 5 U.S.C. 553.

supplemental lending limits rule. Therefore, there is good cause to dispense with the APA prior notice and public comment process.

The APA also requires a 30-day delayed effective date, except for: (1) Substantive rules which grant or recognize an exemption or relieve a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause. As described above, there is good cause to issue this correcting amendment without a delayed effective date. Therefore, this correcting amendment is exempt from the APA’s delayed effective date requirement.

B. Congressional Review Act

For purposes of the Congressional Review Act, the Office of Management and Budget (OMB) makes a determination as to whether a final rule constitutes a “major rule.” If a rule is deemed a “major rule” by the OMB, the Congressional Review Act generally provides that the rule may not take effect until at least 60 days following its publication.

The Congressional Review Act defines a “major rule” as any rule that the Administrator of the Office of Information and Regulatory Affairs of the OMB finds has resulted in or is likely to result in: (1) An annual effect on the economy of $100,000,000 or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

The delayed effective date required by the Congressional Review Act does not apply to “any rule which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” For the same reasons set forth above, the OCC finds that it has good cause to adopt this correcting amendment without the delayed effective date generally prescribed under the Congressional Review Act. As required by the Congressional Review Act, the OCC will submit the correcting amendment and other appropriate reports to Congress and the Government Accountability Office for review.

C. Riegle Community Development and Regulatory Improvement Act of 1994

Pursuant to section 302(a) of the Riegle Community Development and Regulatory Improvement Act of 1994 (RCDRIA), in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions (IDIs), each Federal banking agency must consider, consistent with the principle of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations. In addition, section 302(b) of RCDRIA requires new regulations and amendments to regulations that impose additional reporting, disclosures, or other new requirements on IDIs generally to take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form, with certain exceptions, including for good cause.

For the reasons described above, the OCC finds good cause exists under section 302 of RCDRIA to publish this correcting amendment with an immediate effective date. As such, the correcting amendment will be effective immediately.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to consider whether the rules it proposes will have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which a general notice of proposed rulemaking was not published. Therefore, because the OCC has found good cause to dispense with notice and comment for this correcting amendment, the OCC has not prepared an economic analysis of the rule under the UMRA.

List of Subjects in 12 CFR Part 32

National banks, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, the OCC corrects 12 CFR part 32 by making the following correcting amendment:

PART 32—LENDING LIMITS

§ 32.7 Residential real estate loans, loans to small businesses, and loans or extensions of credit to small farms ("Supplemental Lending Limits Program").

(a) * * *  

(4) The total outstanding amount of a national bank’s or savings association’s loans and extensions of credit to one borrower made under § 32.3(a) and (b), together with loans and extensions of credit to the borrower made pursuant to paragraphs [a](1), (2), and (3) of this section, shall not exceed 25 percent of the bank’s or savings association’s capital and surplus.

(5) The total outstanding amount of a national bank’s or savings association’s loans and extensions of credit to all of its borrowers made pursuant to the supplemental lending limits provided in paragraphs [a](1), (2), and (3) of this section may not exceed 100 percent of

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4 5 U.S.C. 553(d).
5 5 U.S.C. 553(d)(1).
6 5 U.S.C. 801 et seq.
8 5 U.S.C. 804(2).
9 5 U.S.C. 808(2).
12 5 U.S.C. 601 et seq.
13 Under regulations issued by the Small Business Administration, a small entity includes a depository institution, bank holding company, or savings and loan holding company with total assets of $600 million or less and trust companies with total assets of $41.5 million or less.
14 2 U.S.C. 1531 et seq.
15 See 2 U.S.C. 1532(a).
the bank’s or saving association’s capital and surplus.

* * * * *

Jonathan V. Gould, Senior Deputy Comptroller and Chief Counsel.

[FR Doc. 2020–18937 Filed 9–30–20; 8:45 am]

BILLING CODE 4810–33–P

FARM CREDIT ADMINISTRATION

12 CFR Part 624

RIN 3052–AD43

Margin and Capital Requirements for Covered Swap Entities; Correction

AGENCY: Farm Credit Administration.

ACTION: Interim final rule; correction.

SUMMARY: The Farm Credit Administration is correcting a final rule that was published in the Federal Register on July 1, 2020. The Farm Credit Administration (FCA), along with the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, and the Federal Housing Finance Agency published an interim final rule amending regulations that require swap dealers, security-based swap dealers, major swap participants, and major security-based swap participants under the Agencies’ respective jurisdictions to exchange swap margin with their counterparties for swaps that are not centrally cleared (non-cleared swaps) (Swap Margin Rule). In that publication, the Regulatory Identification Number (RIN) for the FCA was incorrect. This document corrects that error.

DATES: Effective October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Richard A. Katz, Senior Counsel, Office of General Counsel, (703) 883–4020,TTY (703) 883–4056, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.

SUPPLEMENTARY INFORMATION: In FR Doc. 2020–14094, “Margin and Capital Requirements for Covered Swap Entities” that published in the Federal Register on Wednesday, July 1, 2020 at 85 FR 39464, in the second column on page 39464, correct the RIN to read 3052–AD43.

Dated: September 1, 2020.

Dale Aultman, Secretary, Farm Credit Administration Board.

[FR Doc. 2020–19712 Filed 9–30–20; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39


RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all General Electric Company (GE) GENx–1B64, –1B64/P1, –1B64/P2, –1B67, –1B67/P1, –1B70, –1B70/75/P1, –1B70/75/P2, –1B70/P1, –1B70/P2, –1B70C/P1, –1B70C/P2, –1B74/75/P1, –1B74/75/P2, –1B76/P2, and –1B76A/P2 model turbofan engines. This AD was prompted by reports of combustor case burn-through. This AD requires installation of electronic engine control (EEC) software, version B205 or later. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 5, 2020.

ADDRESSES: For service information identified in this final rule, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: 513–552–3272; email: aviation.fleetsupport@ae.ge.com; website: www.ge.com. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0443.

Examining the AD Docket

You may examine the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0443; or in person at Docket Operations between 9 a.m. and 5 p.m. Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Mehdi Lamnyi, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7743; fax: 781–238–7199; email: Mehdi.Lamnyi@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all GE GENx–1B64, –1B64/P1, –1B64/P2, –1B67, –1B67/P1, –1B70, –1B70/75/P1, –1B70/75/P2, –1B70/P1, –1B70/P2, –1B70C/P1, –1B70C/P2, –1B74/75/P1, –1B74/75/P2, –1B76/P2, and –1B76A/P2 model turbofan engines. The NPRM published in the Federal Register on May 6, 2020 (85 FR 26891). The NPRM was prompted by reports of combustor case burn-through. The NPRM proposed to require installation of EEC software, version B205 or later. The FAA is issuing this AD to address the unsafe condition on these products.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA’s response to each comment.

Request To Supersede Existing AD

American Airlines (AAL) suggested that the FAA change this AD to supersede docket number FAA–2019–0683, project identifier 2015–NE–02–AD (84 FR 63820, November 19, 2019) (“NPRM 2015–NE–02–AD”). NPRM 2015–NE–02–AD proposed removing EEC software version B195 and earlier from GENx–1B engines, along with an equivalent EEC software for GENx–2B engines to improve safeguards against ice crystal icing. EEC software version B205 incorporates all required changes that satisfy the intent of NPRM 2015–NE–02.

The FAA disagrees. The unsafe condition addressed by this AD was prompted by reports of combustor case burn-through. In contrast, the final rule to NPRM 2015–NE–02–AD, AD 2020–13–04, Amendment 39–21149 (85 FR 37000, June 19, 2020) (“AD 2020–13–04”) was prompted by power loss in ice crystal icing conditions. Although the ice crystal icing required actions of AD 2020–13–04 are achieved through the update to EEC software version B205, the unsafe conditions that prompted each AD are different, and the corrective actions are independent. Further, AD 2020–13–04 affects more GENx model turbofan engines than this AD.
Request To Add Terminating Action

AAL requested the FAA add that compliance with this AD is a terminating action to paragraphs (g) and (i) of AD 2013–24–01, Amendment 39–17675 (78 FR 70851, November 27, 2013) (“AD 2013–24–01”), similar to the terminating action in AD 2017–09–06, Amendment 39–18668 (82 FR 21111, May 5, 2017) (“2017–09–06”). AAL noted that NPRM 2015–NE–02–AD (AD 2020–13–04) indicated that it would supersede AD 2017–09–06, but did not provide a terminating action to paragraphs (g) and (i) of AD 2013–24–01, as was done in AD 2017–09–06. AAL commented that EEC software version B205 incorporated the software changes to address the unsafe ice crystal icing condition so compliance with paragraphs (g) and (i) of AD 2013–24–01 should no longer be required.

The FAA disagrees. As indicated in a comment response to NPRM 2015–NE–02–AD, the FAA disagreed with adding a terminating action in AD 2020–13–04 because the FAA’s approval of alternative methods of compliance to AD 2013–24–01 made a terminating action unnecessary in AD–2020–13–04. In this AD, the FAA finds that adding a terminating action is not justified as this AD does not address the unsafe ice crystal icing condition of AD 2020–13–04, AD 2017–09–06, and AD 2013–24–01. Therefore, no change to this AD is needed.

Request To Add Boeing Service Information

Qantas Airways Limited (Qantas) commented that GE GENx–1B Service Bulletin (SB) 73–0085 R00, dated December 23, 2019, describes procedures for installing the EEC software version B205. Qantas further noted that procedures for on-wing installation of EEC software version B205 is described in Boeing B787–81205 SB–730057–00, Issue 001, dated December 23, 2019; Boeing B787–81205 SB–730057–00, Issue 002, dated February 28, 2020; or later FAA approved revisions. The FAA interprets Qantas’ comment as a request to add Boeing B787–81205 SB–730057–00, Issue 001, dated December 23, 2019, and Issue 002, dated February 28, 2020; and later FAA approved revisions, to the Related Service Information section of this AD.

The FAA disagrees with adding the Boeing service information to this AD as Related Service Information as that service information is not necessary to satisfy the requirements of this AD. This AD requires the installation of the EEC software version B205 or later without imposing an installation method. The EEC software can be installed either at the engine-level or on-wing at the aircraft-level using FAA-approved procedures.

Related Service Information

The FAA reviewed GE GENx–1B SB 73–0085 R00, dated December 23, 2019. The SB describes procedures for installing the EEC software version B205.

Costs of Compliance

The FAA estimates that this AD affects 176 engines installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

<table>
<thead>
<tr>
<th>Action</th>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Install EEC software version B205 or later</td>
<td>1 work-hour × $85 per hour = $85</td>
<td></td>
<td>$0</td>
<td>$85</td>
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Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

(1) Is not a “significant regulatory action” under Executive Order 12866,
(2) Will not affect intrastate aviation in Alaska, and
(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):


(a) Effective Date

This AD is effective November 5, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to General Electric Company GEnx–1B64, –1B64/P1, –1B64/P2, –1B67, –1B67/P1, –1B67/P2, –1B70, –1B70/75/P1, –1B70/75/P2, –1B70/P1, –1B70/P2, –1B70C/P1, –1B70C/P2, –1B74/75/P1, –1B74/75/P2, –1B76/P2, and –1B76/A/P2 model turbofan engines.

(d) Subject


(e) Unsafe Condition

This AD was prompted by two reports of combustor case burn-through. The FAA is issuing this AD to prevent failure of the fuel nozzle. The unsafe condition, if not addressed, could result in damage to the combustor case, engine fire, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

Within 120 days after the effective date of this AD, install electronic engine control (EEC) software that is eligible for installation.

(h) Definition

For the purpose of this AD, EEC software that is eligible for installation is EEC software that is version B205 or later.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD. You may email your request to: ANE-AD-AMOC@faa.gov.

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

(j) Related Information

For more information about this AD, contact Mehdi Lamnyi, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7743; fax: 781–238–7199; email: Mehdi.Lamnyi@faa.gov.

(k) Material Incorporated by Reference

None.

Issued on September 24, 2020.

Gaetano A. Sciortino,
Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

FOR FURTHER INFORMATION CONTACT:
Kara M. Soderstrom of the Office of Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes) at (202) 317–5234 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document sets forth an amendment to the Employment Tax Regulations (26 CFR parts 31 and 35) under section 3405 of the Internal Revenue Code (Code).

1. Periodic Payments

Section 3405 provides Federal income tax withholding rules for payments of pensions, annuities, and certain other deferred income (retirement and annuity payments). Retirement and annuity payments that are subject to withholding under section 3405 include periodic payments, nonperiodic distributions, and eligible rollover distributions.

A periodic payment is defined in section 3405(e)(2) as “a designated distribution which is an annuity or similar periodic payment.” Subject to certain exceptions, a designated distribution generally is defined in section 3405(e)(1)(A) as any distribution or payment from or under an employer deferred compensation plan, an individual retirement plan (as defined in section 7701(a)(37)), or a commercial annuity. For this purpose, an employer deferred compensation plan is defined in section 3405(e)(5) as any pension, annuity, profit-sharing, or stock bonus plan or other plan deferring the receipt of compensation, and a commercial annuity is defined in section 3405(e)(6) as an annuity, endowment, or life insurance contract issued by an insurance company licensed to do business under the laws of any State. Section 35.3405–1T, Q&A a–9, provides that a periodic payment includes an annuity or similar periodic payment, whether paid by a life insurance company, a financial institution, or a plan, and that an “annuity” is a series of payments payable over a period greater than one year and taxable under section 72 as amounts received as an annuity, whether or not the payments are variable in amount.

2. Withholding on Periodic Payments

Section 3405(a) requires the payor of any periodic payment to withhold from...
the payment as if the payment were wages paid by an employer to an employee, unless an individual has elected under section 3405(a)(2) not to have withholding apply, subject to the following exceptions. First, section 3405(c)(1)(A) provides that section 3405(a) does not apply in the case of any designated distribution that is an eligible rollover distribution (as defined in section 402(f)(2)(A)). Second, section 3405(e)(12) provides that no election under section 3405(a)(2) will be treated as in effect (and the provisions of section 3405(a)(4) for determining the default rate of withholding will not apply) if a payee fails to furnish the payee’s Taxpayer Identification Number (TIN) to the payor in the manner required by the Secretary or the Secretary notifies the payor before any payment or distribution that the TIN furnished by the payee is incorrect. Third, under section 3405(e)(13), no election under section 3405(a)(2) may be made with respect to certain periodic payments to be delivered outside of the United States and its possessions.

3. Default Rate of Withholding on Periodic Payments and TCJA Amendment

Before amendment by the Tax Cuts and Jobs Act, Public Law 115–97, 131 Stat. 2054 (2017) (TCJA), section 3405(a)(4) provided that, in the case of any periodic payment with respect to which a withholding certificate is not in effect, the amount withheld from the periodic payment is “determined by treating the payee as a married individual claiming three withholding exemptions.” TCJA amended section 3405(a)(4) to eliminate the requirement that the payee be treated as a married individual claiming three withholding exemptions and to provide instead that, in the case of any periodic payment with respect to which a withholding certificate is not in effect, the amount withheld from the periodic payment will be “determined under rules prescribed by the Secretary.” However, certain provisions of § 35.3405–1T continued to reflect the rule under section 3405(a)(4) prior to amendment by TCJA.

Following enactment of TCJA, the Department of the Treasury (Treasury Department) and the IRS issued three notices addressing this change to section 3405(a)(4). These notices provide that, for calendar years 2018, 2019, and 2020, the default rate of withholding on periodic payments under section 3405(a) is based on treating the payee as a married individual claiming three withholding allowances. See Notice 2020–3, 2020–3 I.R.B. 330 (for 2020); 2 Notice 2018–92, 2018–51 I.R.B. 1038 (for 2019); and Notice 2018–14, 2018–7 I.R.B. 353 (for 2018).

4. Notice of Proposed Rulemaking

On May 27, 2020, the Treasury Department and the IRS published a notice of proposed rulemaking (proposed regulation) (REG–100320–20) in the Federal Register (85 FR 31714) that proposed to update certain provisions of § 35.3405–1T to conform to the TCJA change to section 3405(a)(4). Specifically, the notice of proposed rulemaking proposed to remove from § 35.3405–1T Q&As a–10, b–3, and b–4, which each provided that the default rate of withholding on periodic payments is determined by treating the payee as married and claiming three withholding allowances, and to update and replace the provisions of each of these three Q&As with new § 31.3405(a)–1. These changes are explained in detail in the preamble to the proposed regulation.

The IRS did not receive any requests for a public hearing on the proposed regulation, and therefore no public hearing was held. All written comments responding to the proposed regulation are available for public inspection and copying at http://www.regulations.gov or upon request. After consideration of the comments received on the proposed regulation, this Treasury decision adopts the proposed regulation as final with no modification as explained in the Summary of Comments and Explanation of Provisions.

Summary of Comments and Explanation of Provisions

The Treasury Department and the IRS received two written comments that responded to the proposed regulation. As explained in this Summary of Comments and Explanation of Provisions, these comments make recommendations regarding the default rate of withholding on periodic payments that would not require a change to the proposed regulation. Accordingly, the proposed regulation is adopted as final without modification. However, the comments remain under consideration for future revisions to forms, instructions, publications, and other guidance relating to withholding on periodic payments, including revisions to the Form W–4P, “Withholding Certificate for Pension or Annuity Payments.”

1. Default Rate of Withholding on Periodic Payments

The proposed regulation proposed to remove Q&As a–10, b–3, and b–4 from § 35.3405–1T because they prescribed the substantive default rate of withholding rule under section 3405(a)(4) prior to amendment by TCJA. Specifically, the proposed regulation proposed to update and replace the provisions of each of these three Q&As with new § 31.3405(a)–1, which provides that the default rate of withholding on periodic payments made after December 31, 2020, is determined in the manner described in the applicable forms, instructions, publications, and other guidance prescribed by the Commissioner.

Both responsive comments recommend that the default rate of withholding on periodic payments be a flat 10 percent rate, rather than a rate based on Federal income tax withholding on wages, to simplify the default rate of withholding on periodic payments and provide transparency, flexibility, efficiency, and accuracy.

The proposed regulation did not set forth a specific default rate of withholding on periodic payments, instead providing a flexible and administrable rule that leaves the communication and mechanical details of the default rate of withholding on periodic payments to be provided in applicable forms, instructions, publications, and other guidance prescribed by the Commissioner. This approach enables the Treasury Department and the IRS to make updates more quickly, including to address legislative changes, to provide payors and plan administrators processing payments adequate time to program their systems to withhold the proper amount of income tax. Accordingly, this final regulation adopts the proposed regulation without modification.
2. Implementation of a New Default Rate of Withholding on Periodic Payments

As an alternative to a flat 10 percent rate for the default rate of withholding on periodic payments, both comments recommend that a new default rate of withholding on periodic payments apply prospectively only and have a January 1 (rather than a mid-year) effective date. The comments additionally recommend a January 1 effective date that is at least two full years after the end of the 2020 calendar year (or at least two full years after the end of the calendar year for which Form W–4P is redesigned to mirror Form W–4, “Employee’s Withholding Certificate,” if later), in order to provide payors time to update their systems, forms, and procedures. (The comments also recommend avoiding a mid-year implementation deadline for any revised version of Form W–4P that reflects changes made to Form W–4 in light of TCJA.)

The proposed regulation did not specify an effective date for a new default rate of withholding on periodic payments or how a new default rate of withholding should be applied. Although the proposed regulation was proposed to apply to periodic payments made after December 31, 2020, this applicability date describes the periodic payments for which the default rate of withholding is determined in the manner described in the applicable forms, instructions, publications and other guidance prescribed by the Commissioner. The effective date and application of a new default rate of withholding on periodic payments, like the default rate of withholding on periodic payments itself, would be described in that guidance. The proposed approach provides a flexible and administrable rule that leaves the communication and mechanical details of the default rate of withholding on periodic payments to be provided in applicable forms, instructions, publications, and other guidance prescribed by the Commissioner that may be updated more quickly, including to address legislative changes. Accordingly, this final regulation adopts the proposed regulation without modification.

Effective and Applicability Dates

This regulation is effective October 1, 2020. This regulation applies to periodic payments made after December 31, 2020.

Special Analyses

1. Regulatory Planning and Review

This final regulation is not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations.

2. Paperwork Reduction Act

Any collection of information associated with this final regulation has been submitted to the Office of Management and Budget (OMB) for review under OMB control number 1545–0074 in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). In general, the collection of information is required under section 3405 of the Code. The Treasury Department and the IRS request comments on all aspects of information collection burdens related to this final regulation, including estimates for how much time it would take to comply with the paperwork burdens described in OMB control number 1545–0074 and ways for the IRS to minimize the paperwork burden. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a valid OMB control number.

3. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. chapter 6), it is hereby certified that this final regulation will not have a significant economic impact on a substantial number of small entities that are directly affected by the final regulation. This final regulation will apply to all payors of periodic payments, including small entities, and is likely to affect a substantial number of small entities. The economic impact, however, will not be significant. The primary change is to effect a TCJA legislative amendment to remove the reference in section 3405(a)(4) to a married individual claiming three exemptions as the default withholding rate and to provide, in its place, that the amount to be withheld is determined pursuant to the applicable forms, instructions, publications, and other guidance prescribed by the Commissioner. Accordingly, this rule would conform the current regulation to the statute and will not have a significant economic impact on a substantial number of small entities.

Pursuant to section 7805(f), the notice of proposed rulemaking preceding this regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business, and no comments were received.

Statement of Availability of IRS Documents


Drafting Information

The principal author of this final regulation is Kara M. Soderstrom, Office of Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes). However, other personnel from the Treasury Department and the IRS participated in its development.

List of Subjects

26 CFR Part 31

Employment taxes, Fishing vessels, Gambling, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and recordkeeping requirements, Social security, Unemployment compensation.

26 CFR Part 35

Employment taxes, Income taxes, Pensions, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 31 and 35 are amended as follows:

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT SOURCE

Paragraph 1. The authority citation for part 31 is amended by adding an entry for § 31.3405(a)–1 in numerical order to read in part as follows:


* * * * *

Section 31.3405(a)–1 also issued under 26 U.S.C. 3405(a)(4).

* * * * *

Par. 2. Section 31.3405(a)–1 is added to read as follows:

§ 31.3405(a)–1 Questions and answers relating to Federal income tax withholding on periodic retirement and annuity payments.

(a) The questions and answers in this section relate to Federal income tax withholding on periodic payments under section 3405(a), as amended by section 11041(c)(2)(C) of the Tax Cuts and Jobs Act (Pub. L. 115–97, 131 Stat. 2054 (2017)). The withholding rules of
section 3405(a) do not apply to periodic payments that are eligible rollover distributions (as defined in section 402(f)(2)(A)). See generally section 3405(c) and § 31.3405–1 for Federal income tax withholding rules applicable to eligible rollover distributions. See section 3405(e)(13) for additional rules applicable to certain periodic payments under section 3405(a) and nonperiodic distributions under section 3405(b) that are to be delivered outside the United States and its possessions. For additional guidance regarding periodic payments, see §§ 35.3405–1 and 35.3405–1T of this chapter.

(b)(1) Q–1: How will Federal income tax be withheld from a periodic payment?

(2) A–1: In the case of a periodic payment that is subject to withholding under section 3405(a), amounts are withheld as if the payment were a payment of wages by an employer to the employee for the appropriate payroll period. If the payee has not furnished a withholding certificate, the amount to be withheld is determined in the manner described in the applicable forms, instructions, publications, and other guidance prescribed by the Commissioner. The rules for withholding when the payee has not furnished a withholding certificate apply regardless of whether the payor is aware of the payee’s actual marital status or actual Federal income tax filing status.

(c)(1) Q–2: Do rules similar to those for wage withholding apply to the furnishing of a withholding certificate for periodic payments?

(2) A–2: Yes. Unless the rules of section 3405 specifically conflict with the rules of section 3402, the rules for withholding on periodic payments that are not eligible rollover distributions will parallel the rules for wage withholding. Thus, if a withholding certificate is furnished by a payee, it will generally take effect in accordance with section 3402(f)(3) and as provided in applicable forms, instructions, publications, and other guidance prescribed by the Commissioner. If no withholding certificate is furnished, the amount withheld must be determined in the manner described in the applicable forms, instructions, publications, and other guidance prescribed by the Commissioner for withholding on periodic payments when no withholding certificate is furnished.

(d)(1) Q–3: What is the applicability date of this section?

(2) A–3: This section applies with respect to periodic payments made after December 31, 2020.

## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

#### 31 CFR Part 520

**International Criminal Court-Related Sanctions Regulations**

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Treasury’s Office of Foreign Assets Control (OFAC) is adding regulations to implement Executive Order 13928 of June 11, 2020 (“Blocking Property of Certain Persons Associated With the International Criminal Court”). OFAC intends to supplement these regulations with a more comprehensive set of regulations, which may include additional interpretive and definitional guidance, general licenses, and statements of licensing policy.

**DATES:** This rule is effective October 1, 2020.


## SUPPLEMENTARY INFORMATION:

### Electronic Availability

This document and additional information concerning OFAC are available on OFAC’s website (www.treasury.gov/ofac).

### Background

On June 11, 2020, the President, invoking the authority of, *inter alia*, the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) (IEEPA), issued Executive Order 13928 (85 FR 36139, June 15, 2020) (E.O. 13928). In E.O. 13928, the President found that the situation with respect to the International Criminal Court (ICC) and its illegitimate assertions of jurisdiction over personnel of the United States and certain of its allies, including the ICC Prosecutor’s investigation into actions allegedly committed by United States military, intelligence, and other personnel in or relating to Afghanistan, threatens to subject current and former United States Government and allied officials to harassment, abuse, and possible arrest. The President therefore determined that any attempt by the ICC to investigate, arrest, detain, or prosecute any United States personnel without the consent of the United States, or of personnel of countries that are United States allies and who are not parties to the Rome Statute or have not otherwise consented to ICC jurisdiction, constitutes an unusual and extraordinary threat to the national security and foreign policy of the United States and declared a national emergency to deal with that threat.

OFAC is issuing the International Criminal Court-Related Sanctions Regulations, 31 CFR part 520 (the “Regulations”), to implement E.O. 13928, pursuant to authorities delegated to the Secretary of the Treasury in E.O. 13928. A copy of E.O. 13928 appears in appendix A to this part.

The Regulations are being published in abbreviated form at this time for the purpose of providing immediate guidance to the public. OFAC intends to supplement this part 520 with a more comprehensive set of regulations, which may include additional interpretive and definitional guidance, general licenses, and statements of licensing policy. The appendix to the Regulations will be removed when OFAC supplements this part with a more comprehensive set of regulations.

### Public Participation

Because the Regulations involve a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, as well as the provisions of
Executive Order 13771, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

**Paperwork Reduction Act**  
The collections of information related to the Regulations are contained in 31 CFR part 501 (the “Reporting, Procedures and Penalties Regulations”). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

**List of Subjects in 31 CFR Part 520**  
Administrative practice and procedure, Banks, banking, Blocking of assets, International Criminal Court, Penalties, Reporting and recordkeeping requirements, Sanctions.

For the reasons set forth in the preamble, the Department of the Treasury’s Office of Foreign Assets Control adds part 520 to 31 CFR chapter V to read as follows:

**PART 520—INTERNATIONAL CRIMINAL COURT-RELATED SANCTIONS REGULATIONS**

Subpart A—Relation of This Part to Other Laws and Regulations  
Sec. 520.101 Relation of this part to other laws and regulations.

Subpart B—Prohibitions  
520.201 Prohibited transactions.
520.202 Effect of transfers violating the provisions of this part.
520.203 Holding of funds in interest-bearing accounts; investment and reinvestment.
520.204 Expenses of maintaining blocked tangible property; liquidation of blocked property.
520.205 Exempt transactions.

Subpart C—General Definitions  
520.300 Applicability of definitions.
520.301 Blocked account; blocked property.
520.302 Effective date.
520.303 Entity.
520.304 Financial, material, or technological support.
520.305 [Reserved]
520.306 Interest.
520.307 Licenses; general and specific.
520.308 OFAC.
520.309 Person.
520.310 Property; property interest.
520.311 Transfer.
520.312 United States.
520.313 United States person; U.S. person.
520.314 U.S. financial institution.

Subpart D—Interpretations  
520.401 [Reserved]
520.402 Effect of amendment.
520.403 Termination and acquisition of an interest in blocked property.
520.404 Transactions ordinarily incident to a licensed transaction.
520.405 Setoffs prohibited.
520.406 Entities owned by one or more persons whose property and interests in property are blocked.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy  
520.501 General and specific licensing procedures.
520.502 [Reserved]
520.503 Exclusion from licenses.
520.504 Payments and transfers to blocked accounts in U.S. financial institutions.
520.505 Entries in certain accounts for normal service charges.
520.506 Provision of certain legal services.
520.507 Payments for legal services from funds originating outside the United States.
520.508 Emergency medical services.

Subpart F—Reports  
520.601 Records and reports.

Subpart G—Penalties and Findings of Violation  
520.701 Penalties and Findings of Violation.

Subpart H—Procedures  
520.801 Procedures.
520.802 Delegation of certain authorities of the Secretary of the Treasury.

Subpart I—Paperwork Reduction Act  
520.901 Paperwork Reduction Act notice. Appendix A to Part 520—Executive Order 13928 of June 11, 2020 

Subpart A—Relation of This Part to Other Laws and Regulations  
§ 520.101 Relation of this part to other laws and regulations.

This part is separate from, and independent of, the other parts of this chapter, with the exception of part 501 of this chapter, the recordkeeping and reporting requirements and other procedures of which apply to this part. Actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. Differing foreign policy and national security circumstances may result in differing interpretations of similar language among the parts of this chapter. No license or authorization contained in or issued pursuant to these other parts authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to any other provision of law or regulation authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to this part relieves the involved parties from complying with any other applicable laws or regulations.

Note 1 to § 520.101: This part has been published in abbreviated form for the purpose of providing immediate guidance to the public. OFAC intends to supplement this part with a more comprehensive set of regulations, which may include additional interpretive and definitional guidance, general licenses, and statements of licensing policy.

Subpart B—Prohibitions  
§ 520.201 Prohibited transactions.

All transactions prohibited pursuant to Executive Order 13928 of June 11, 2020 (E.O. 13928), or any further Executive orders issued pursuant to the national emergency declared in E.O. 13928, are prohibited pursuant to this part.

Note 1 to § 520.201: The names of persons determined by the Secretary of State to meet the criteria for the imposition of sanctions and designated pursuant to E.O. 13928, or listed in or designated or identified pursuant to any further Executive orders issued pursuant to the national emergency declared in E.O. 13928, whose property and interests in property therefore are blocked pursuant to this section, are published in the Federal Register and incorporated into OFAC’s Specially Designated Nationals and Blocked Persons List (SDN List) using the identifier formulation “[[ICC–E.O.[E.O. number pursuant to which the person’s property and interests in property are blocked]].” The SDN List is accessible through the following page on OFAC’s website: www.treasury.gov/sdn. Additional information pertaining to the SDN List can be found in appendix A to this chapter. See § 520.406 concerning entities that may not be listed on the SDN List but whose property and interests in property are nevertheless blocked pursuant to this section.

Note 2 to § 520.201: The International Emergency Economic Powers Act (50 U.S.C. 1701–1706), in Section 203 (50 U.S.C. 1702), authorizes the blocking of property and interests in property of a person during the pendency of an investigation. The names of persons whose property and interests in property are blocked pending investigation pursuant to this section also are published in the Federal Register and incorporated into the SDN List using the identifier formulation “[BPi–E.O.[E.O. number pursuant to which the person’s property and interests in property are blocked pending investigation]].”

Note 3 to § 520.201: Sections 501.806 and 501.807 of this chapter describe the
§ 520.202 Effect of transfers violating the provisions of this part.

(a) Any transfer after the effective date that is in violation of any provision of this part or of any regulation, order, directive, ruling, instruction, or license issued pursuant to this part, and that involves any property or interest in property blocked pursuant to § 520.201, is null and void and shall not be the basis for the assertion or recognition of any interest in or right, remedy, power, or privilege with respect to such property or interest in property.

(b) No transfer before the effective date shall be the basis for the assertion or recognition of any right, remedy, power, or privilege with respect to, or any interest in, any property or interest in property blocked pursuant to § 520.201, unless the person who holds or maintains such property, prior to that date, had written notice of the transfer or by any written evidence had recognized such transfer.

(c) Unless otherwise provided, a license or other authorization issued by OFAC before, during, or after a transfer shall be valid and enforceable to the same extent that it would be valid or enforceable but for the provisions of this part and any regulation, order, directive, ruling, instruction, or license issued pursuant to this part.

(d) Transfers of property that otherwise would be null and void or unenforceable by virtue of the provisions of this section shall not be deemed to be null and void or unenforceable as to any person with whom such property is or was held or maintained (and as to such person only) in cases in which such person is able to establish to the satisfaction of OFAC each of the following:

(1) Such transfer did not represent a willful violation of the provisions of this part by the person with whom such property is or was held or maintained (and as to such person only);

(2) The person with whom such property is or was held or maintained did not have reasonable cause to know or suspect, in view of all the facts and circumstances known or available to such person, that such transfer required a license or authorization issued pursuant to this part and was not so licensed or authorized, or, if a license or authorization did purport to cover the transaction, that such license or authorization had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained; and

(3) The person with whom such property is or was held or maintained filed with OFAC a report setting forth in full the circumstances relating to such transfer promptly upon discovery that:

(i) Such transfer was in violation of the provisions of this part or any regulation, ruling, instruction, license, or other directive or authorization issued pursuant to this part;

(ii) Such transfer was not licensed or authorized by OFAC; or

(iii) If a license did purport to cover the transfer, such license had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained.

(e) The filing of a report in accordance with the provisions of paragraph (d)(3) of this section shall not be deemed evidence that the terms of paragraphs (d)(1) and (2) of this section have been satisfied.

(f) Unless licensed pursuant to this part, any attachment, judgment, decree, lien, execution, garnishment, or other judicial process is null and void with respect to any property or interest in property blocked pursuant to § 520.201.

§ 520.203 Holding of funds in interest-bearing accounts; investment and reinvestment.

(a) Except as provided in paragraph (e) or (f) of this section, or as otherwise directed or authorized by OFAC, any U.S. person holding funds, such as currency, bank deposits, or liquidated financial obligations, subject to § 520.201 shall hold or place such funds in a blocked interest-bearing account located in the United States.

(b)(1) For purposes of this section, the term blocked interest-bearing account means a blocked account:

(i) In a federally insured U.S. bank, thrift institution, or credit union, provided the funds are earning interest at rates that are commercially reasonable; or

(ii) With a broker or dealer registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq.), provided the funds are invested in a money market fund or in U.S. Treasury bills.

(2) Funds held or placed in a blocked account pursuant to paragraph (a) of this section may not be invested in instruments the maturity of which exceeds 180 days.

(c) For purposes of this section, a rate is commercially reasonable if it is the rate currently offered to other depositors on deposits or instruments of comparable size and maturity.

(d) For purposes of this section, if interest is credited to a separate blocked account or subaccount, the name of the account party on each account must be the same.

(e) Blocked funds held in instruments the maturity of which exceeds 180 days at the time the funds become subject to § 520.201 may continue to be held until maturity in the original instrument, provided any interest, earnings, or other proceeds derived therefrom are paid into a blocked interest-bearing account in accordance with paragraph (a) or (f) of this section.

(f) Blocked funds held in accounts or instruments outside the United States at the time the funds become subject to § 520.201 may continue to be held in the same type of accounts or instruments, provided the funds earn interest at rates that are commercially reasonable.

§ 520.204 Expenses of maintaining blocked tangible property; liquidation of blocked property.

(a) Except as otherwise authorized, and notwithstanding the existence of any rights or obligations conferred or imposed by any international agreement or contract entered into or any license or permit granted prior to the effective date, all expenses incident to the maintenance of tangible property blocked pursuant to § 520.201 shall be the responsibility of the owners or operators of such property, which expenses shall not be met from blocked funds.

(b) Property blocked pursuant to § 520.201 may, in the discretion of OFAC, be sold or liquidated and the net proceeds placed in a blocked interest-bearing account in the name of the owner of the property.
§ 520.205 Exempt transactions.

(a) Personal communications. The prohibitions contained in this part do not apply to any postal, telegraphic, telephonic, or other personal communication that does not involve the transfer of anything of value.

(b) Official business. The prohibitions contained in § 520.201 do not apply to transactions for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof.

Subpart C—General Definitions

§ 520.300 Applicability of definitions.

The definitions in this subpart apply throughout the entire part.

§ 520.301 Blocked account; blocked property.

The terms blocked account and blocked property shall mean any account or property subject to the prohibitions in § 520.201 held in the name of a person whose property and interests in property are blocked pursuant to § 520.201, or in which such person has an interest, and with respect to which payments, transfers, exportations, withdrawals, or other dealings may not be made or effected except pursuant to a license or other authorization from OFAC expressly authorizing such action.

Note 1 to § 520.301: See § 501.801 of this chapter on licensing procedures.

§ 520.302 Effective date.

(a) The term effective date refers to the effective date of the applicable prohibitions and directives contained in this part, and with respect to a person whose property and interests in property are blocked pursuant to § 520.201, the earlier of the date of actual or constructive notice that such person’s property and interests in property are blocked pursuant to § 520.201, the earlier date of the date of actual or constructive notice that such person’s property and interests in property are blocked pursuant to § 520.201, the earlier of the date of actual or constructive notice that such person’s property and interests in property are blocked pursuant to § 520.201.

(b) For the purposes of this section, constructive notice is the date that a notice of the blocking of the relevant person’s property and interests in property is published in the Federal Register.

§ 520.303 Entity.

The term entity means a government or instrumentality of such government, partnership, association, trust, joint venture, corporation, group, subgroup, or other organization, including an international organization.

§ 520.304 Financial, material, or technological support.

The term financial, material, or technological support means any property, tangible or intangible, including currency, financial instruments, securities, or any other transmission of value; weapons or related materiel; chemical or biological agents; explosives; false documentation or identification; communications equipment; computers; electronic or other devices or equipment; technologies; lodging; safe houses; facilities; vehicles or other means of transportation; or goods.

“Technologies” as used in this section means specific information necessary for the development, production, or use of a product, including related technical data such as blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals, or other recorded instructions.

§ 520.305 [Reserved]

§ 520.306 Interest.

Except as otherwise provided in this part, the term interest, when used with respect to property (e.g., “an interest in property”), means an interest of any nature whatsoever, direct or indirect.

§ 520.307 Licenses; general and specific.

(a) Except as otherwise provided in this part, the term license means any license or authorization contained in or issued pursuant to this part.

(b) The term general license means any license or authorization the terms of which are set forth in subpart E of this part or made available on OFAC’s website: www.treasury.gov/ofac.

(c) The term specific license means any license or authorization issued pursuant to this part but not set forth in subpart E of this part or made available on OFAC’s website: www.treasury.gov/ofac.

Note 1 to § 520.307: See § 501.801 of this chapter on licensing procedures.

§ 520.308 OFAC.

The term OFAC means the Department of the Treasury’s Office of Foreign Assets Control.

§ 520.309 Person.

The term person means an individual or entity.

§ 520.310 Property; property interest.

The terms property and property interest include money, checks, drafts, bullion, bank deposits, savings accounts, debts, indebtedness, obligations, notes, guarantees, debentures, stocks, bonds, coupons, any other financial instruments, bankers acceptances, mortgages, pledges, liens or other rights in the nature of security, warehouse receipts, bills of lading, trust receipts, bills of sale, any other evidences of title, ownership, or indebtedness, letters of credit and any documents relating to any rights or obligations thereunder, powers of attorney, goods, wares, merchandise, chattels, stocks on hand, ships, goods on ships, real estate mortgages, deeds of trust, vendors’ sales agreements, land contracts, leaseholds, ground rents, real estate and any other interest therein, options, negotiable instruments, trade acceptances, royalties, book accounts, accounts payable, judgments, patents, trademarks or copyrights, insurance policies, safe deposit boxes and their contents, annuities, pooling agreements, services of any nature whatsoever, contracts of any nature whatsoever, and any other property, real, personal, or mixed, tangible or intangible, or interest or interests therein, present, future, or contingent.

§ 520.311 Transfer.

The term transfer means any actual or purported act or transaction, whether or not evidenced by writing, and whether or not done or performed within the United States, the purpose, intent, or effect of which is to create, surrender, release, convey, transfer, or alter, directly or indirectly, any right, remedy, power, privilege, or interest with respect to any property. Without limitation on the foregoing, it shall include the making, execution, or delivery of any assignment, power, conveyance, check, declaration, deed, deed of trust, power of attorney, power of appointment, bill of sale, mortgage, receipt, agreement, contract, certificate, gift, sale, affidavit, or statement; the making of any payment; the setting off of any obligation or debt; the appointment of any agent, trustee, or fiduciary; the creation or transfer of any lien; the issuance, docketing, filing, or levy of or under any judgment, decree, attachment, injunction, execution, or other judicial or administrative process or order, or the service of any garnishment; the acquisition of any interest of any nature whatsoever by reason of a judgment or decree of any foreign country; the fulfillment of any condition; the exercise of any power of appointment, power of attorney, or other power; or the acquisition, disposition, transportation, importation, exportation, or withdrawal of any security.
§ 520.312 United States.

The term United States means the United States, its territories and possessions, and all areas under the jurisdiction or authority thereof.

§ 520.313 United States person; U.S. person.

The term United States person or U.S. person means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States.

§ 520.314 U.S. financial institution.

The term U.S. financial institution means any U.S. entity (including its foreign branches) that is engaged in the business of accepting deposits, making, granting, transferring, holding, or brokering loans or other extensions of credit, or purchasing or selling foreign exchange, securities, commodity futures or options, or procuring purchasers and sellers thereof, as principal or agent. It includes depository institutions, banks, savings banks, trust companies, securities brokers and dealers, futures and options brokers and dealers, forward contract and foreign exchange merchants, securities and commodities exchanges, clearing corporations, investment companies, employee benefit plans, and U.S. holding companies, U.S. affiliates, or U.S. subsidiaries of any of the foregoing. This term includes those branches, offices, and agencies of foreign financial institutions that are located in the United States, but not such institutions' foreign branches, offices, or agencies.

Subpart D—Interpretations

§ 520.401 [Reserved]

§ 520.402 Effect of amendment.

Unless otherwise specifically provided, any amendment, modification, or revocation of any provision in or appendix to this part or chapter, or of any order, regulation, ruling, instruction, or license issued by OFAC does not affect any act done or omitted, or any civil or criminal proceeding commenced or pending, prior to such amendment, modification, or revocation. All penalties, forfeitures, and liabilities under any such order, regulation, ruling, instruction, or license continue and may be enforced as if such amendment, modification, or revocation had not been made.

§ 520.403 Termination and acquisition of an interest in blocked property.

(a) Whenever a transaction licensed or authorized by or pursuant to this part results in the transfer of property (including any property interest) away from a person whose property and interests in property are blocked pursuant to § 520.201, such property shall no longer be deemed to be property blocked pursuant to § 520.201, unless there exists in the property another interest that is blocked pursuant to § 520.201, the transfer of which has not been effected pursuant to license or other authorization.

(b) Unless otherwise specifically provided in a license or authorization issued pursuant to this part, if property (including any property interest) is transferred or attempted to be transferred to a person whose property and interests in property are blocked pursuant to § 520.201, such property shall be deemed to be property in which such person has an interest and therefore blocked.

§ 520.404 Transactions ordinarily incident to a licensed transaction.

Any transaction ordinarily incident to a licensed transaction and necessary to give effect thereto is also authorized, except:

(a) An ordinarily incident transaction, not explicitly authorized within the terms of the license, by or with a person whose property and interests in property are blocked pursuant to § 520.201; or

(b) An ordinarily incident transaction, not explicitly authorized within the terms of the license, involving a debit to a blocked account or a transfer of blocked property.

§ 520.405 Setoffs prohibited.

A setoff against blocked property (including a blocked account), whether by a U.S. bank or other U.S. person, is a prohibited transfer under § 520.201 if effected after the effective date.

§ 520.406 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 520.201 have an interest in all property and interests in property of an entity in which such persons directly or indirectly own, whether individually or in the aggregate, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 520.201, regardless of whether the name of the entity is incorporated into OFAC’s Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

§ 520.501 General and specific licensing procedures.

For provisions relating to licensing procedures, see part 501, subpart E, of this chapter. Licensing actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. General licenses and statements of licensing policy relating to this part also may be available through the International Criminal Court-Related Sanctions Regulations page on OFAC’s website: www.treasury.gov/ofac.

§ 520.502 [Reserved]

§ 520.503 Exclusion from licenses.

OFAC reserves the right to exclude any person, property, transaction, or class thereof from the operation of any license or from the privileges conferred by any license. OFAC also reserves the right to restrict the applicability of any license to particular persons, property, transactions, or classes thereof. Such actions are binding upon actual or constructive notice of the exclusions or restrictions.

§ 520.504 Payments and transfers to blocked accounts in U.S. financial institutions.

Any payment of funds or transfer of credit in which a person whose property and interests in property are blocked pursuant to § 520.201 has any interest that comes within the possession or control of a U.S. financial institution must be blocked in an account on the books of that financial institution. A transfer of funds or credit by a U.S. financial institution between blocked accounts in its branches or offices is authorized, provided that no transfer is made from an account within the United States to an account held outside the United States, and further provided that a transfer from a blocked account may be made only to another blocked account held in the same name.

Note 1 to § 520.504: See § 501.603 of this chapter for mandatory reporting requirements regarding financial transfers. See also § 520.203 concerning the obligation to hold blocked funds in interest-bearing accounts.

§ 520.505 Entries in certain accounts for normal service charges.

(a) A U.S. financial institution is authorized to debit any blocked account held at that financial institution in
payment or reimbursement for normal service charges owed it by the owner of that blocked account.

(b) As used in this section, the term "normal service charges" shall include charges in payment or reimbursement for interest due; cable, telegraph, internet, or telephone charges; postage costs; custody fees; small adjustment charges to correct bookkeeping errors; and, but not by way of limitation, minimum balance charges, notary and protest fees, and charges for reference books, photocopied, credit reports, transcripts of statements, registered mail, insurance, stationery and supplies, and other similar items.

§ 520.506 Provision of certain legal services.

(a) The provision of the following legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 520.201 is authorized, provided that any receipt of payment of professional fees and reimbursement of incurred expenses must be authorized pursuant to § 520.507, which authorizes certain payments for legal services from funds originating outside the United States; via specific license; or otherwise pursuant to this part:

(1) Provision of legal advice and counseling on the requirements of and compliance with the laws of the United States or any jurisdiction within the United States, provided that such advice and counseling are not provided to facilitate transactions in violation of this part;

(2) Representation of persons named as defendants in or otherwise made parties to legal, arbitration, or administrative proceedings before any U.S. Federal, state, or local court or agency;

(3) Initiation and conduct of legal, arbitration, or administrative proceedings before any U.S. Federal, state, or local court or agency;

(4) Representation of persons before any U.S. Federal, state, or local court or agency with respect to the imposition, administration, or enforcement of U.S. sanctions against such persons; and

(5) Provision of legal services in any other context in which prevailing U.S. law requires access to legal counsel at public expense.

(b) The provision of any other legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 520.201, not otherwise authorized in this part, requires the issuance of a specific license.

(c) U.S. persons do not need to obtain specific authorization to provide related services, such as making filings and providing other administrative services, that are ordinarily incident to the provision of services authorized by this section. Additionally, U.S. persons who provide services authorized by this section do not need to obtain specific authorization to contract for related services that are ordinarily incident to the provision of those legal services, such as those provided by private investigators or expert witnesses, or to pay for such services. See § 520.404.

(d) Entry into a settlement agreement or the enforcement of any lien, judgment, arbitral award, decree, or other order through execution, garnishment, or other judicial process purporting to transfer or otherwise alter or affect property or interests in property blocked pursuant to § 520.201 is prohibited unless licensed pursuant to this part.

Note 1 to § 520.506: Pursuant to part 501, subpart E, of this chapter, U.S. persons seeking administrative reconsideration or judicial review of their designation or the blocking of their property and interests in property may apply for a specific license from OFAC to authorize the release of certain blocked funds for the payment of professional fees and reimbursement of incurred expenses for the provision of such legal services where alternative funding sources are not available.

§ 520.507 Payments for legal services from funds originating outside the United States.

(a) Professional fees and incurred expenses. (1) Receipt of payment of professional fees and reimbursement of incurred expenses for the provision of legal services authorized pursuant to § 520.506(a) to or on behalf of any person whose property and interests in property are blocked pursuant to § 520.201 is authorized from funds originating outside the United States, provided that the funds do not originate from:

(i) A source within the United States;

(ii) Any source, wherever located, within the possession or control of a U.S. person;

(iii) Any individual or entity, other than the person on whose behalf the legal services authorized pursuant to § 520.506(a) are to be provided, whose property and interests in property are blocked pursuant to any part of this chapter or any Executive order or statute.

(2) Nothing in this paragraph (a) authorizes payments for legal services using funds in which any other person whose property and interests in property are blocked pursuant to § 520.201, any other part of this chapter, or any Executive order or statute has an interest.

(b) Reports. (1) U.S. persons who receive payments pursuant to paragraph (a) of this section must submit annual reports no later than 30 days following the end of the calendar year during which the payments were received providing information on the funds received. Such reports shall specify:

(i) The individual or entity from whom the funds originated and the amount of funds received; and

(ii) If applicable:

(A) The names of any individuals or entities providing related services to the U.S. person receiving payment in connection with authorized legal services, such as private investigators or expert witnesses;

(B) A general description of the services provided; and

(C) The amount of funds paid in connection with such services.

(2) The reports, which must reference this section, are to be submitted to OFAC using one of the following methods:

(i) Email (preferred method): OFAC.Regulations.Reports@treasury.gov; or

(ii) U.S. mail: OFAC Regulations Reports, Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Avenue, NW, Freedman’s Bank Building, Washington, DC 20220.

§ 520.508 Emergency medical services.

The provision and receipt of nonscheduled emergency medical services that are otherwise prohibited by this part are authorized.

Subpart F—Reports

§ 520.601 Records and reports.

For provisions relating to required records and reports, see part 501, subpart C, of this chapter. Recordkeeping and reporting requirements imposed by part 501 of this chapter with respect to the prohibitions contained in this part are considered requirements arising pursuant to this part.

Subpart G—Penalties and Findings of Violation

§ 520.701 Penalties and Findings of Violation.

displays a valid control number applicable to violations of the provisions of this part.

(b) OFAC has the authority, pursuant to IEEPA, to issue Pre-Penalty Notices, Penalty Notices, and Findings of Violation; impose monetary penalties; engage in settlement discussions and enter into settlements; refer matters to the United States Department of Justice for administrative collection; and, in appropriate circumstances, refer matters to appropriate law enforcement agencies for criminal investigation and/or prosecution. For more information, see appendix A to part 501 of this chapter, which provides a general framework for the enforcement of all economic sanctions programs administered by OFAC, including enforcement-related definitions, types of responses to apparent violations, general factors affecting administrative actions, civil penalties for failure to comply with a requirement to furnish information or keep records, and other general civil penalties information.

Subpart H—Procedures

§ 520.801 Procedures.

For license application procedures and procedures relating to amendments, modifications, or revocations of licenses; administrative decisions; rulemaking; and requests for documents pursuant to the Freedom of Information and Privacy Acts (5 U.S.C. 552 and 552a), see part 501, subpart E, of this chapter.

§ 520.802 Delegation of certain authorities of the Secretary of the Treasury.

Any action that the Secretary of the Treasury is authorized to take pursuant to Executive Order 13928 of June 11, 2020 (E.O. 13928), and any further Executive orders issued pursuant to the national emergency declared in E.O. 13928, may be taken by the Director of OFAC or by any other person to whom the Secretary of the Treasury has delegated authority so to act.

Subpart I—Paperwork Reduction Act

§ 520.901 Paperwork Reduction Act notice.

For approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) of information collections relating to recordkeeping and reporting requirements, licensing procedures, and other procedures, see § 501.901 of this chapter. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

Appendix A to Part 520—Executive Order 13928 of June 11, 2020

Executive Order 13928 of June 11, 2020

Blocking Property of Certain Persons Associated With the International Criminal Court

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 et seq.) (NEA), section 212(f) of the Immigration and Nationality Act of 1952 (8 U.S.C. 1182(f)), and section 301 of title 3, United States Code,

I, DONALD J. TRUMP, President of the United States of America, find that the situation with respect to the International Criminal Court (ICC) and its illegitimate assertions of jurisdiction over personnel of the United States and certain of its allies, including the ICC Prosecutor’s investigation into actions allegedly committed by United States military, intelligence, and other personnel in or relating to Afghanistan, threatens to subvert current and former United States Government and allied officials to harassment, abuse, and possible arrest. These actions on the part of the ICC, in turn, threaten to infringe upon the sovereignty of the United States and impede the critical national security and foreign policy work of United States Government and allied officials, and thereby threaten the national security and foreign policy of the United States. The United States is not a party to the Rome Statute, has never accepted ICC jurisdiction over its personnel, and has consistently rejected ICC assertions of jurisdiction over United States personnel. Furthermore, in 2002, the United States Congress enacted the American Service-Members’ Protection Act (22 U.S.C. 7421 et seq.) which restricts the ICC’s overbroad, non-consensual assertions of jurisdiction. The United States remains committed to accountability and to the peaceful cultivation of international order, but the ICC and parties to the Rome Statute must respect the decisions of the United States and other countries not to subject their personnel to the ICC’s jurisdiction, consistent with their respective sovereign prerogatives. The United States seeks to impose tangible and significant consequences on those responsible for the ICC’s transgressions, which may include the suspension of entry into the United States of ICC officials, employees, and agents, as well as their immediate family members. The entry of such aliens into the United States would be detrimental to the interests of the United States and denying them entry will further demonstrate the resolve of the United States in opposing the ICC’s overreach by seeking to exercise jurisdiction over personnel of the United States as well as personnel of countries that are not parties to the Rome Statute or have not otherwise consented to ICC jurisdiction.

I therefore determine that any attempt by the ICC to investigate, arrest, detain, or prosecute any United States personnel without the consent of the United States, or of personnel of countries that are United States allies and who are not parties to the Rome Statute or have not otherwise consented to ICC jurisdiction, constitutes an unusual and extraordinary threat to the national security and foreign policy of the United States, and I hereby declare a national emergency to deal with that threat.

I hereby determine and order:

Section 1. (a) All property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person, of Start the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in:

(i) any foreign person determined by the Secretary of State, in consultation with the Secretary of the Treasury and the Attorney General:

(A) to have directly engaged in any effort by the ICC to investigate, arrest, detain, or prosecute any United States personnel without the consent of the United States;

(B) to have directly engaged in any effort by the ICC to investigate, arrest, detain, or prosecute any personnel of a country that is an ally of the United States without the consent of that country’s government;

(C) to have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, any activity described in subsection (a)(i)(A) or (a)(i)(B) of this section or any person whose property and interests in property are property blocked pursuant to this order;

(D) to be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are property blocked pursuant to this order.

(b) The prohibitions in subsection (a) of this section apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted before the date of this order.

Sec. 2. I hereby determine that the making of donations of the types of articles specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)) by, to, or for the benefit of any person whose property and interests in property are property blocked pursuant to section 1(a) of this order would seriously impair my ability to deal with the national emergency declared in this order, and I hereby prohibit such donations as provided by section 1(a) of this order.

Sec. 3. The prohibitions in section 1(a) of this order include:

(a) the making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are property blocked pursuant to section 1(a) of this order; and

(b) the receipt of any contribution or provision of funds, goods, or services from any such person.

Sec. 4. The unrestricted immigrant and nonimmigrant entry into the United States of aliens determined to meet one or more of the
DEPARTMENT OF THE TREASURY
Office of Foreign Assets Control

31 CFR Parts 544 and 560

Weapons of Mass Destruction Proliferators Sanctions Regulations and Iranian Transactions and Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury’s Office of Foreign Assets Control (OFAC) is amending the Weapons of Mass Destruction Proliferators Sanctions Regulations (WMD Regulations) to update a note to describe how persons designated pursuant to the WMD Regulations for North Korea-related activities are identified on OFAC’s Specially Designated Nationals and Blocked Persons List (SDN List). Specifically, OFAC is amending the note to explain that SDN List entries for these designated persons will include additional information regarding certain risks associated with dealings with such persons. Separately, OFAC is amending the Iranian Transactions and Sanctions Regulations to refine the list of organizations whose activities are authorized under the general license for the official business of certain international organizations, and to make a technical correction. OFAC is also making technical edits to the authority citations in both sets of regulations to conform to Federal Register guidance.

DATES: This rule is effective October 1, 2020.


SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC’s website (www.treasury.gov/ofac).

Background

 Weapons of Mass Destruction Proliferators Sanctions Regulations

On April 13, 2009, OFAC issued the Weapons of Mass Destruction Proliferators Sanctions Regulations, 31 CFR part 544 (74 FR 16771, April 13, 2009) (“WMD Regulations”), to implement Executive Order 13382 of
June 28, 2005 (“Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters”) (E.O. 13382), Note 1 to paragraph (a) of §544.201 of the WMD Regulations states that the names of persons listed in or designated pursuant to E.O. 13382 will be incorporated into OFAC’s SDN List with the identifier “[NPWMD].” OFAC is amending this note to add text to explain that certain persons who are incorporated into OFAC’s SDN List pursuant to §544.201(a) of the WMD Regulations for engaging in North Korea-related WMD activities will have additional information in their SDN List entries about relevant provisions under the North Korea Sanctions Regulations, 31 CFR part 510 (NKSR). Specifically, engaging in certain transactions with persons blocked pursuant to §544.201(a) in connection with North Korea-related WMD activities may result in the imposition of secondary sanctions, and therefore such blocked persons’ entries on the SDN List will also include the descriptive prefix text “Secondary sanctions risk:”, followed by information about the applicable secondary sanctions authority. Additionally, pursuant to §510.214 of the NKSR, persons owned or controlled by a U.S. financial institution are subject to certain prohibitions under the NKSR; as a result, the entries of certain persons blocked pursuant to §544.201(a) of the WMD Regulations in connection with North Korea-related activities will also include the descriptive prefix text “Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions:”, followed by information about the applicable sanctions authority. Additionally, OFAC is amending the authority citation of the WMD Regulations to shorten citations to conform to Federal Register guidance.

Iranian Transactions and Sanctions Regulations

On October 22, 2012, OFAC published a final rule in the Federal Register rescinding the Iranian Transactions and Sanctions Regulations, 31 CFR part 560 in their entirety (77 FR 64664, October 22, 2012) (“ITSR”). Since then, OFAC has amended the ITRS on several occasions. This rule amends the general license at §560.539 of the ITRS, which authorizes transactions for the conduct of the official business of several international organizations. OFAC is amending the list of organizations whose activities are authorized under the general license to include the United Nations’ Specialized Agencies, Programmes, Funds, and Related Organizations, as well as to refer

to the World Bank as the “World Bank Group.” OFAC is also correcting a sequencing error of two identically numbered paragraphs in the ITRS, at §560.701(a)(3), by redesignating the second occurrence of §560.701(a)(3) as §560.701(a)(4), and modifying a cross-reference accordingly. Finally, OFAC is amending the authority citation in the ITRS to shorten citations to conform to Federal Register guidance.

Public Participation

Because the amendment of the WMD Regulations and the ITRS involves a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, as well as the provisions of Executive Order 13771, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to the WMD Regulations and the ITRS are contained in 31 CFR part 501 (the “Reporting, Procedures and Penalties Regulations”). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

List of Subjects

31 CFR Part 544

Administrative practice and procedure, Banks, banking, Blocking of assets, Foreign trade, Penalties, Proliferation, Reporting and recordkeeping requirements, Sanctions, Securities, Services, Weapons of mass destruction.

31 CFR Part 560

Administrative practice and procedure, Banks, banking, Blocking of assets, Credit, Foreign trade, Iran, Penalties, Reporting and recordkeeping requirements, Sanctions, Securities, Services.

For the reasons set forth in the preamble, the Department of the Treasury’s Office of Foreign Assets Control amends 31 CFR parts 544 and 560 as follows:

PART 544—WEAPONS OF MASS DESTRUCTION PROLIFERATORS SANCTIONS REGULATIONS

1. The authority citation for part 544 is revised to read as follows:


Subpart B—Prohibitions

2. Revise Note 1 to paragraph (a) of §544.201 to read as follows:

§544.201  Prohibited transactions involving blocked property.

(a) * * *

Note 1 to paragraph (a): The names of persons listed in or designated pursuant to Executive Order 13382, whose property and interests in property are blocked pursuant to paragraph (a) of this section, are published in the Federal Register and incorporated into the Office of Foreign Assets Control’s (OFAC) Specially Designated Nationals and Blocked Persons List (“SDN List”) with the identifier “[NPWMD].” Certain transactions with persons blocked pursuant to E.O. 13382 for activities involving North Korea or for activities involving persons designated pursuant to a North Korea sanctions authority may result in the imposition of secondary sanctions, and therefore such blocked persons’ entries on the SDN List will include the descriptive prefix text “Secondary sanctions risk:”, followed by information about the applicable sanctions authority. Pursuant to 31 CFR 510.214 (the North Korea Sanctions Regulations (NKSR)), persons owned or controlled by a U.S. financial institution are subject to certain prohibitions under the NKSR; as a result, the entries of persons blocked pursuant to E.O. 13382 in connection with North Korea-related activities will also include the descriptive prefix text “Transactions Prohibited For Persons Owned or Controlled By U.S. Financial Institutions:”, followed by information about the applicable sanctions authority. The SDN List is accessible through the following page on OFAC’s website: http://www.treasury.gov/sdn. Additional information pertaining to the SDN List can be found in appendix A to this chapter. See §544.411 concerning entities that may not be listed on the SDN List but whose property and interests in property are nevertheless blocked pursuant to paragraph (a) of this section.

* * * * *

PART 560—IRANIAN TRANSACTIONS AND SANCTIONS REGULATIONS

3. The authority citation for part 560 is revised to read as follows:

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 16

Chemical Drug Testing

CFR Correction

In Title 46 of the Code of Federal Regulations, Parts 1 to 40, revised as of October 1, 2019, on page 321, in §16.113, paragraph (a), second sentence, remove the terms “documented and licensed” and add the term “credentialed” in their place.

[FR Doc. 2020–21805 Filed 9–30–20; 8:45 am]

BILLING CODE 1301–00–D

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 2


SUMMARY: The Federal Communications Commission (Commission) previously published two documents revising portions of the Table of Frequency Allocations (Allocation Table). Because of the way the Allocation Table pages were printed in the Federal Register, they cannot be displayed in the CFR. This technical amendment corrects that printing error by republishing the affected pages. There is no new regulatory action involved; this is only a correction of a previous misprinting.

DATES: This technical amendment is effective October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Tom Mooring, Office of Engineering and Technology, Policy and Rules Division, (202) 418–2450 or Tom.Mooring@fcc.gov.

SUPPLEMENTARY INFORMATION: The Federal Communications Commission recently published two documents in the Federal Register, each of which made revisions to the Table of Frequency Allocations (Allocation Table). The first publication, on June 26, 2020 (85 FR 38630), made non-substantive, editorial revisions to the Table of Frequency Allocations (Allocation Table) and to various other Commission rules. Within that document, the following pages of the Allocation Table were published in a way that they could not be accurately displayed in the Code of Federal Regulations (CFR): 7–9, 19, 22–27, 29–34, and 38–68. Pages 52 and 53 were subsequently overwritten by a publication on July 24, 2020 (85 FR 44772) and published in a way that they could be accurately displayed in the CFR. The second publication, on July 16, 2020 (85 FR 43124), adopted rules for broadband license operations in the 897.5–900.5/936.5–939.5 MHz segment of the 900 MHz band (896–901/935–940 MHz), which necessitated a change to the Allocation Table. Within that document, pages 31 and 32 of the Allocation Table were published in a way that they could not be accurately displayed in the CFR. These pages replaced pages 31 and 32 that had been modified by 85 FR 38630. Finally, we correct the placement of footnote US64 in the 456–459 MHz band within the Federal Table, i.e., we place US64 in ascending numerical order. There is no new regulatory action involved in these revisions; the technical amendment only changes how the affected Allocation Table pages (7–9, 19, 22–27, 29–34, 38–51, and 54–68) are displayed.

List of Subjects in 47 CFR Part 2

Telecommunications.

Marlene Dortch,
Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 2 as follows:

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

1. The authority citation for part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

2. Section 2.106 is amended by revising pages 7 through 9, 19, 22 through 27, 29 through 34, 38 through 51, and 54 through 68 to read as follows:

§2.106 Table of Frequency Allocations.

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SPACE RESEARCH (space-to-Earth)
5.207 5.213

143.6-144
AERONAUTICAL MOBILE (OR)

143.6-144
FIXED
MOBILE
RADIOLOCATION
Space research (space-to-Earth)
5.207 5.213

144-146
AMATEUR
AMATEUR-SATELLITE

144-146
AMATEUR
AMATEUR-SATELLITE

146-148
FIXED
MOBILE except aeronautical mobile (R)

146-148
AMATEUR

146-148
AMATEUR

148-149.9
FIXED
MOBILE except aeronautical mobile (R)
MOBILE-SATELLITE (Earth-to-space) 5.209

148-149.9
FIXED
MOBILE
MOBILE-SATELLITE (Earth-to-space) 5.209

148-149.9
MOBILE-SATELLITE (Earth-to-space) US320 US323 US325

149.9-150.05
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149.9-150.05
MOBILE-SATELLITE (Earth-to-space) US319 US320

150.05-153
FIXED
MOBILE except aeronautical mobile
RADIO ASTRONOMY
5.149

150.05-154
FIXED
MOBILE

150.05-150.8
FIXED
MOBILE
US73 G30

150.05-150.8
FIXED
MOBILE
US73
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*Notes:*
- **Fixed Mobile (FM):** Services designed for fixed or near-fixed locations.
- **Aeronautical Mobile (AM):** Services for aircraft.
- **Maritime Mobile (MM):** Services for maritime vessels.
- **Satellite Communications (SC):** Services using satellite technology.
- **Private Land Mobile (PLM):** Services for land-based private users.
- **Remote Pickup (RP):** Services for remote pickup applications.

*Frequencies are in MHz.*
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- Maritime (80) Private Land Mobile (90)
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Private Land Mobile (90)
Radiolocation
Space research
Standard frequency and time signal-satellite (Earth-to-space)

Satellite
Communications (25)

Private Land Mobile (90)
Radiolocation
Space research
Standard frequency and time signal-satellite (Earth-to-space)

Satellite
Communications (25)

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Space research
Standard frequency and time signal-satellite (Earth-to-space)
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SUMMARY: This document denies an Application for Review filed by PMCM the grant of a rulemaking petition filed by Connecticut Public Broadcasting, Inc. (CPBI), licensee of noncommercial educational television station WEDW, Bridgeport, Connecticut, to change WEDW’s community of license from Bridgeport to Stamford, Connecticut. The document finds that the Bureau’s reallocation was proper.

DATES: Effective October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Jeremy Miller, Jeremy.Miller@fcc.gov, Media Bureau, (202) 418–1507.

SYNOPSIS: In the Report and Order in this proceeding, the Bureau granted CPBI’s request to change its community of license over the objection of PMCM. See 84 FR 16413–01 (April 19, 2019). The document rejects all of PMCM’s challenges to this grant. First, the Commission disagrees with PMCM’s argument that while the Commission partially lifted a freeze on community of license changes for petitions that do not require a change in the station’s technical facilities, CPBI’s rulemaking petition was not eligible because CPBI subsequently sought to relocate WEDW’s technical facilities from Bridgeport to Stamford after filing the Petition. The Commission finds that consistent with these requirements of the partially lifted freeze, CPBI’s petition did not request a change in WEDW’s authorized technical facilities nor was such a change required to comply with the Commission’s community coverage requirements. In particular, the Commission finds that the later-filed request to move transmission facilities to Stamford is a separate matter from CPBI’s community of license petition and disagree with PMCM that the modification application is integral to consideration of the Petition.

The document also finds that the Application for Review was an impermissible collateral attack on CPBI’s separate application to move its transmission facilities to Stamford, which had been final for over a year and not pending before the Commission. In addition, the Commission also denies PMCM’s argument that grant of this community of license change would effectively relocate WEDW to New York City. The petition for rulemaking did not propose to move the authorized technical facilities from its site near Bridgeport and, thus, CPBI did not propose a change to WEDW’s service area as part of this rulemaking.


This document is not subject to the Congressional Review Act. (The Commission, is, therefore, not required to submit a copy of this Memorandum Opinion and Order to GAO, pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A) because the Application for Review was denied.)

Federal Communications Commission
Marlene Dortch,
Secretary.

SYNOPSIS: This document denies an Application for Review filed by PMCM the grant of a rulemaking petition filed by Connecticut Public Broadcasting, Inc. (CPBI), licensee of noncommercial educational television station WEDW, Bridgeport, Connecticut, to change WEDW’s community of license from Bridgeport to Stamford, Connecticut. The document finds that the Bureau’s reallocation was proper.

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Federal Communications Commission
Marlene Dortch,
Secretary.
I. Background
As part of GSA’s regulatory reform efforts, GSA determined that GSAR 532.905–70 should no longer require contracting officers to obtain approval of legal counsel before processing final payments for construction and building service contracts where, after 60 days, the contracting officers are unable to obtain releases of claims from contractors. Legal review is not a statutory requirement, and the decision to process final payments in such cases is a business decision, rather than a legal one.

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

III. Discussion and Analysis
Prior to the issuance of this rule, GSA guidance on final payments for construction and building service contracts provided that, “in cases where, after 60 days from the initial attempt, the contracting officer is unable to obtain a release of claims from the contractor, the final payment may be processed with the approval of assigned legal counsel.” GSA is proposing to amend GSAR 532.905–70(c) by removing the legal approval requirement because this is a business decision to be made by the contracting officer, not a legal decision. Therefore, upon implementation of this rule, a contracting officer may instead process a final payment in such a situation after documenting in the contract file: (i) The contractor submitted a properly documented claim; or (ii) The contractor submitted a properly documented claim and did not receive a response within 60 calendar days; and (iii) Approval to process the final payment from one level above the contracting officer.

IV. Executive Orders 12866 and 13563
Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771
This final rule was not subject to E.O. 13771 because this rule is not a significant regulatory action under E.O. 12886.

VI. Regulatory Flexibility Act
The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant GSAR revision.

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

List of Subjects in 48 CFR Part 532
Government procurement.

Jeffrey A. Koses,
Senior Procurement Executive, Office of Acquisition Policy, Office of Governmentwide Policy, General Services Administration.

Therefore, GSA amends 48 CFR part 532 as set forth below:

PART 532—CONTRACT FINANCING

1. The authority citation for 48 CFR part 532 continues to read as follows:
Authority: 40 U.S.C. 121(c).

2. Amend section 532.905–70 by:
(a) Removing from paragraph (a) “amount due to the Contractor” and adding “amount due to the contractor” in its place;
(b) Revising paragraph (b); and
(c) Removing paragraphs (c) and (d).

The revision reads as follows:

532.905–70 Final payment—construction and building service contracts.

* * * * *
(b) A contracting officer may only process the final payment for a construction or building service contract once:
(1) The contractor submits a properly executed GSA Form 1142, Release of Claims; or
(2) The contracting officer documents in the contract file:
(i) That the contracting officer requested a release of claims from the contractor and did not receive a response within 60 calendar days; and,
(ii) Approval to process the final payment from one level above the contracting officer.

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

50 CFR Part 635

[FR Doc. 2020–18597 Filed 9–30–20; 8:45 am]
BILLING CODE 6820–61–P

DEPARTMENT OF VETERANS AFFAIRS

48 CFR Part 852

Solicitation Provisions and Contract Clauses

CFR Correction

In Title 48 of the Code of Federal Regulations, Chapters 7 to 14, revised as of October 1, 2019, on page 272, remove the second printing of section 852.232–70, and on page 278, remove the second printing of section 852.236–72.

[FR Doc. 2020–21868 Filed 9–30–20; 8:45 am]
BILLING CODE 1301–00–D

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

Atlantic Highly Migratory Species; Adjustments to 2020 Northern Albacore Tuna Quota, 2020 North and South Atlantic Swordfish Quotas, and 2020 Atlantic Bluefin Tuna Reserve Category Quota

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

ACTION: Temporary final rule.

SUMMARY: NMFS adjusts the 2020 baseline quotas for U.S. North Atlantic albacore tuna (northern albacore), North and South Atlantic swordfish, and the Atlantic bluefin Reserve category based on available overharvest of the 2019 adjusted U.S. quotas. This action is necessary to implement binding recommendations of the International Commission for the Conservation of Atlantic Tunas (ICCAT), as required by the Atlantic Tunas Convention Act (ATCA), and to achieve domestic management objectives under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Effective October 1, 2020, through December 31, 2020.
northern albacore (which amends portions of Recommendation 17–04 on northern albacore fishery. ICCAT Adjustment Process

Northern Albacore Annual Quota and Adjustment Process

Since 1998, ICCAT has adopted recommendations regarding the northern albacore fishery. ICCAT Recommendation 17–04 on northern albacore (which amends portions of Recommendation 16–06) includes a total allowable catch (TAC) at 33,600 mt for 2018 through 2020 and specific provisions regarding northern albacore conservation and management. The U.S. share of that TAC is a quota for 2019 and 2020 of 630 mt, annually, which is codified at §635.27(e) and will remain in effect until changed.

Portions of ICCAT Recommendation 16–06 remain active. Relevant to the northern albacore quota adjustment in this action, and as codified at §635.27(e)(2), the maximum underharvest that a Contracting Party may carry forward from one year to the next is 25 percent of its initial catch quota, which would be 158.1 mt for the United States.

Adjustment of the 2020 Northern Albacore Quota

Consistent with regulations at §635.27(e), NMFS adjusts the U.S. annual northern albacore quota for allowable underharvest, if any, in the previous year. NMFS makes such adjustments consistent with ICCAT limits when complete catch information for the prior year is available and finalized. Under ICCAT Recommendation 17–04, the maximum underharvest that a Contracting Party may carry forward from one year to the next is 25 percent of its initial catch quota, which, relevant to 2020, would be 158.1 mt for the United States (25 percent of 632.4 mt).

For 2019, the adjusted quota was 790.5 mt (632.4 mt plus 158.1 mt of 2018 underharvest carried forward to 2019, based on 25 percent of the 632.4-mt quota in place for 2018) (83 FR 51391, October 11, 2018). The total 2019 northern albacore catch, which includes landings and dead discards, was 221.36 mt, which is an underharvest of 569.14 mt of the 2019 adjusted quota. Of this underharvest, 158.1 mt may be carried forward to the 2020 fishing year. Thus, the adjusted 2020 northern albacore quota is 632.4 mt plus 158.1 mt, totaling 790.5 mt.

North and South Atlantic Swordfish Annual Quota and Adjustment Process

North Atlantic Swordfish

Consistent with the North Atlantic swordfish quota regulations at §635.27(c), NMFS adjusts the U.S. annual North Atlantic swordfish quota for allowable underharvest, if any, in the previous year. NMFS makes such adjustments consistent with ICCAT limits and when complete catch information for the prior year is available and finalized. Under ICCAT Recommendation 17–03, the U.S. North Atlantic swordfish baseline annual quota for 2020 is 75.2 mt dw (100 mt ww) and the amount of underharvest that the United States can carry forward from one year to the next is 100 percent of the baseline quota (75.2 mt dw).

Recommendation 17–03 continues to require the United States to transfer a total of 75.2 mt dw (100 mt ww) to other countries. These transfers are 37.6 mt dw (50 mt ww) to Namibia, 18.8 mt dw (25 mt ww) to Côte d’Ivoire, and 18.8 mt dw (25 mt ww) to Belize. U.S. fishermen landed no South Atlantic swordfish in 2019. The adjusted 2019 South Atlantic swordfish quota was 75.1 mt dw due to nominal landings in previous years. Therefore, 75.1 mt dw of underharvest is available to carry over to 2020. NMFS is carrying forward 75.1 mt dw to be added to the

South Atlantic Swordfish

Consistent with the South Atlantic swordfish quota regulations at §635.27(c), NMFS adjusts the U.S. annual South Atlantic swordfish quota for allowable underharvest, if any, in the previous year. NMFS makes such adjustments consistent with ICCAT limits when complete catch information for the prior year is available and finalized. Under ICCAT Recommendation 17–03, the U.S. South Atlantic swordfish baseline annual quota for 2020 is 75.2 mt dw (100 mt ww) and the amount of underharvest that the United States can carry forward from one year to the next is 100 percent of the baseline quota (75.2 mt dw).

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75.2 mt dw baseline quota. The quota is then reduced by the 75.2 mt dw of annual international quota transfers outlined above, resulting in an adjusted South Atlantic swordfish quota of 75.1 mt dw for the 2020 fishing year (Table 1).

### TABLE 1—2020 NORTH AND SOUTH ATLANTIC SWORDFISH QUOTAS

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<tr>
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<th>2019</th>
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<tr>
<td><strong>North Atlantic Swordfish Quota (mt dw)</strong></td>
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<tr>
<td>Baseline Quota</td>
<td>2,937.6</td>
<td>2,937.6</td>
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<tr>
<td>International Quota Transfer</td>
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<tr>
<td>Total Underharvest from Previous Year</td>
<td>1,979</td>
<td>1,906.25</td>
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<td>Underharvest Carryover from Previous Year †</td>
<td>(+) 440.6</td>
<td>(+) 440.6</td>
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<tr>
<td>Adjusted Quota</td>
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<td>Incidental Category</td>
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<td>Reserve Category</td>
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| **South Atlantic Swordfish Quota (mt dw)** |          |          |
| Baseline Quota            |75.2      | 75.2     |
| International Quota Transfers * | (-) 75.2 | (-) 75.2 |
| Total Underharvest from Previous Year | 75.1     | 75.1     |
| Underharvest Carryover from Previous Year † | 75.1     | 75.1     |
| Adjusted quota            | 75.1     | 75.1     |

† Allowable underharvest carryover is capped at 15 percent of the baseline quota allocation for the North Atlantic and 75.2 mt (100 mt ww) for the South Atlantic.

* Under ICCAT Recommendations 17–04, the United States transfers 75.2 mt dw (100 mt ww) annually to Namibia (37.6 mt dw, 50 mt ww), Côte d’Ivoire (18.8 mt dw, 25 mt ww), and Belize (18.8 mt dw, 25 mt ww).

**BFT Annual Quota and Adjustment Process**

Consistent with the regulations regarding annual BFT quota adjustment at §635.27(a), NMFS annually announces the addition of available underharvest, if any, to the BFT Reserve category once complete catch information is available and finalized.

NMFS implemented relevant provisions of the current ICCAT western Atlantic BFT recommendation (Recommendation 17–06) in a final rule that published in October 2018 (83 FR 51391, October 11, 2018). That rulemaking implemented the recommended annual U.S. baseline quota of 1,247.86 mt, plus an additional 25 mt to account for bycatch related to pelagic longline fisheries in the Northeast Distant gear restricted area (NED), for a total of 1,272.86 mt. The total annual U.S. BFT quota of 1,272.86 mt is codified at §635.27(a) and will remain in effect until changed (for instance, if a new ICCAT western Atlantic BFT TAC recommendation is adopted). The maximum underharvest that a Contracting Party may carry forward from one year to the next is 10 percent of its initial catch quota, which, for the United States, is 127.3 mt for 2020 (10 percent of 1,272.86 mt).

**Adjustment of the 2020 BFT Reserve Category Quota**

The United States is carrying forward the full, allowable 127.3 mt for 2020. In 2019, the adjusted BFT quota was 1,400.16 mt (baseline quota of 1,272.86 mt + 127.3 mt of 2018 underharvest carried over to 2019). The total 2019 BFT catch, including landings and dead discards, was 1,185.11 mt, which is an underharvest of 215.05 mt from the 2019 adjusted quota and exceeds the allowable carryover of 127.3 mt. When carrying over underharvest from one year to the next, NMFS uses the underharvest to augment the BFT Reserve category quota. Thus, for 2020, NMFS augments the Reserve category quota with the allowable carryover of 127.3 mt.

The codified Reserve category quota is 29.5 mt. Effective February 5, 2020, NMFS adjusted the Reserve category quota for 2020 to 143 mt by reallocating 164.5 mt of Purse Seine quota to the Reserve category (based on 2019 catch by Purse Seine category participants) and also transferring 51 mt of Reserve category quota to the General category (85 FR 6828, February 6, 2020). Effective July 13, 2020, NMFS transferred 30 mt from the Reserve category quota to the Harpoon category (85 FR 43148, July 16, 2020), leaving a total of 113 mt in the Reserve category. Thus, as of the effective date of this action (October 1, 2020) the adjusted 2020 Reserve category quota is 240.3 mt (113 mt + 127.3 mt).

**Classification**

This action is being taken under the authority of the Magnuson-Stevens Act, section 304(g), and ATCA, section 971(d)(1)(A).

The Assistant Administrator for NMFS (AA) finds that it is unnecessary and would be contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the reasons described below.

Pursuant to section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)), the AA finds that it is unnecessary and would be contrary to the public interest to provide prior notice of, and an opportunity for public comment on, the formulaic quota adjustment processes for the northern albacore, Atlantic bluefin tuna, and swordfish fisheries and the manner in which they occur. These processes have not changed, and the application of these formulas in this action does not have discretionary aspects requiring additional agency consideration. Thus, it would be unnecessarily duplicative to
accept public comment for this action. There are no new quotas for 2020, and the quota formulas are the same as in previous years. NMFS therefore is issuing this temporary final rule to adjust the northern albacore, North and South Atlantic swordfish, and western Atlantic BFT quotas for 2020 without prior notice and an additional opportunity for comment.

There is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date and to make the rule effective upon publication in the Federal Register. The fisheries for northern albacore, North and South Atlantic swordfish, and BFT began on January 1, 2020. NMFS monitors northern albacore, North and South Atlantic swordfish, and BFT annual catch and measures the annual catch data against the applicable available quotas. Delaying the effective date of these quota adjustments would affect reasonable opportunity to catch the available quotas. It could also cause complications for management under certain circumstances. For example, under the northern albacore fishery closure regulations, NMFS must close the fishery when the annual fishery quota is reached. Closure of the fishery based only on the baseline (codified) quota versus the adjusted northern albacore quota could preclude the fishery from harvesting northern albacore that are legally available consistent with the ICCAT recommendations and the 2006 Consolidated HMS FMP, as amended. Adjusting the North and South Atlantic swordfish quota allows the United States to take advantage of the ICCAT allowance to carry over quota underharvest and to comply with the South Atlantic swordfish recommendation’s obligation to transfer quota internationally. Adjusting the BFT Reserve category as soon as possible provides NMFS the flexibility to transfer quota from the Reserve to other fishing categories inseason after considering the regulatory determination criteria, including fishery conditions at the time of the transfer.

This action is exempt from review under Executive Order 12866.

This action does not contain a collection-of-information requirement for purposes of the Paperwork Reduction Act.

Because prior notice and opportunity for public comment are not required for this rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., are inapplicable.

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


Samuel D. Rauch III,
Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2020–20399 Filed 9–30–20; 8:45 am]
BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
50 CFR Part 679
[Docket No. 200221–0062; RTID 0648–XA530]

Fisheries of the Exclusive Economic Zone Off Alaska; Exchange of Flatfish in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is exchanging allocations of Amendment 80 cooperative quota (CQ) for Amendment 80 acceptable biological catch (ABC) reserves. This action is necessary to allow the 2020 total allowable catch (TAC) of flathead sole, rock sole, and yellowfin sole in the Bering Sea and Aleutian Islands management area (BSAI) to be harvested.


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

The 2020 flathead sole, rock sole, and yellowfin sole Amendment 80 allocations of the TAC specified in the BSAI are 14,414 metric tons (mt), 36,060 mt, and 113,403 mt, respectively, as established by the final 2020 and 2021 harvest specifications for groundfish in the BSAI (85 FR 13553, March 9, 2020). The 2020 flathead sole, rock sole, and yellowfin sole Amendment 80 ABC reserves are 43,430 mt, 94,837 mt, and 98,425 mt, respectively, as established by the final 2020 and 2021 harvest specifications for groundfish in the BSAI (85 FR 13553, March 9, 2020).

The Alaska Seafood Cooperative has requested that NMFS exchange 1,530 mt of flathead sole Amendment 80 allocation of the TAC for 30 mt of rock sole and 1,500 mt of yellowfin sole Amendment 80 ABC reserves under § 679.91(i). Therefore, in accordance with § 679.91(i), NMFS exchanges 1,530 mt of flathead sole Amendment 80 allocation of the TAC for 30 mt of rock sole and 1,500 mt of yellowfin sole Amendment 80 ABC reserves in the BSAI. This action also decreases and increases the TACs and Amendment 80 ABC reserves by the corresponding amounts. Tables 11 and 13 of the final 2020 and 2021 harvest specifications for groundfish in the BSAI (85 FR 13553, March 9, 2020) and as revised (85 FR 59204, September 21, 2020) are further revised as follows:

TABLE 11—FINAL 2020 COMMUNITY DEVELOPMENT QUOTA (CDQ) RESERVES, INCIDENTAL CATCH AMOUNTS (ICAS), AND AMENDMENT 80 ALLOCATIONS OF THE ALEUTIAN ISLANDS PACIFIC OCEAN PERCH, AND BSAI FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE TACS

[Amounts are in metric tons]

<table>
<thead>
<tr>
<th>Sector</th>
<th>Pacific ocean perch</th>
<th>Flathead sole</th>
<th>Rock sole</th>
<th>Yellowfin sole</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Eastern Aleutian</td>
<td>Central</td>
<td>Western</td>
<td>BSAI</td>
</tr>
<tr>
<td></td>
<td>District</td>
<td>Aleutian</td>
<td>Aleutian</td>
<td></td>
</tr>
<tr>
<td>TAC</td>
<td>10,613</td>
<td>8,094</td>
<td>10,000</td>
<td>17,845</td>
</tr>
<tr>
<td>CDQ</td>
<td>1,136</td>
<td>666</td>
<td>1,070</td>
<td>1,962</td>
</tr>
<tr>
<td>ICA</td>
<td>100</td>
<td>60</td>
<td>10</td>
<td>3,000</td>
</tr>
</tbody>
</table>
### Table 11—Final 2020 Community Development Quota (CDQ) Reserves, Incidental Catch Amounts (ICAS), and Amendment 80 Allocations of the Aleutian Islands Pacific Ocean Perch, and BSAI Flathead Sole, Rock Sole, and Yellowfin Sole TACs—Continued

[Amounts are in metric tons]

<table>
<thead>
<tr>
<th>Sector</th>
<th>Pacific ocean perch</th>
<th>Flathead sole</th>
<th>Rock sole</th>
<th>Yellowfin sole</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Eastern Aleutian</td>
<td>BSAI</td>
<td>BSAI</td>
<td>BSAI</td>
</tr>
<tr>
<td></td>
<td>District</td>
<td>District</td>
<td>District</td>
<td></td>
</tr>
<tr>
<td>BSASI trawl limited access</td>
<td>938</td>
<td>717</td>
<td>178</td>
<td>17,172</td>
</tr>
<tr>
<td>Amendment 80</td>
<td>8,440</td>
<td>6,451</td>
<td>8,742</td>
<td>12,884</td>
</tr>
</tbody>
</table>

**Note:** Sector apportionments may not total precisely due to rounding.

### Table 13—Final 2020 and 2021 ABC Surplus, ABC Reserves, Community Development Quota (CDQ) ABC Reserves, and Amendment 80 ABC Reserves in the BSAI for Flathead Sole, Rock Sole, and Yellowfin Sole

[Amounts are in metric tons]

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC</td>
<td>68,134</td>
<td>153,300</td>
<td>260,918</td>
<td>71,079</td>
<td>230,700</td>
<td>261,497</td>
</tr>
<tr>
<td>TAC</td>
<td>17,845</td>
<td>46,955</td>
<td>152,530</td>
<td>24,000</td>
<td>49,000</td>
<td>168,900</td>
</tr>
<tr>
<td>ABC surplus</td>
<td>50,289</td>
<td>106,345</td>
<td>108,388</td>
<td>47,079</td>
<td>181,700</td>
<td>92,597</td>
</tr>
<tr>
<td>ABC reserve</td>
<td>50,289</td>
<td>106,345</td>
<td>108,388</td>
<td>47,079</td>
<td>181,700</td>
<td>92,597</td>
</tr>
<tr>
<td>CDQ ABC reserve</td>
<td>5,329</td>
<td>11,538</td>
<td>11,493</td>
<td>5,037</td>
<td>19,442</td>
<td>9,908</td>
</tr>
<tr>
<td>Amendment 80 ABC reserve</td>
<td>44,960</td>
<td>94,807</td>
<td>96,895</td>
<td>42,042</td>
<td>162,258</td>
<td>82,689</td>
</tr>
</tbody>
</table>

1 The 2021 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2020.

### Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866. Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the flatfish exchange by the Alaska Seafood Cooperative in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 23, 2020.

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


Jennifer M. Wallace,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–21751 Filed 9–28–20; 4:15 pm]
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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39


RIN 2120–AA64

Airworthiness Directives; Saab AB, Support and Services (Formerly Known as Saab AB, Saab Aeronautics) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Saab AB, Support and Services Model SAAB 2000 airplanes. This proposed AD was prompted by a report of inadvertently reversed connections of the outboard and inboard channel harnesses of the wheel speed transducers in the main landing gear (MLG) wheel axles. This proposed AD would require an inspection for correct installation of the MLG anti-skid system harnesses and corrective actions if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which will be incorporated by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by November 16, 2020.

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

- **Federal eRulemaking Portal:** Go to https://www.regulations.gov. Follow the instructions for submitting comments.
- **Fax:** 202–493–2251.
- **Mail:** U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

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

For material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADs@easa.europa.eu; internet: www.easa.europa.eu. You may find this IBR material on the EASA website at https://ad.easa.europa.eu. You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0855.

Examining the AD Docket

You may examine the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0855; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Shahram Daneshmandi, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 50318; phone and fax: 206–231–3220; email: shahram.daneshmandi@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to participate in this rulemaking by submitting written comments, data, or views about this proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time. Send your comments to an address listed under the

Federal Register

Vol. 85, No. 191

Thursday, October 1, 2020


Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments received by the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this NPRM because of those comments.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to the person identified in the FOR FURTHER INFORMATION CONTACT section. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0137, dated June 18, 2020 (“EASA AD 2020–0137”) (also referred to as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for all Saab AB, Support and Services Model SAAB 2000 airplanes.
This proposed AD was prompted by a report of inadvertently reversed connections of the outboard and inboard channel harnesses of the wheel speed transducers in the MLG wheel axles. The FAA is proposing this AD to address inadvertently reversed connections of the outboard and inboard channel of the wheel speed transducers harnesses in the MLG wheel axles, which could lead to wrong inputs to the anti-skid function, whenever activated, with consequent reduced braking capability, and possibly result in damage to the airplane and loss of control during landing. See the MCAI for additional background information.

Related IBR Material Under 1 CFR Part 51

EASA AD 2020–0137 describes procedures for a one-time inspection for correct installation of the outboard and inboard left-hand and right-hand MLG anti-skid system harnesses and corrective actions if necessary. Corrective actions include troubleshooting and verification of the installation of inboard and outboard anti-skid harnesses on the left-hand and right-hand MLG; and removal, inspection, and repair of any incorrectly installed inboard and outboard anti-skid harnesses. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

FAA’s Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is proposing this AD because the FAA evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in EASA AD 2020–0137 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2020–0137 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2020–0137 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in the EASA AD. Service information specified in EASA AD 2020–0137 that is required for compliance with EASA AD 2020–0137 will be available on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0855 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD affects 11 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

<table>
<thead>
<tr>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 work-hours x $85 per hour = $340</td>
<td>$0</td>
<td>$340</td>
<td>$3,740</td>
</tr>
</tbody>
</table>

The FAA has received no definitive data that would enable providing cost estimates for the on-condition actions specified in this proposed AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a “significant regulatory action” under Executive Order 12866,
(2) Will not affect intrastate aviation in Alaska, and
(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

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

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

§39.13 [Amended]

2. The FAA amends §39.13 by adding the following new airworthiness directive (AD):

Saab AB, Support and Services (Formerly Known as Saab AB, Saab Aeronautics):


(a) Comments Due Date

The FAA must receive comments by November 16, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Saab AB, Support and Services Model SAAB 2000 airplanes, certified in any category.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Reason

This AD was prompted by a report of inadvertently reversed connections of the outboard and inboard channel harnesses of the wheel speed transducers in the main landing gear (MLG) wheel axles. The FAA is issuing this AD to address inadvertently reversed connections of the outboard and inboard channel harnesses of the wheel speed transducers in the MLG wheel axles, which could lead to wrong inputs to the anti-skid function, whenever activated, with consequent reduced braking capability, and possibly result in damage to the airplane and loss of control during landing.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2020–0137, dated June 18, 2020 (“EASA AD 2020–0137”).

(h) Exceptions to EASA AD 2020–0137

(1) Where EASA AD 2020–0137 refers to its effective date, this AD requires using the effective date of this AD.

(2) The “Remarks” section of EASA AD 2020–0137 does not apply to this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (j)(2) of this AD.

Action: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Bell Helicopter Textron Canada Limited Model 429 helicopters. This proposed AD was prompted by the introduction of a new life limit for the centrifugal force bearing (CFB). This proposed AD would require determining the accumulated retirement index number (RIN) and removing each affected CFB from service before it accumulates 8,000 total RIN. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by November 16, 2020.

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

• Federal eRulemaking Portal: Go to https://www.regulations.gov. Follow the instructions for submitting comments.

• Fax: 202–493–2251.


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

For service information identified in this NPRM, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l’Avenir, Mirabel, Quebec J7J 1R4; telephone 450–437–2862 or 800–363–0823; fax 450–433–0272; or at https://www.bellcustomer.com. You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

Examining the AD Docket

You may examine the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0860; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the AD docket contains this AD, the

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39


RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron Canada Limited Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Bell Helicopter Textron Canada Limited Model 429 helicopters. This proposed AD was prompted by the introduction of a new life limit for the centrifugal force bearing (CFB). This proposed AD would require determining the accumulated retirement index number (RIN) and removing each affected CFB from service before it accumulates 8,000 total RIN. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by November 16, 2020.

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

• Federal eRulemaking Portal: Go to https://www.regulations.gov. Follow the instructions for submitting comments.

• Fax: 202–493–2251.


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For service information identified in this NPRM, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l’Avenir, Mirabel, Quebec J7J 1R4; telephone 450–437–2862 or 800–363–0823; fax 450–433–0272; or at https://www.bellcustomer.com. You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.
Airworthiness Products Section, General Aviation and Rotorcraft Unit, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email matthew.fuller@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the ADDRESSES section. Include “Docket No. FAA–2020–0860; Product Identifier 2019–SW–005–AD” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this NPRM because of those comments.

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

Confidential Business Information

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

Discussion

TCCA, which is the aviation authority for Canada, issued Transport Canada AD CF–2019–03, dated January 31, 2019 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Bell Helicopter Textron Canada Limited Model 429 helicopters. TCCA advises that an airworthiness limitations schedule document introduces a new life limit for CFB part number (P/N) 429–310–003–103, a component that was not previously included. Failure to observe the CFB life limit could result in excessive vibration and loss of control of the helicopter.


Estimated Costs for Required Actions

<table>
<thead>
<tr>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per helicopter</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>28 work-hours × $85 per hour = $2,380</td>
<td>$42,576 ($10,644 per bearing × 4 blades)</td>
<td>$44,956</td>
<td>$3,821,260</td>
</tr>
</tbody>
</table>

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency’s authority. The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

Other Related Service Information

Bell Helicopter has issued Bell Model 429 Maintenance Planning Information BHT–429–MPI, Chapter 4, Airworthiness Limitations Schedule, DMC–429–A–04–00–00A–28A–A, Issue 1, dated January 10, 2019. This service information describes new maintenance requirements and airworthiness limitations.
For the reasons discussed above, I certify this proposed regulation:
(1) Is not a “significant regulatory action” under Executive Order 12866,
(2) Will not affect intrastate aviation in Alaska, and
(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39
Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

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

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:
Authority: 49 U.S.C. 106(g), 40113, 44701.

§39.13 [Amended]
2. The FAA amends §39.13 by adding the following new airworthiness directive (AD):

Bell Helicopter Textron Canada Limited:

(a) Comments Due Date
The FAA must receive comments by November 16, 2020.

(b) Affected ADs
None.

(c) Applicability
This AD applies to Bell Helicopter Textron Canada Limited Model 429 helicopters, certified in any category, serial numbers 57001 through 57351 inclusive.

(d) Subject
Joint Aircraft Service Component (JASC) Code 6200, Main rotor system.

(e) Reason
This AD was prompted by the introduction of a new life limit for the centrifugal force bearing (CFB). The FAA is issuing this AD to address a CFB remaining in service beyond its fatigue life. Failure to observe the CFB life limit could result in excessive vibration and loss of control of the helicopter.

(f) Compliance
Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions
For each CFB having part number 429–310–005–103 (the affected CFB); Within 50 hours time-in-service, determine the accumulated retirement index number (RIN). For purposes of this AD, count 1 RIN each time one or both engines are started. If any affected CFB has accumulated 8,000 or more total RIN, before further flight, remove the affected CFB from service. If any affected CFB has accumulated less than 8,000 total RIN, create a component history card or equivalent record indicating a life limit of 8,000 total RIN. Thereafter, continue to count RIN and record the life limit of the affected CFB on its component history card or equivalent record and remove the affected CFB from service before accumulating 8,000 total RIN.

(h) Alternative Methods of Compliance (AMOCs)
(1) The Manager, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Fuller, AD Program Manager, Continued Operational Safety Branch, Airworthiness Products Section, General Aviation and Rotorcraft Unit, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email 9–ASW–FTW–AMOC–Requests@faa.gov.
(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, notify your principal inspector or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(i) Related Information
(1) Bell Model 429 Maintenance Planning Information BHT–429–MPI, Chapter 4, Airworthiness Limitations Schedule, DMC–429–A–04–00–000A–288A–A, Issue 1, dated January 10, 2019, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l’Avenir, Mirabel, Quebec J7I 1R4; telephone 450–437–2862 or 800–363–8023; fax 450–433–0272; or at https://www.bellecustomer.com. You may view a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

Lance T. Gant,
Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–21608 Filed 9–30–20; 8:45 am]
BILLING CODE 4910–13–P
and locating Docket No. FAA–2020–0859; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:
Siddeeq Bacchus, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7362; fax 516–794–5531; email 9-avs-nyuco-cos@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited
The FAA invites you to participate in this rulemaking by submitting written comments, data, or views about this proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time. Send your comments to an address listed under the ADDRESSES section. Include “Docket No. FAA–2020–0859; Product Identifier 2020–NM–084–AD” at the beginning of your comments. Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments received by the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this NPRM because of those comments.

Confidential Business Information
CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to the person identified in the FOR FURTHER INFORMATION CONTACT section. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion
Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2020–12, dated April 17, 2020 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Bombardier, Inc., Model BD–100–1A10 airplanes. You may examine the MCAI in the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0859.

This proposed AD was prompted by reports of failure of a certain FIREX control unit. The subsequent investigation determined that the potential cause of these failures is the FIREX control unit’s susceptibility to internal electrical noise. The FAA is proposing this AD to address the failure of a FIREX control unit, which could result in the loss of the ability to detect a fire. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51
Bombardier, Inc., has issued Service Bulletin 100–26–01, Revision 01, dated December 5, 2019; and Service Bulletin 350–26–001, Revision 01, dated December 5, 2019. This service information describes procedures for replacing FIREX control units having part number (P/N) 474112–2 with units having P/N 474112–3. These documents are distinct since they apply to different airplane configurations. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

FAA’s Determination
This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because the FAA evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed Requirements of This NPRM
This proposed AD would require accomplishing the actions specified in the service information described previously.

Costs of Compliance
The FAA estimates that this proposed AD affects 223 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

<table>
<thead>
<tr>
<th>ESTIMATED COSTS FOR REQUIRED ACTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labor cost</td>
</tr>
<tr>
<td>1 work-hour × $85 per hour = $85</td>
</tr>
</tbody>
</table>

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in our cost estimate.

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a “significant regulatory action” under Executive Order 12866, (2) Will not affect intrastate aviation in Alaska, and (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

§ 39.13 [Amended]

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):


(a) Comments Due Date

The FAA must receive comments by November 16, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–100–1A10 airplanes, certificated in any category, serial numbers 20003 through 20500 inclusive, and 20501 through 20669 inclusive, fitted with fire detection and extinguishing (FIREX) control unit part number (P/N) 474112–2.

(d) Subject

Air Transport Association (ATA) of America Code 26, Fire protection.

(e) Reason

This AD was prompted by reports of failure of a certain FIREX control unit. The FAA is issuing this AD to address failure of a FIREX control unit, which could result in the loss of the ability to detect a fire.

(f) Compliance

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

(g) Replacement

Within 24 months after the effective date of this AD: Replace any FIREX control unit having P/N 474112–2 with a unit having P/N 474112–3, in accordance with paragraphs 2.B.(1) and (3) of the Accomplishment Instructions of the applicable Bombardier, Inc., service bulletin specified in paragraphs (g)(1) and (2) of this AD.

(1) For airplanes having serial numbers 20003 through 20500 inclusive: Bombardier Service Bulletin 100–26–01, Revision 01, dated December 5, 2019.

(2) For airplanes having serial numbers 20501 through 20669 inclusive: Bombardier Service Bulletin 350–26–001, Revision 01, dated December 5, 2019.

(h) Parts Installation Prohibition

As of the effective date of this AD, no person may install a FIREX control unit having P/N 474112–2 on any airplane.

(i) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 100–26–01, dated December 20, 2016; or Bombardier Service Bulletin 350–26–001, dated December 20, 2016, as applicable.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) Contacting the Manufacturer: For any reopening of this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier Inc.’s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) TCCA AD CF–2020–12, dated May 1, 2020, for related information. This MCAI may be found in the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0859.

(2) For more information about this AD, contact Siddeeq Bacchus, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7362; fax 516–794–5531; email 9-avs-nyaco-cos@faa.gov.

(3) For service information identified in this AD, contact Bombardier, Inc., 200 Côte Vertu Road West, Dorval, Québec H4S 2A3, Canada; North America toll-free telephone 1 866 538 1247 or direct-dial telephone 1 514 855 2999; email ac.yul@aero.bombardier.com; internet https://www.bombardier.com. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on September 24, 2020.

Gaetano A. Sciortino,
Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–21565 Filed 9–30–20; 8:45 am]

BILLING CODE 4910–13–P
DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39


RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus SAS Model A318 series airplanes; Model A319–111, A319–112, A319–113, A319–114, A319–115, A319–131, A319–132, A319–133, A319–151N, and A319–153N airplanes; Model A320 series airplanes; and Model A321 series airplanes. This proposed AD was prompted by the results of laboratory tests on non-rechargeable lithium batteries installed in emergency locator transmitters (ELT), which highlighted a lack of protection against certain currents that could lead to thermal runaway and a battery fire. This proposed AD would require modifying a certain ELT by installing a diode in the airplane circuit connecting the ELT battery, as specified in a European Union Aviation Safety Agency (EASA) AD, which will be incorporated by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by November 16, 2020.

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

- Federal eRulemaking Portal: Go to https://www.regulations.gov. Follow the instructions for submitting comments.
- Hand Delivery: Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this IBR material on the EASA website at https://ad.easa.europa.eu. You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0900.

Examining the AD Docket

You may examine the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0900; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:
Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 50318; telephone and fax 206–231–2323; email Sanjay.Ralhan@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to participate in this rulemaking by submitting written comments, data, or views about this proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one copy of the comments. Send your comments to an address listed under the ADDRESSES section. Include “Docket No. FAA–2020–0900; Product Identifier 2020–NM–080–AD” at the beginning of your comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments received by the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this NPRM because of those comments.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to the person identified in the FOR FURTHER INFORMATION CONTACT section. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion


This proposed AD was prompted by the results of laboratory tests on nonrechargeable lithium batteries installed in ELTs, which highlighted a
lack of protection against currents of 28 volts DC or 115 volts AC that could lead to thermal runaway and a battery fire. The FAA is proposing this AD to address this unsafe condition, which could result in local (temporary) fires and could result in damage to the airplane and injury to occupants. See the MCAI for additional background information.

Related IBR Material Under 1 CFR Part 51

EASA AD 2020–0103 describes procedures for modifying a certain ELT by installing a diode in the airplane circuit connecting the ELT battery. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

FAA’s Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is proposing this AD because the FAA evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in EASA AD 2020–0103 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2020–0103 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2020–0103 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled...

ESTIMATED COSTS FOR REQUIRED ACTIONS

<table>
<thead>
<tr>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 work-hours × $85 per hour = $255</td>
<td>$450</td>
<td>$705</td>
<td>$775,500</td>
</tr>
</tbody>
</table>

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in our cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a “significant regulatory action” under Executive Order 12866,
(2) Will not affect intrastate aviation in Alaska, and
(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.
List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

§ 39.13 [Amended]

1. The authority citation for part 39 continues to read as follows:
   Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):


(a) Comments Due Date

The FAA must receive comments by November 16, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Airbus SAS airplanes specified in paragraphs (c)(1) through (4) of this AD, certificated in any category, all manufacturer serial numbers.


(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings.

(e) Reason

This AD was prompted by the results of laboratory tests on non-rechargeable lithium batteries installed in emergency locator transmitters (ELT), which highlighted a lack of protection against currents of 28 volts DC or 115 volts AC that could lead to thermal runaway and a battery fire. The FAA is issuing this AD to address this unsafe condition, which could result in local (temporary) fires, and could result in damage to the airplane and injury to occupants.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2020–0103, dated May 7, 2020; corrected May 8, 2020 (“EASA AD 2020–0103”).

(h) Exceptions to EASA AD 2020–0103

(1) Where EASA AD 2020–0103 refers to its effective date, this AD requires using the effective date of this AD.

(2) The “Remarks” section of EASA AD 2020–0103 does not apply to this AD.

(3) Where paragraph (3) of EASA AD 2020–0103 specifies the parts installation limitation, for this AD, comply with paragraph (i) of this AD.

(i) Parts Installation Limitation

(1) For airplanes that do not have an ELT having part number (P/N) 01N65900 installed as of the effective date of this AD: As of the effective date of this AD, no person may install an ELT having P/N 01N65900 on any airplane unless the airplane has been modified as required by paragraph (1) of EASA AD 2020–0103.

(2) For airplanes that have an ELT having P/N 01N65900 installed as of the effective date of this AD: After modification of the airplane as required by paragraph (1) of EASA AD 2020–0103, no person may install an ELT having P/N 01N65900 on that airplane if the modification is removed.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: 9-AVS-AIR-730-AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) Required for Compliance (RC): For any service information referenced in EASA AD 2020–0103 that contains RC procedures and tests: Except as required by paragraph (j)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

(1) For information about EASA AD 2020–0103, contact the EASA, Konrad-Adenauer Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may view this EASA AD on the EASA website at https://ad.easa.europa.eu. You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0900.

(2) For more information about this AD, contact Sanjay Balhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98178; telephone and fax 206–231–3223; email Sanjay.Balhan@faa.gov.

Issued on September 25, 2020.

Lance T. Gant,
Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–21628 Filed 9–30–20; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39


RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Division Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Pratt & Whitney Division (PW) PW4164, PW4164–1D, PW4168, PW4168–1D, PW4168A, PW4168A–1D,
and PW4170 model turbofan engines. This AD was prompted by several reports of low pressure turbine (LPT) 4th stage vane cluster assemblies leaning back and notching into the rotating LPT 4th stage blades, causing some blades to fracture and release. An investigation by the manufacturer into those reports determined that the leaning back of the LPT 4th stage vane cluster assemblies was caused by damage to the LPT 4th stage air sealing ring segment assemblies. This proposed AD would require initial and repetitive replacements of the LPT 4th stage air sealing ring segment assemblies with parts eligible for installation. This proposed AD would also require initial and repetitive dimensional inspections of the LPT case for bulging and, depending on the results of the dimensional inspection, repair or replacement of the LPT case. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by November 16, 2020.

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

• Federal eRulemaking Portal: Go to https://www.regulations.gov. Follow the instructions for submitting comments.

• Fax: 202–493–2251.


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

For service information identified in this NPRM, contact Pratt & Whitney Division, 400 Main Street, East Hartford, CT 06118; phone: (800) 565–0140; email: help24@pw.utc.com; website: http://fleetcare.pw.utc.com. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759.

Examining the AD Docket
You may examine the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–00901; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Carol Nguyen, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7655; fax: (781) 238–7199; email: carol.nguyen@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited
The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the ADDRESSES section. Include “Docket No. FAA–2020–00901; Project Identifier AD–2020–00705–E” at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information
Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ‘‘PROPIN.’’ The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Carol Nguyen, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background
The FAA received 6 reports from the manufacturer concerning LPT 4th stage vane cluster assemblies leaning back and notching into rotating LPT 4th stage blades, causing some blades to fracture and release. These incidents resulted in an aborted takeoff, air turnbacks, engine surges, high vibrations, and unplanned engine removals. The incidents were attributed to the LPT 4th stage air sealing ring segment assemblies moving into the LPT 4th stage blades knife edge seals, resulting in damage to the ring segment assemblies. As a result of this damage, gas-path air escapes and impinging on the LPT case. This can distort (create local bulging) the LPT case rail, causing the LPT 4th stage vanes to lean back and contact the LPT 4th stage blades. This condition, if not addressed, could result in uncontained release of LPT 4th stage blades, damage to the engine, and damage to the airplane.

FAA’s Determination
The FAA is proposing this AD because the agency evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Service Information Incorporated by Reference Under 1 CFR Part 51
The FAA reviewed PW Alert Service Bulletin (ASB) No. PW4G–100–A72–262, revision No. 1, dated September 3, 2020. The ASB describes procedures for replacing the LPT 4th stage air sealing ring segment assemblies and inspecting the LPT case for bulging. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Proposed AD Requirements
This proposed AD would require initial and repetitive replacement of the LPT 4th stage air sealing ring segment assemblies with parts eligible for installation. This proposed AD would also require initial and repetitive dimensional inspections of the LPT case for bulging and, depending on the results of the dimensional inspection, repair or replacement of the LPT case.

Costs of Compliance
The FAA estimates that this AD, as proposed, would affect 99 engines installed on airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:
The FAA estimates the following costs to perform necessary repair or replacement that would be required based on the results of the proposed dimensional inspection. The FAA has no way of determining how many engines will need to repair or replace the LPT case.

<table>
<thead>
<tr>
<th>Action</th>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>LPT case dimensional inspection</td>
<td>2 work-hours × $85 per hour = $170</td>
<td>$0</td>
<td>$170</td>
<td>$16,830</td>
</tr>
<tr>
<td>Replace the LPT 4th stage air sealing ring</td>
<td>50 work-hours × $85 per hour = $4,250</td>
<td>64,592</td>
<td>68,842</td>
<td>6,815,358</td>
</tr>
</tbody>
</table>

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866,
2. Will not affect intrastate aviation in Alaska, and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):


(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by November 16, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pratt & Whitney Division (PW) PW4164, PW4164–1D, PW4168, PW4168–1D, PW4168A, PW4168A–1D, and PW4170 model turbofan engines with low pressure turbine (LPT) 4th stage air sealing ring segment assemblies, part number (P/N) 50N463–01 or P/N 50N526–1, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7250, Turbine Section.

(e) Unsafe Condition

This AD was prompted by several reports from the manufacturer concerning LPT 4th stage vane cluster assemblies leaning back and notching into the rotating LPT 4th stage blades, causing some blades to fracture and release. A manufacturer investigation into those reports determined that the leaning back of the LPT 4th stage vane cluster assemblies was caused by damage to the LPT 4th stage air sealing ring segment assemblies. The FAA is issuing this AD to prevent damage to the LPT 4th stage air sealing ring segment assemblies, the LPT case, and the LPT 4th stage blades. The unsafe condition, if not addressed, could result in uncontained release of the LPT 4th stage blades, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

1. For affected engines that have either the Talon HA outer combustion chamber assembly, part number (P/N) 51J100 or P/N 51J382, or the Talon IIB outer combustion chamber assembly, P/N 51J381 or P/N 51J500, installed, at the next engine shop visit after the effective date of this AD, remove from service the LPT 4th stage air sealing ring segment assemblies, P/N 50N463–01 or P/N 50N526–01, and replace with parts eligible for installation.

2. For affected engines not referenced in paragraph (g)(1) of this AD, at the next LPT overhaul after the effective date of this AD, remove from service the LPT 4th stage air sealing ring segment assemblies, P/N 50N463–01 or P/N 50N526–01, and replace with parts eligible for installation.

3. For all affected engines, at each LPT overhaul after compliance with the required actions in paragraphs (g)(1) or (g)(2) of this AD, remove from service the LPT 4th stage air sealing ring segment assemblies, P/N 50N463–01 or P/N 50N526–01, and replace with parts eligible for installation.

4. During each replacement of the LPT 4th stage air sealing ring segment assemblies

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### ESTIMATED COSTS

<table>
<thead>
<tr>
<th>Action</th>
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<th>Parts cost</th>
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<td>6,815,358</td>
</tr>
</tbody>
</table>

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### On-Condition Costs

<table>
<thead>
<tr>
<th>Action</th>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>LPT case repair to restore dimensions</td>
<td>250 work-hours × $85 per hour = $21,250</td>
<td>$0</td>
<td>$0</td>
<td>$21,250</td>
</tr>
<tr>
<td>Replace the LPT case</td>
<td>0 work-hours × $85 per hour = $0</td>
<td>1,300,000</td>
<td>1,300,000</td>
<td></td>
</tr>
</tbody>
</table>

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required by paragraphs (g)(1), (g)(2), and (g)(3) of this AD, perform a dimensional inspection of the LPT case for bulging in accordance with the Accomplishment Instructions, paragraph 2, of PW ASB PW4G–100–A72–262 revision No. 1, dated September 3, 2020 ("the ASB").

(5) If, during the dimensional inspection of the LPT case required by paragraph (g)(4) of this AD, any LPT case is found to be outside the serviceable limits specified in Table 1: Serviceable Limits and Repairs of the ASB, repair or replace the LPT case before further flight.

(h) Definitions

For the purpose of this AD:

(1) An "engine shop visit" is the induction of an engine into the shop for maintenance involving the separation of pairs of mating engine flanges (lettered flanges). The separation of engine flanges solely for the purpose of transportation without subsequent engine maintenance does not constitute an engine shop visit.

(2) An "LPT overhaul" is when the LPT rotor is removed from the engine, all four disks are removed from the LPT rotor, and all blades are removed from the disks.

(3) "Parts eligible for installation" are LPT 4th stage air sealing ring segment assemblies, P/N 50N526–01, with zero flight cycles since 4th stage air sealing ring segment assemblies, disks are removed from the LPT rotor, and all disks are removed from the disks.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. You may email your request to: AINE-AMOC@faa.gov.

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

(j) Related Information

(1) For more information about this AD, contact Carol Nguyen, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA, 01803; phone: (781) 238–7655; fax: (781) 238–7199; email: carol.nguyen@faa.gov.

(2) For service information identified in this AD, contact Pratt & Whitney Division, 400 Main Street, East Hartford, CT 06118; phone: (800) 565–0140; email: help24@pw.utc.com; website: http://fleetcare.pw.utc.com. You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759.

Issued on September 25, 2020.

Lance T. Gant,
Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–21607 Filed 9–30–20; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

14 CFR Part 39


RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2020–01–10, which applies to certain Airbus SAS Model A350–941 airplanes. AD 2020–01–10 requires installing flight control and guidance system (FCGSS) software (SW) X11 Standard (STD). Since the FAA issued AD 2020–01–10, Airbus has developed a modification that forces the air generation system (AGS) ram air outlet doors to be flush in cases of total engine flameout or loss of the main electrical supply. Because of this additional modification, certain airplanes that were excluded from the applicability of AD 2020–01–10 are included in the applicability of this proposed AD. This proposed AD would retain the requirements of AD 2020–01–10, require modifying the electrical power supply of the AGS ram air outlet door actuators, and expand the applicability by adding airplanes, as specified in a European Union Aviation Safety Agency (EASA) AD, which will be incorporated by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by November 16, 2020.

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

• Federal eRulemaking Portal: Go to https://www.regulations.gov. Follow the instructions for submitting comments.
• Fax: 202–493–2251.

• Hand Delivery: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For the material identified in this proposed AD that will be incorporated by reference (IBR), contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may find this IBR material on the EASA website at https://ad.easa.europa.eu. You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0854.

Examining the AD Docket

You may examine the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0854; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Kathleen Arrigotti, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 50198; telephone and fax 206–231–3218; email Kathleen.Arrigotti@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to participate in this rulemaking by submitting written comments, data, or views about this proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time. Send your comments to an address listed under the ADDRESSES section. Include “Docket No. FAA–2020–0854; Project Identifier
MCAI–2020–01067–T” at the beginning of your comments. Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.33, the FAA will post all comments received, without change, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments received by the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this NPRM because of those comments.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to the person identified in the FOR FURTHER INFORMATION CONTACT section. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The FAA issued AD 2020–01–10, Amendment 39–19816 (85 FR 6747, February 6, 2020) (“AD 2020–01–10”), which applies to certain Airbus SAS Model A350–941 airplanes. AD 2020–01–10 requires installing FCGS SW X11 STD. The FAA issued AD 2020–01–10 to address ram air turbine (RAT) performance that may be below the expected (certificated) level when the landing gear is extended. This condition, if not corrected, could lead to partial or total loss of RAT electrical power generation when the RAT is deployed in an emergency situation, possibly resulting in reduced control of the airplane.

Actions Since AD 2020–01–10 Was Issued

Since the FAA issued AD 2020–01–10, Airbus has developed a modification that forces the AGS ram air outlet doors to be flush in cases of total engine flameout or loss of the main electrical supply. Because of this additional modification, certain airplanes that were excluded from the applicability of AD 2020–01–10 are included in the applicability of this proposed AD.

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0167, dated July 27, 2020 (“EASA AD 2020–0167”) (also referred to as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Airbus A350–941 airplanes. EASA AD 2020–0167 supersedes EASA AD 2019–0203 (which corresponds to FAA AD 2020–01–10).

This proposed AD was prompted by a determination through testing that RAT performance may be below the expected (certificated) level when the landing gear is extended, and by the development of a modification that forces the AGS ram air outlet doors to be flush in cases of total engine flameout or loss of the main electrical supply. The FAA is proposing this AD to address RAT performance that may be below the expected (certificated) level when the landing gear is extended, which could lead to partial or total loss of RAT electrical power generation when the RAT is deployed in an emergency situation, possibly resulting in reduced control of the airplane. See the MCAI for additional background information.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2020–01–10, this proposed AD would retain all of the requirements of AD 2020–01–10. Those requirements are referenced in EASA AD 2020–0167, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related IBR Material Under 1 CFR Part 51

EASA AD 2020–0167 describes procedures for installing FCGS SW X11 STD and for modifying the electrical power supply of the AGS ram air outlet door actuators. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

FAA’s Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is proposing this AD because the FAA evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in EASA AD 2020–0167 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2020–0167 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2020–0167 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in the EASA AD. Service information specified in EASA AD 2020–0167 that is required for compliance with EASA AD 2020–0167 will be available on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0854 after the FAA final rule is published.
Costs of Compliance

The FAA estimates that this proposed AD affects 13 airplanes of U.S. registry.

### ESTIMATED COSTS FOR REQUIRED ACTIONS

<table>
<thead>
<tr>
<th>Action</th>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retained actions from AD 2020–01–10</td>
<td>8 work-hours × $85 per hour = $680</td>
<td>$4,650</td>
<td>$5,330</td>
<td>$69,290</td>
</tr>
<tr>
<td>New proposed actions</td>
<td>8 work-hours × $85 per hour = $680</td>
<td>1,950</td>
<td>2,630</td>
<td>34,190</td>
</tr>
</tbody>
</table>

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in the cost estimate.

### Authority for This Rulemaking

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

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

### Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

1. Is not a “significant regulatory action” under Executive Order 12866,
2. Will not affect intrastate aviation in Alaska, and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 39

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

### The Proposed Amendment

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

**PART 39—AIRWORTHINESS DIRECTIVES**

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

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

2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2020–01–10, Amendment 39–19816 (85 FR 6747, February 6, 2020), and adding the following new AD:

   **EASA AD 2020–0167**

   - **Applicability**
     - This AD applies to Airbus SAS Model A350–941 airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2020–0167, dated July 27, 2020 (“EASA AD 2020–0167”).

   **(a) Comments Due Date**

   The FAA must receive comments by November 16, 2020.

   **(b) Affected ADs**


   **(c) Applicability**

   This AD applies to Airbus SAS Model A350–941 airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2020–0167, dated July 27, 2020 (“EASA AD 2020–0167”).

   **(d) Subject**

   Air Transport Association (ATA) of America Code 21, Air Conditioning; and 42, Flight Control and Guidance System.

   **(e) Reason**

   This AD was prompted by a determination through testing that ram air turbine (RAT) performance may be below the expected (certificated) level when the landing gear is extended, and by the development of a modification that forces the air generation system (AGS) ram air outlet doors to be flush in cases of total engine flameout or loss of the main electrical supply. The FAA is issuing this AD to address RAT performance that may be below the expected (certificated) level when the landing gear is extended, which could lead to partial or total loss of RAT electrical power generation when the RAT is deployed in an emergency situation, possibly resulting in reduced control of the airplane.

   **(f) Compliance**

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

   **(g) Requirements**

   Except as specified in paragraph (b) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2020–0167.

   **(h) Exceptions to EASA AD 2020–0167**

   1. Where EASA AD 2020–0167 refers to its effective date, this AD requires using the effective date of this AD.

   2. Where EASA AD 2020–0167 references to September 3, 2019 (the effective date of EASA AD 2019–0203), this AD requires using March 12, 2020 (the effective date of AD 2020–01–10).

   3. The “Remarks” section of EASA AD 2020–0167 does not apply to this AD.

   **(i) Other FAA AD Provisions**

   The following provisions also apply to this AD:

   1. **Alternative Methods of Compliance (AMOCs):** The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD.

   Information may be emailed to: 9-AVS-AIR-730-AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

   2. **Contacting the Manufacturer:** For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section,
SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2016–07–14, which applies to certain Airbus Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –217, –218, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –214, –216, –231, –232, and –233 airplanes. AD 2016–07–14 requires replacing the clips, shear webs, and angles, related investigative actions, and repair if necessary. Since the FAA issued AD 2016–07–14, it has been determined that the fatigue life associated with the clips, shear webs, and angles is not sufficient to reach the limit of validity (LOV) in certain configurations; therefore, additional modifications to the airplane are required. The FAA has also determined that additional airplanes are subject to the unsafe condition. This proposed AD would retain the actions of AD 2016–07–14, and require modifying (replacing) the clips, shear webs, and angles at a certain rear fuselage area with new parts, as specified in a European Union Aviation Safety Agency (EASA) AD, which will be incorporated by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by November 16, 2020.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.35 and 11.45, by any of the following methods:


• Fax: 206–231–3223.

• Mail: U.S. Department of Transportation, Docket Operations, 2000 South 216th St., Des Moines, WA 50321–3200.

• Hand Delivery: U.S. Department of Transportation, Docket Operations, 2200 South 216th St., Des Moines, WA 50328–0001.

Issued on September 23, 2020.

Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 50328–0001; telephone and fax 206–231–3223; email Sanjay.Ralhan@faa.gov.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 50328–0001; telephone and fax 206–231–3223; email Sanjay.Ralhan@faa.gov.

SUPPLEMENTARY INFORMATION: Comments Invited

The FAA invites you to participate in this rulemaking by submitting written comments, data, or views about this proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time. Send your comments to an address listed under the ADDRESSES section. Include “Docket No. FAA–2020–0858; Project Identifier MCAI–2020–00949–T” at the beginning of your comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments received by the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this NPRM because of those comments.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0858; Project Identifier MCAI–2020–00949–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

BILLING CODE 4910–13–P
Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to the person identified in the FOR FURTHER INFORMATION CONTACT section. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion


Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2016–07–14, this proposed AD would retain all requirements of AD 2016–07–14. This proposed AD would add airplanes to the applicability. This proposed AD would also require a modification by replacing the clips, shear webs, and angles at the rear fuselage area of section 19 at FR72 and FR74 with new parts without pilot holes, and installing oversized Hi-Loks, nominal aluminum rivets, and nominal Hi-Loks in certain positions. Those requirements are referenced in EASA AD 2020–0153, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related IBR Material Under 1 CFR Part 51

EASA AD 2020–0153 describes procedures for replacement of affected parts (as required by FAA AD 2016–07–14). EASA AD 2020–0153 also describes procedures for a modification by replacing the clips, shear webs, and angles at the rear fuselage area of section 19 at FR72 and FR74 with new parts without pilot holes, and installing oversized Hi-Loks, nominal aluminum rivets, and nominal Hi-Loks in certain positions. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

FAA’s Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is proposing this AD because the FAA evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in EASA AD 2020–0153 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2020–0153 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2020–0153 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to “all required actions and compliance times,” compliance with this AD requirement is not limited to the section titled “Required Action(s) and Compliance Time(s)” in the EASA AD. Service information specified in EASA AD 2020–0153 that is required for compliance with EASA AD 2020–0153 will be available on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0858 after the FAA final rule is published.
Costs of Compliance

The FAA estimates that this proposed AD affects 219 airplanes of U.S. registry.

ESTIMATED COSTS FOR REQUIRED ACTIONS

<table>
<thead>
<tr>
<th>Action</th>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retained actions from AD 2016–07–14 (for 44 airplanes affected)</td>
<td>Up to 110 work-hours × $85 per hour = $9,350</td>
<td>$10,000</td>
<td>$19,350</td>
<td>$851,400</td>
</tr>
<tr>
<td>New proposed actions</td>
<td>126 work-hours × $85 per hour = $10,710</td>
<td>51,750</td>
<td>62,460</td>
<td>13,678,740</td>
</tr>
</tbody>
</table>

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a “significant regulatory action” under Executive Order 12866,
(2) Will not affect intrastate aviation in Alaska, and
(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.
that are not identified as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an AMOC. Provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Related Information

(1) For information about EASA AD 2020–0153, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email ADs@easa.europa.eu; internet www.easa.europa.eu. You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0858.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, FAA–2020–0858. You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email Sanjay.Ralhan@faa.gov.

Issued on September 24, 2020.

Gaetano A. Sciortino,
Deputy Director for Strategic Initiatives,
Compliance & Airworthiness Division,
Aircraft Certification Service.

[FR Doc. 2020–21564 Filed 9–30–20; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB–2020–0010; Notice No. 195]

RIN 1513–AC71

Proposed Establishment of the Virginia Peninsula Viticultural Area

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) proposes to establish the 673,059-acre “Virginia Peninsula” viticultural area in southeastern Virginia. The proposed viticultural area is not located within, nor does it contain, any other established viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase. TTB invites comments on this proposed addition to its regulations.

DATES: Comments must be received by November 30, 2020.

ADDRESSES: You may electronically submit comments to TTB on this proposal, and view copies of this document, its supporting materials, and any comments TTB receives on it within Docket No. TTB–2020–0010 as posted on Regulations.gov (https://www.regulations.gov), the Federal e-rulemaking portal. Please see the “Public Participation” section of this document below for full details on how to comment on this proposal via Regulations.gov or U.S. mail, and for full details on how to obtain copies of this document, its supporting materials, and any comments related to this proposal.

FOR FURTHER INFORMATION CONTACT: Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; phone 202–453–1039, ext. 175.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels, and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated the functions and duties in the administration and enforcement of these provisions to the TTB Administrator through Treasury Order 120–01, dated December 10, 2013, (superseding Treasury Order 120–01, dated January 24, 2003).

Part 4 of the TTB regulations (27 CFR part 4) authorizes TTB to establish definitive viticultural areas and regulate the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) sets forth standards for the preparation and submission of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features, as described in part 9 of the regulations, and a name and a delineated boundary, as established in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to the wine’s geographic origin. The establishment of AVAs allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of an AVA is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations (27 CFR 4.25(e)(2)) outlines the procedure for proposing an AVA and provides that any interested party may petition TTB to establish a grape-growing region as an AVA. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions for the establishment or modification of AVAs. Petitions to establish an AVA must include the following:

Evidence that the area within the proposed AVA boundary is nationally or locally known by the AVA name specified in the petition:

• An explanation of the basis for defining the boundary of the proposed AVA;

• A narrative description of the features of the proposed AVA affecting viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed AVA distinctive and distinguish it from adjacent areas outside the proposed AVA boundary;

• The appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed AVA, with the boundary of the proposed AVA clearly drawn thereon; and

• A detailed narrative description of the proposed AVA boundary based on USGS map markings.

Virginia Peninsula Petition

TTB received a petition from the Williamsburg Winery proposing to establish the 673,059-acre “Virginia Peninsula” AVA. The proposed AVA is
located in southeastern Virginia and encompasses the counties of James City, York, New Kent, and Charles City, as well as the independent cities of Poquoson, Hampton, Newport News, and Williamsburg. At the time the petition was submitted, the proposed AVA had 5 commercial vineyards, covering a total of approximately 112 acres. According to the petition, an additional 61 acres of vineyards are planned for planting in the near future. In addition, there are 5 wineries located within the proposed AVA.

According to the petition, the distinguishing features of the proposed Virginia Peninsula AVA are its geology and climate. Unless otherwise noted, all information and data pertaining to the proposed AVA contained in this proposed rule come from the petition for the proposed Virginia Peninsula AVA and its supporting exhibits.

Name Evidence

The proposed Virginia Peninsula AVA is located on Virginia’s southernmost peninsula on the western shore of the Chesapeake Bay. The petition included multiple examples of local, State, and Federal websites that refer to the region of the proposed AVA as “Virginia Peninsula.” For example, the government website for New Kent County, which is located within the proposed AVA, notes that the county airport’s location “on the Virginia Peninsula” allows visitors easy access to various historic and natural recreational sites. The Virginia travel and tourism site’s web page for the city of Hampton, which is within the proposed AVA, notes that the city is “located on the Virginia Peninsula.” Finally, the National Weather Service’s website includes a web page titled “The Hurricane History of Central and Eastern Virginia” which notes that Hurricane Ernesto caused significant damage “across portions of the Virginia Peninsula” in 2006. The petition also included examples of various businesses and organizations within the proposed AVA that use the term “Virginia Peninsula” in their names. For example, the Virginia Peninsula Foodbank, the Virginia Peninsula Rotary Club, and the Virginia Peninsula Regional Jail all serve the region of the proposed AVA. Other examples include the Virginia Peninsula Association of Realtors, the Virginia Peninsula Chamber of Commerce, and the Virginia Peninsula Public Service Authority.

Boundary Evidence

The proposed Virginia Peninsula AVA is located on the natural feature known as the Virginia Peninsula in southeastern Virginia. The northern, eastern, and southern boundaries of the proposed AVA follow the natural features that delineate the peninsula. The York River forms the northern boundary of both the peninsula and the proposed AVA, while the James River forms the southern boundary. The eastern boundary of the proposed AVA is formed by the Chesapeake Bay. According to the petition, the western boundary of the peninsula is less precisely defined and is marked by a change in elevation and soil type. In order to approximate this change in elevation and soil, the petition places the western boundary of the proposed AVA east of the city of Richmond, along the western boundary of New Kent County and Charles City County.

Distinguishing Features

The distinguishing features of the proposed Virginia Peninsula AVA are its geology and climate.

Geology

According to the petition, the geology of the proposed AVA serves to distinguish it from the region to the west. The proposed Virginia Peninsula AVA, along with the regions to the north and south, is located on the Atlantic Coastal Plain, a region of low topographic relief with elevations ranging from sea level to approximately 250 feet. The Atlantic Coastal Plain is underlain by Cenozoic-era sand, mud, and gravel which were deposited during periods of higher sea levels. These sediments are geologically young, ranging from 4 to 5 million years in age to less than 100,000 years. As a result, very few fault lines are found within the Atlantic Coastal Plain. According to the petition, the geological formations of the proposed AVA are ideal for viticulture, as the bedrock tends to be fractured, allowing for greater root depth and greater rainfall permeability.

To the west of the proposed Virginia Peninsula AVA are the Hopewell fault and the Atlantic Seaboard Fall Line, which mark the beginning of the Piedmont and Blue Ridge regions of Virginia. The geology of these regions consists of igneous and metamorphic rock, including granite and gneiss. The bedrock is older than that of the proposed AVA, dating back approximately 700 million years to the Precambrian age. The bedrock is less porous and less fractured than the bedrock of the proposed AVA. As a result, neither grapevine roots nor rain can penetrate as deeply as within the more fractured bedrock of the proposed AVA.

Climate

The proposed Virginia Peninsula AVA is characterized by a humid subtropical climate, with long, humid summers and moderate to mild winters. The petition included on the average growing season high and low temperatures, growing season maximum high and minimum low temperatures, and the annual number of days during the growing season with temperatures over 90 and 100 degrees Fahrenheit (F) for locations within the proposed AVA, to the north, and to the south. Additionally, the petition included data on the average annual and harvest period rainfall amounts for the same locations. Data was not provided for the region to the west. The data was collected from 2013 to 2017 and is reproduced in the following tables.

TABLE 1—2013–2017 GROWING SEASON Temperatures

<table>
<thead>
<tr>
<th>Location (direction from proposed AVA)</th>
<th>Average high</th>
<th>Average low</th>
<th>Average maximum high</th>
<th>Average Minimum Low</th>
<th>Average days over 90 Degrees F</th>
<th>Average days over 100 Degrees F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Williamsburg (within)</td>
<td>84</td>
<td>65</td>
<td>100</td>
<td>35</td>
<td>57</td>
<td>2.6</td>
</tr>
<tr>
<td>West Point (North)</td>
<td>81</td>
<td>61</td>
<td>96</td>
<td>32</td>
<td>32</td>
<td>0</td>
</tr>
<tr>
<td>Surry (South)</td>
<td>80</td>
<td>62</td>
<td>95</td>
<td>35</td>
<td>17</td>
<td>0</td>
</tr>
</tbody>
</table>

2 virginia.org/cities/hampton/.
3 www.weather.gov/media/akq/miscNEWS/hurricanehistory.pdf.
4 “Growing season” is defined in the petition as the period from the last spring frost to the first fall frost. The length of the growing season varies from year to year but typically lasts from April 10 to November 8.
The climate data suggests that the proposed Virginia Peninsula AVA has temperatures that are warmer than the regions to the north and south. Rainfall amounts in the proposed AVA are generally greater than in the region to the north and lower than in the region to the south.

According to the petition, temperatures above 90 degrees Fahrenheit reduce photosynthesis in grapevines. Because photosynthesis is the process which produces sugar, reduced photosynthesis rates would require fruit to hang longer to achieve optimal sugar levels. The longer hang time increases the risk of disease or animals destroying a crop before it can be harvested. The petition states that, on average, almost 30 percent of the growing season days within the proposed AVA have temperatures above 90 degrees. Additionally, frequent rains during the harvest period, particularly rainfall amounts over 1/2 inch, can cause ripening fruit to swell or split and can dilute flavors. The high growing season temperatures combined with frequent rainfall during the typical harvest season mean that vineyard managers frequently face the decision whether to pick grapes before they’ve reached peak ripeness, or to let the fruit continue to ripen but potentially spoil.

**Summary of Distinguishing Features**

The evidence provided in the petition indicates that the geology and climate of the proposed Virginia Peninsula AVA distinguish it from the surrounding regions in each direction. The proposed AVA is located on the Atlantic Coastal Plain, which is comprised of geologically young sand, mud, and gravel over fractured bedrock. The geology of the proposed AVA is distinct from that of the region to the west, which is made up of the Piedmont and Blue Ridge regions, which are comprised of geologically older igneous and metamorphic rock over less-fractured bedrock. Climate distinguishes the proposed AVA from the regions to the north and south, with average maximum and minimum temperatures being warmer in the proposed AVA than in both of the other regions.

Additionally, when compared to the region to the south, the proposed AVA has lower average annual rainfall amounts and more harvest days without rainfall. Average annual and harvest period rainfall amounts in the proposed AVA are higher than those within the region to the north.

**TTB Determination**

TTB concludes that the petition to establish the approximately 673,059-acre “Virginia Peninsula” AVA merits consideration and public comment, as invited in this document.

**Boundary Description**

See the narrative boundary descriptions of the petitioned-for AVA in the proposed regulatory text published at the end of this document.

**Maps**

The petitioner provided the required maps, and they are listed below in the proposed regulatory text. You may also view the proposed Virginia Peninsula AVA boundary on the AVA Map Explorer on the TTB website, at [https://www.ttb.gov/wine/ava-map-explorer](https://www.ttb.gov/wine/ava-map-explorer).

**Impact on Current Wine Labels**

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine’s true place of origin. For a wine to be labeled with an AVA name, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name, and the wine must meet the other conditions listed in § 4.25(e)(3) of the TTB regulations (27 CFR 4.25(e)(3)). If the wine is not eligible for labeling with an AVA name and that name appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the AVA name appears in another reference on the label, the bottler would have to obtain approval of a new label. Different rules apply if a wine has a brand name containing an AVA name that was used as a brand name on a label approved before July 7, 1986. See § 4.39(i)(2) of the TTB regulations (27 CFR 4.39(i)(2)) for details.

If TTB establishes this proposed AVA, its name, “Virginia Peninsula,” will be recognized as a name of viticultural significance under § 4.39(i)(3) of the TTB regulations (27 CFR 4.39(i)(3)). The text of the proposed regulation clarifies this point. Consequently, wine bottlers using “Virginia Peninsula” in a brand name, including a trademark, or in another label reference as to the origin of the wine, would have to ensure that the product is eligible to use the AVA name as an appellation of origin if this proposed rule is adopted as a final rule.

**Public Participation**

**Comments Invited**

TTB invites comments from interested members of the public on whether it should establish the proposed Virginia Peninsula AVA. TTB is interested in receiving comments on the sufficiency and accuracy of the name, boundary, geology, climate, and other required information submitted in support of the AVA petition. Please provide any available specific information in support of your comments.

Because of the potential impact of the establishment of the proposed Virginia Peninsula AVA on wine labels that include the term “Virginia Peninsula,” as discussed above under Impact on Current Wine Labels, TTB is particularly interested in comments regarding whether there will be a conflict between the proposed area name and currently used brand names. If a commenter believes that a conflict will arise, the comment should describe the nature of that conflict, including any anticipated negative economic impact that approval of the proposed AVA will have on an existing viticultural enterprise. TTB is also interested in receiving suggestions for ways to avoid conflicts, for example, by adopting a modified or different name for the proposed AVA.
Submitting Comments

You may submit comments on this proposal by using one of the following two methods:

• Federal e-Rulemaking Portal: You may send comments via the online comment form posted with this document within Docket No. TTB–2020–0010 on “Regulations.gov,” the Federal e-rulemaking portal, at https://www.regulations.gov. A direct link to that docket is available under Notice No. 195 on the TTB website at https://www.ttb.gov/wine/wine-rulemaking.shtml. Supplemental files may be attached to comments submitted via Regulations.gov. For complete instructions on how to use Regulations.gov, visit the site and click on the “Help” tab at the top of the page.

• U.S. Mail: You may send comments via postal mail to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005.

Please submit your comments by the closing date shown above in this document. Your comments must reference Notice No. 195 and include your name and mailing address. Your comments also must be made in English, be legible, and be written in language acceptable for public disclosure. TTB does not acknowledge receipt of comments, and TTB considers all comments as originals.

Your comment must clearly state if you are commenting on your own behalf or on behalf of an organization, business, or other entity. If you are commenting on behalf of an organization, business, or other entity, your comment must include the entity’s name, as well as your name and position title. If you comment via Regulations.gov, please enter the entity’s name in the “Organization” blank of the online comment form. If you comment via postal mail, please submit your entity’s comment on letterhead.

You may also write to the Administrator before the comment closing date to ask for a public hearing. The Administrator reserves the right to determine whether to hold a public hearing.

Confidentiality

All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

Public Disclosure

TTB will post, and you may view, copies of this document, selected supporting materials, and any online or mailed comments received about this proposal within Docket No. TTB–2020–0010 on the Federal e-rulemaking portal, Regulations.gov, at https://www.regulations.gov. A direct link to that docket is available on the TTB website at https://www.ttb.gov/wine/wine-rulemaking.shtml under Notice No. 195. You may also reach the relevant docket through the Regulations.gov search page at https://www.regulations.gov. For instructions on how to use Regulations.gov, click on the site’s “Help” tab at the top of the page.

All posted comments will display the commenter’s name, organization (if any), city, and State, and, in the case of mailed comments, all address information, including email addresses. TTB may omit voluminous attachments or material that it considers unsuitable for posting.

You may also obtain copies of this proposed rule, all related petitions, maps and other supporting materials, and any electronic or mailed comments that TTB receives about this proposal at 20 cents per 8.5 x 11-inch page. Please note that TTB is unable to provide copies of USGS maps or any similarly-sized documents that may be included as part of the AVA petition. Contact TTB’s Regulations and Rulings Division by email using the web form at https://www.ttb.gov/contact-rrd, or by telephone at 202–453–1039, ext. 175, to request copies of comments or other materials.

Regulatory Flexibility Act

TTB certifies that this proposed regulation, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposed regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of an AVA name would be the result of a proprietor’s efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

It has been determined that this proposed rule is not a significant regulatory action as defined by Executive Order 12866. Therefore, no regulatory assessment is required.

Drafting Information

Karen A. Thornton of the Regulations and Rulings Division drafted this document.

List of Subjects in 27 CFR Part 9

Wine.

Proposed Regulatory Amendment

For the reasons discussed in the preamble, we propose to amend title 27, chapter I, part 9, Code of Federal Regulations, as follows:

PART 9—AMERICAN VITICULTURAL AREAS

1. The authority citation for part 9 continues to read as follows:


Subpart C—Approved American Viticultural Areas

2. Subpart C is amended by adding §9.195 to read as follows:

§9.195 Virginia Peninsula.

(a) Name. The name of the viticultural area described in this section is “Virginia Peninsula”. For purposes of part 4 of this chapter, “Virginia Peninsula” is a term of viticultural significance.

(b) Approved maps. The 5 United States Geological Survey (USGS) 1:100,000 scale topographic maps used to determine the boundary of the Virginia Peninsula viticultural area are titled:

(1) Norfolk, Virginia–North Carolina; 1985;

(2) Petersburg, Virginia, 1984;

(3) Richmond, Virginia, 1984;

(4) Tappahannock, Virginia–Maryland; 1984; and


(c) Boundary. The Virginia Peninsula viticultural area is located in James City, York, New Kent, and Charles City Counties, Virginia, as well as the independent Virginia cities of Poquoson, Hampton, Newport News, and Williamsburg. The boundary of the Virginia Peninsula viticultural area is as described below:

(1) The beginning point is on the Norfolk, Virginia–North Carolina map at the intersection of the Newport News City boundary and the James River Bridge. From the beginning point, proceed northwesterly along the Newport News City boundary to the point in the James River where the city boundary becomes concurrent with the James City County boundary; then

(2) Proceed northwesterly along the James City County boundary to the point where it becomes concurrent with the Charles City County boundary; then
DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB–2020–0009; Notice No. 194]

RIN 1513–AC59

Proposed Establishment of the San Luis Obispo Coast (SLO Coast) Viticultural Area

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) proposes to establish the 408,585-acre “San Luis Obispo Coast” viticultural area in San Luis Obispo County, California. TTB is proposing to recognize both “San Luis Obispo Coast” and the abbreviated “SLO Coast” as the name of the proposed AVA. The proposed AVA is located entirely within the existing Central Coast AVA and would encompass the established Edna Valley and Arroyo Grande Valley AVAs. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase. TTB invites comments on this proposed addition to its regulations.

DATES: TTB must receive your comments on or before November 30, 2020.

ADDRESSES: You may electronically submit comments to TTB on this proposal, and view copies of this document, its supporting materials, and any comments TTB receives on it within Docket No. TTB–2020–0009 as posted on Regulations.gov (https://www.regulations.gov), the Federal e-rulemaking portal. Please see the “Public Participation” section of this document below for full details on how to comment on this proposal via Regulations.gov or U.S. mail, and for full details on how to obtain copies of this document, its supporting materials, and any comments related to this proposal.

FOR FURTHER INFORMATION CONTACT: Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; phone 202–453–1039, ext. 175.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

**TTB Authority**

Section 105(e) of the Federal Alcoholic Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels, and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated the functions and duties in the administration and enforcement of these provisions to the TTB Administrator through Treasury Order 120–01, dated December 10, 2013 (superseding Treasury Order 120–01, dated January 24, 2003).

Part 4 of the TTB regulations (27 CFR part 4) authorizes TTB to establish definitive viticultural areas and regulate the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) sets forth standards for the preparation and submission of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

**Definition**

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features, as described in part 9 of the regulations, and a name and a delineated boundary, as established in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to the wine’s geographic origin. The establishment of AVAs allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of an AVA is neither an approval nor an endorsement by TTB of the wine produced in that area.

**Requirements**

Section 4.25(e)(2) of the TTB regulations (27 CFR 4.25(e)(2)) outlines the procedure for proposing an AVA and provides that any interested party...
may petition TTB to establish a grape-growing region as an AVA. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions for the establishment or modification of AVAs. Petitions to establish an AVA must include the following:

- Evidence that the area within the proposed AVA boundary is nationally or locally known by the AVA name specified in the petition;
- An explanation of the basis for defining the boundary of the proposed AVA;
- A narrative description of the features of the proposed AVA that affect viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed AVA distinctive and distinguish it from adjacent areas outside the proposed AVA;
- If the proposed AVA is to be established within, or overlapping, an existing AVA, an explanation that both identifies the attributes of the proposed AVA that are consistent with the existing AVA and explains how the proposed AVA is sufficiently distinct from the existing AVA and therefore appropriate for separate recognition;
- The appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed AVA, with the boundary of the proposed AVA clearly drawn thereon; and
- A detailed narrative description of the proposed AVA boundary based on USGS map markings.

Petition To Establish the San Luis Obispo Coast (SLO Coast) AVA

TTB received a petition from the SLO Coast AVA Association, proposing to establish the “San Luis Obispo Coast” AVA. The petition also requested that TTB recognize the abbreviated name “SLO Coast” as an approved alternative name for the proposed AVA. For purposes of the remainder of this document, TTB will refer to the proposed AVA as “SLO Coast.”

The proposed SLO Coast AVA is located in San Luis Obispo County, California, and is entirely within the existing Central Coast AVA (27 CFR 9.75). The proposed AVA would also encompass the existing Edna Valley (27 CFR 9.35) and Arroyo Grande Valley (27 CFR 9.129) AVAs. Within the 408,585-acre proposed AVA, there are over 50 wineries and approximately 78 commercial vineyards, which cover a total of approximately 3,942 acres. The petition states that of those 3,942 acres of vineyards, approximately 2,661 acres are in the existing Edna Valley AVA, 838 acres are in the existing Arroyo Grande AVA, and 398 acres are distributed throughout the remaining portion of the proposed AVA. The distinguishing features of the proposed SLO Coast AVA are its topography, climate, and soils. Unless otherwise noted, all information and data contained in the following sections are from the petition to establish the proposed AVA and its supporting exhibits.

Proposed SLO Coast AVA

Name Evidence

The proposed SLO Coast AVA derives its name from its location in coastal San Luis Obispo County. The petition notes that the region is often referred to as “SLO,” which is a reference to both the county’s initials and its relaxed culture. The petition states that although the full name of the proposed AVA is “San Luis Obispo Coast,” the frequently-used abbreviation “SLO” should also be recognized by TTB in order to avoid consumer confusion.

The petition included a number of examples of the use of the name “SLO Coast” to describe the region of the proposed AVA. For example, a book about Santa Barbara County and California’s Central Coast contains a chapter titled “Coastal SLO” that uses the phrase “SLO Coast” nearly a dozen times. The petition shows that businesses within the proposed AVA include SLO Coast Jerky, SLO Coast Diner, SLO Coast Catering, SLO Coast Realty, SLO Coast Insurance Services, SLO Coast Custom Print and Laser, SLO Coast Construction, and SLO Coast Coffee. An online magazine featuring information about the region of the proposed AVA is called SLO Coast Journal. Finally, on his 2016 campaign website, State Senate Majority Leader Bill Monning described his district as encompassing “the SLO Coast towns of Pismo Beach, Grover Beach, and Arroyo Grande,” all of which are within the proposed AVA.

Boundary Evidence

The proposed SLO Coast AVA is a long, relatively narrow region that encompasses the portion of San Luis Obispo County that is oriented towards the Pacific Ocean and experiences an immediate marine influence. The proposed AVA is 1.7 miles across at its narrowest point and 15.1 miles across at its widest point. According to the petition, approximately 97 percent of the proposed AVA sits at elevations below 1,800 feet, which is described in the petition as the approximate limit of strong marine influence.

The northern boundary of the proposed AVA follows the northern Piedras Blancas Grant boundary and separates the proposed AVA from the Los Padres National Forest. Beyond the northern boundary, the elevations rise sharply and become more rugged. The eastern boundary follows a series of straight lines between peaks of the Santa Lucia Range, as well as the boundary of the Los Padres National Forest, to separate the proposed AVA from regions that are oriented away from the Pacific Ocean and receive little direct marine influence. The southern boundary generally follows the Nipomo Mesa and the boundary of the Oceano State Vehicular Recreation Area. The region south of this boundary is sandier than the proposed AVA and also contains State recreational area lands that are not appropriate for vineyard development. The western boundary of the proposed AVA follows the coastline of the Pacific Ocean.

Distinguishing Features

According to the petition, the distinguishing features of the proposed SLO Coast AVA are its topography, climate, and soils. Because the Pacific Ocean is to the west of the proposed AVA, the following sections will only compare the features of the proposed AVA to the surrounding regions to the north, east, and south.

Topography

The petition describes the proposed SLO Coast AVA as a region of coastal terraces, foothills, and small valleys along the Pacific Coast. The region is oriented to the west, allowing the region to experience marine fog and cool marine air. According to the petition, 97 percent of the proposed AVA is at or below 1,800 feet in elevation, which corresponds to the approximate limit of the influence of the maritime climate. The petition states that the steady maritime influence prevents temperatures from rising too high or dropping too low for optimal vineyard conditions.

According to U.S.G.S maps provided with the petition, to the north of the proposed AVA, the elevations rise to over 3,000 feet and the terrain is steep and rough. The higher elevations are above the maximum extent of the marine air and fog that characterizes the proposed AVA. Additionally, the land north of the proposed AVA was excluded because most of it is within the Los Padres National Forest and thus is unavailable for commercial
viticulture. To the east of the proposed AVA is the eastern side of the Santa Lucia Range. This region is oriented to the east, away from the Pacific Ocean, and is thus not as exposed to the marine influence as the proposed AVA. To the south of the proposed AVA is the Santa Maria Valley, which has a much flatter topography.

The proposed SLO Coast AVA, as a whole, has a lower GDD accumulation and is in a lower Winkler Region than the surrounding regions. The established Edna Valley and Arroyo Grande Valley AVAs, which are located within the proposed AVA, have higher individual GDD accumulations and are in a higher Winkler Region than the remainder of the proposed AVA. The petition explains that both of these AVAs are somewhat sheltered from the marine influence but still receive more marine air and fog than the regions outside the proposed AVA on the eastern side of the Santa Lucia Range, such as the Paso Robles AVA. The petition suggests that the Arroyo Grande Valley AVA’s GDD accumulation may be skewed high due to the fact that the far eastern portion of that AVA, which represents approximately 5 percent of the total acreage of the proposed SLO Coast AVA, is in a narrow, sheltered canyon that is classified as a Winkler Region III. Furthermore, Appendices 4 through 6 of the petition8 include evidence that other protected pockets with Winkler Region II GDD accumulations exist within the proposed SLO Coast AVA, so including the Arroyo Grande Valley and Edna Valley AVAs would not be inconsistent with the characteristics of the rest of the proposed AVA.

According to the petition, low GDD accumulations limit which grape varietals can be successfully grown in the region. The petition states that areas classified as Winkler Region I, like the majority of the proposed AVA, are well-suited for growing early-to-mid-season-ripening varietals such as Chardonnay and Pinot Noir, which comprise 43 percent and 35 percent, respectively, of the total planted vineyard acreage within the proposed SLO Coast AVA.

Average minimum and maximum growing season temperatures: The petition states that the average minimum growing season temperature for nearly 90 percent of the proposed SLO Coast AVA is between 47.5 degrees F and 52 degrees F.9 The petition attributes the mild minimum temperatures of the proposed AVA to its proximity to the waters of the Pacific Ocean, which have a high heat capacity that provides a constant moderation on the climate. Likewise, the ocean moderates the average maximum growing season temperature of the proposed AVA. Sea breeze circulation, driven by inland heating, keeps the daytime temperatures lower along the coast than within the inland valleys east of the proposed AVA. According to the petition, 21 percent of the proposed SLO Coast AVA has an average maximum growing season temperature of less than 70 degrees F, while another 68 percent of the proposed AVA has an average maximum growing season temperature of between 70 and 78 degrees F.10

By contrast, the region east of the proposed AVA is sheltered by the Santa Lucia Mountains from the moderating influence of the Pacific Ocean. As a result, the region has lower average minimum temperatures and higher average maximum temperatures than the proposed AVA. For example, the majority of the established Paso Robles AVA has an average minimum growing season temperature that is below 50 degrees F, but a large portion of that AVA is even cooler, with an average minimum temperature below 46 degrees F. The average maximum growing

### TABLE 1—GDD ACCUMULATIONS AND WINKLER REGIONS

<table>
<thead>
<tr>
<th>AVA name</th>
<th>GDD accumulation</th>
<th>Winkler region</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposed SLO Coast</td>
<td>2,493</td>
<td>I</td>
</tr>
<tr>
<td>Edna Valley (within)</td>
<td>2,738</td>
<td>II</td>
</tr>
<tr>
<td>Arroyo Grande Valley (within)</td>
<td>2,786</td>
<td>II</td>
</tr>
<tr>
<td>Monterey (NE)</td>
<td>2,594</td>
<td>II</td>
</tr>
<tr>
<td>Arroyo Seco (NE)</td>
<td>2,680</td>
<td>II</td>
</tr>
<tr>
<td>York Mountain (E)</td>
<td>2,772</td>
<td>II</td>
</tr>
<tr>
<td>Paso Robles (E)</td>
<td>3,425</td>
<td>III</td>
</tr>
<tr>
<td>Santa Maria Valley (S)</td>
<td>2,733</td>
<td>II</td>
</tr>
<tr>
<td>Santa Ynez Valley (S)</td>
<td>2,844</td>
<td>II</td>
</tr>
</tbody>
</table>

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8 According to the petition, GDDs for a particular region are calculated by adding the total mean daily temperatures above 50 degrees Fahrenheit [F] for the days from April 1 through October 31. The formula is based on the concept that most vine- shoot growth occurs in temperatures over 50 degrees F.

9 Derived from climate data from 1971–2000. See Appendix 4 through 6 of the petition for additional information regarding GDD calculations.
season temperature within the Paso Robles AVA is above 80 degrees F. The region south of the proposed AVA, which includes the established Santa Maria Valley AVA, has a flatter terrain than the proposed SLO Coast AVA and is thus more exposed to the marine air. As a result, the region to the south has a higher average minimum growing season temperature and a lower average maximum growing season temperature than the proposed AVA.

The petition states that the mild minimum and maximum growing season temperatures within the proposed SLO Coast AVA affect viticulture. Mild minimum temperatures lead to a shorter period of wintertime vine dormancy and earlier spring bud breaks. However, early spring bud breaks are not a concern for grape growers in the proposed AVA because potentially damaging frost events that can damage or kill early vine growth in the spring are far less common in coastal regions than they are in inland valleys. Lower maximum temperatures lead to a reduced risk of fruit desiccation and also produce higher levels of malic acid in the grapes, which increases total acidities and lowers pH values. Finally, the petition notes that the cooler temperatures of the proposed AVA can affect the flavor profile of certain grape varietals, specifically Syrah. The petition claims that Syrah grown in cooler climates such as the proposed AVA features more pepper and gamay flavors compared to the riper, fruitier flavors found in Syrah grown in warmer regions.

Cloud cover: The petition also provided information about nighttime cloud cover over the proposed SLO Coast AVA and the surrounding regions. The petition states that daytime fog is typically present in coastal regions of California, but that it quickly dissipates as the air heats up. In the evening, land temperatures decrease and the moist air above cools to its dew point, resulting in nighttime fog.

According to the petition, the majority of the proposed SLO Coast AVA experiences nighttime fog cover between 35 and 55 percent of all nights during the growing season. The region of the proposed AVA immediately adjacent to the coast, the Morro Bay area, and the southernmost region of the proposed AVA all experience fog 55 of 75 percent of all nights during the growing season. By contrast, the majority of the region east of the proposed AVA experiences fog less than 30 percent of all nights during the growing season, while the region south of the proposed AVA has fog over 55 percent of all nights during the growing season.

The petition states that cloud cover in the form of nighttime fog has an effect on viticulture within the proposed AVA. The fog prevents nighttime temperatures from dropping significantly. As a result, the proposed AVA generally experiences temperature changes of no more than 20 to 30 degrees F throughout the day. The moderate nighttime temperatures lead to longer growing seasons within the proposed AVA. By contrast, regions to the east with less nighttime fog experience 40 to 50 degree swings and a greater risk of damaging early spring frosts.

Soils

The petition states that the soils of the proposed SLO Coast AVA can be classified into four groups. The first group is derived from older Franciscan Formation geology. This group represents the largest proportion of soils within the boundaries of the proposed AVA and is found in the northern and central portions of the proposed AVA. These soils derive from sandstone, shale, and metamorphosed sedimentary rocks, and they vary from very thin, rocky soils on hills and mountains to very deep clay and clay-loam soils along lower-lying alluvial fans and terraces. These soils are highly varied due to the highly complex nature of the Franciscan Formation geology that produced these soils. The soils of this group that are most suitable for viticulture are found on foothills, terraces, and valleys and have good drainage, moderate water holding capacity, and a high mineral content. Examples of soil series in this group include Diablo, San Simeon, Shinnon, Conception, and Santa Lucia series.

The second group of soils found in the proposed AVA consists of younger marine deposits and basin sediments from the Miocene and Pliocene periods. These soils represent the second largest proportion of soils in the proposed AVA and are mostly found in the southern region of the proposed AVA. Most of these soils are composed of sandy loam and loams derived from marine deposits of sandstone and shale, and they have less clay than soils in the northern portion of the proposed AVA. The higher sand content provides excellent drainage for vineyards, but often requires irrigation during the growing season. Examples of soil series in this group include Pismo, Briones, Tierras, Gazos, Nacimiento, Linne, Balcom, and Sorrento series.

The third group of soils found in the proposed AVA is derived from volcanic intrusion and represents a very small proportion of the soils within the proposed AVA, occurring mostly in isolated instances on very steep terrain within the Santa Lucia Mountains, as well as among the rocky outcrops near Morro Bay. Most soils in this group are thick and are found on excessively steep terrain or rocky outcrops that are unsuitable for viticulture.

The fourth group of soils within the proposed AVA is derived from wind deposits and comprises the sand dunes and low areas near the coast. These soils comprise a very small portion of the proposed AVA, mainly along the coastline near Morro Bay and around the township of Nipomo. They consist of very deep sands at low elevations and are excessively drained soils with a high sodium content, making them generally unsuitable for viticulture.

To the south of the proposed AVA, within the established Santa Maria AVA, the soils are largely from younger geological periods and consist of deep, fertile, sandy soils that are well-suited for viticulture. These soils are derived from alluvial deposits and contain less clay and clay loam than the majority of soils in the proposed AVA. To the east of the proposed AVA, within the established Paso Robles AVA, the soils consist of alluvial and terrace deposits. The region north of the proposed AVA is characterized by rocky outcrops, shallow soils derived from sandstone and metamorphic rock, and soils derived from igneous and granitic rocks.

Summary of Distinguishing Features

The topography, climate, and soils of the proposed SLO Coast AVA distinguish it from the surrounding regions to the north, east, and south. To the west of the proposed AVA is the Pacific Ocean. The following table summarizes the distinguishing features of the proposed AVA and the surrounding regions.

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TABLE 2—SUMMARY OF DISTINGUISHING FEATURES

<table>
<thead>
<tr>
<th>Region</th>
<th>Topography</th>
<th>Climate</th>
<th>Soils</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposed SLO Coast AVA.</td>
<td>Coastal terraces, foothills, and</td>
<td>Marine influenced climate with average GDD</td>
<td>Majority of soils derived from</td>
</tr>
<tr>
<td></td>
<td>small valleys with western</td>
<td>accumulation of 2.493, average minimum growing</td>
<td>Franciscan Formation and marine</td>
</tr>
<tr>
<td></td>
<td>orientations and elevations below</td>
<td>season temperatures between 47.5 and 52 degrees F,</td>
<td>deposits and basin sediments, with</td>
</tr>
<tr>
<td></td>
<td>1,800 feet.</td>
<td>average maximum growing season temperatures between 70</td>
<td>some soils formed from volcanic</td>
</tr>
<tr>
<td>North</td>
<td>Steep, mountainous region with</td>
<td>and 78 degrees, and frequent nighttime fog.</td>
<td>intrusion and wind deposited sand.</td>
</tr>
<tr>
<td></td>
<td>elevations over 3,000 feet.</td>
<td></td>
<td>Shallow soils derived from sand-</td>
</tr>
<tr>
<td>East</td>
<td>Eastern slope orientation</td>
<td>Less marine influence, higher GDD accumulations,</td>
<td>stone and metamorphic rocks and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>lower average growing season minimum temperature,</td>
<td>igneous and granitic rocks.</td>
</tr>
<tr>
<td>South</td>
<td>Flat valley terrain</td>
<td>lower average growing season maximum temperature,</td>
<td>Alluvial and terrace deposits, as</td>
</tr>
<tr>
<td></td>
<td></td>
<td>less nighttime fog.</td>
<td>well rock outcrop in the Santa</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lucia Mountain Range.</td>
</tr>
</tbody>
</table>

Comparison of the Proposed SLO Coast AVA to the Existing Edna Valley AVA

The Edna Valley AVA was established by T.D. ATF–101, which was published in the Federal Register on May 12, 1982 (47 FR 20298). The AVA is located in the southeastern portion of the proposed SLO Coast AVA and covers approximately 35 square miles. T.D. ATF–101 states that the Edna Valley AVA consists of a natural valley that has a predominately Region II climate with a few pockets that classify as Region I. A gap in the coastal mountains allows marine air and fog to enter the valley and keep the summer temperatures lower and the winter temperatures warmer than the temperature farther to the east, beyond the Santa Lucia Mountains. Elevations range from 120 to 300 feet, and the soils are generally sandy clay loam, clay loam, or clay.

The proposed SLO Coast AVA shares some of the general viticultural features of the Edna Valley AVA. For example, temperatures within both the proposed AVA and the established AVA are influenced by marine air and fog and are generally cooler than temperatures in the region to the east. Both the proposed AVA and the established AVA also have similar soils of clay and loam. However, the proposed AVA also has some unique characteristics. For instance, the majority of the proposed AVA can be classified as a Region I climate with pockets of Region II microclimates, whereas most of the established Edna Valley AVA is classified as a Region II climate with pockets of Region I microclimates. Additionally, the proposed SLO Coast AVA has a wider range of elevations than the Edna Valley AVA.

Comparison of the Proposed SLO Coast AVA to the Existing Arroyo Grande Valley AVA

The Arroyo Grande Valley AVA was established by T.D. ATF–291, which was published in the Federal Register on January 4, 1990 (55 FR 285). The AVA is located in the southeastern region of the proposed SLO Coast AVA, adjacent to the Edna Valley AVA, and covers approximately 67 square miles. T.D. ATF–291 states that the Arroyo Grande Valley AVA is primarily distinguished by its climate, which is described as ranging from high Region I to Region II. The AVA experiences frequent morning and evening fog and temperatures, and is moderated by the marine influence.

The proposed SLO Coast AVA shares some of the general viticultural features of the Arroyo Grande Valley AVA. For example, both the proposed AVA and the established AVA experience fog, have temperatures that are influenced by marine air, and are generally milder than temperatures in the inland region to the east. However, due to its smaller size, the climate, topography, and soils of the proposed AVA are less varied than those of the much larger Central Coast AVA.

TTB Determination

TTB concludes that the petition to establish the 408,585-acre “SLO Coast” AVA merits consideration and public comment, as invited in this proposed rule.

Boundary Description

See the narrative boundary descriptions of the petitioned-for AVA in the proposed regulatory text published at the end of this notice of proposed rulemaking.

Maps

The petitioner provided the required maps, and they are listed below in the proposed regulatory text. You may also view the proposed SLO Coast AVA

Impact on Current Wine Labels

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine’s true place of origin. For a wine to be labeled with an AVA name or with a brand name that includes an AVA name, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name, and the wine must meet the other conditions listed in § 4.25(e)(3) of the TTB regulations (27 CFR 4.25(e)(3)). If the wine is not eligible for labeling with an AVA name and that name appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the AVA name appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label. Different rules apply if a wine has a brand name containing an AVA name that was used as a brand name on a label approved before July 7, 1986. See § 4.39(i)(2) of the TTB regulations (27 CFR 4.39(i)(2)) for details.

If TTB establishes this proposed AVA, its name, “San Luis Obispo Coast” or its abbreviated name “SLO Coast,” will be recognized as a name of viticultural significance under § 4.39(i)(3) of the TTB regulations (27 CFR 4.39(i)(3)). The text of the proposed regulation clarifies this point. Consequently, wine bottlers using “San Luis Obispo Coast” or “SLO Coast” in a brand name, including a trademark, or in another label reference as to the origin of the wine, would have to ensure that the product is eligible to use the viticultural area’s name “San Luis Obispo Coast” or the alternative abbreviated name “SLO Coast” as an appellation of origin.

The approval of the proposed “San Luis Obispo Coast” or “SLO Coast” AVA would not affect any existing AVA. If approved, the establishment of the proposed SLO Coast AVA would allow vintners to use “San Luis Obispo Coast,” “SLO Coast,” or “Central Coast” as appellations of origin for wines made from grapes grown within the SLO Coast AVA, if the wines meet the eligibility requirements for the appellation. Furthermore, vintners whose wines meet the eligibility requirements to use either “Edna Valley” or “Arroyo Grande Valley” as appellations of origin would also be able to use “San Luis Obispo Coast,” “SLO Coast,” and “Central Coast” as appellations of origin on those wines.

Public Participation

Comments Invited

TTB invites comments from interested members of the public on whether TTB should establish the proposed SLO Coast AVA. TTB is interested in receiving comments on the sufficiency and accuracy of the name, boundary, topography, and other required information submitted in support of the SLO Coast AVA petition. In addition, because the proposed SLO Coast AVA would be within the existing Central Coast AVA and would encompass the existing Edna Valley and Arroyo Grande Valley AVAs, TTB is interested in comments on whether the evidence submitted in the petition regarding the distinguishing features of the proposed AVA sufficiently differentiates it from the existing AVAs. TTB is also interested in comments on whether the geographic features of the proposed AVA are so distinguishable from the Central Coast AVA that the proposed SLO Coast AVA should not be part of the established AVA. Finally, TTB invites comments on whether the geographical features of either the Edna Valley or Arroyo Grande Valley AVA are so distinguishable from the proposed SLO Coast AVA that one or both of the established AVAs should not be part of the proposed AVA. Please provide any available specific information in support of your comments.

Because of the potential impact of the establishment of the proposed SLO Coast AVA on wine labels that include the term “SLO Coast” or “San Luis Obispo Coast” as discussed above under Impact on Current Wine Labels, TTB is particularly interested in comments regarding whether there will be a conflict between the proposed area names and currently used brand names. If a commenter believes that a conflict will arise, the comment should describe the nature of that conflict, including any anticipated negative economic impact that approval of the proposed AVA will have on an existing viticultural enterprise. TTB is also interested in receiving suggestions for ways to avoid conflicts, for example, by adopting a modified or different name for the proposed AVA.

Submitting Comments

You may submit comments on this proposal by using one of the following two methods:

• Federal e-Rulemaking Portal: You may send comments via the online comment form posted with this document within Docket No. TTB–2020–0009 on “Regulations.gov,” the Federal e-rulemaking portal, at https://www.regulations.gov. A direct link to that docket is available under Notice No. 194 on the TTB website at https://www.ttb.gov/wine/rulemaking.shtml. Supplemental files may be attached to comments submitted via Regulations.gov. For complete instructions on how to use Regulations.gov, visit the site and click on the “Help” tab at the top of the page.

• U.S. Mail: You may send comments via postal mail to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005.

Please submit your comments by the closing date shown above in this document. Your comments must reference Notice No. 194 and include your name and mailing address. Your comments also must be made in English, be legible, and be written in language acceptable for public disclosure. We do not acknowledge receipt of comments, and we consider all comments as originals. Your comment must clearly state if you are commenting on your own behalf or on behalf of an organization, business, or other entity. If you are commenting on behalf of an organization, business, or other entity, your comment must include the entity’s name as well as your name and position title. If you comment via Regulations.gov, please enter the entity’s name in the “Organization” blank of the online comment form. If you comment via postal mail, please submit your entity’s comment on letterhead.

You may also write to the Administrator before the comment closing date to ask for a public hearing. The Administrator reserves the right to determine whether to hold a public hearing.

Confidentiality

All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

Public Disclosure

TTB will post, and you may view, copies of this document, selected supporting materials, and any online or mailed comments received about this proposal within Docket No. TTB–2020–0009 on the Federal e-rulemaking portal, Regulations.gov, at https://www.regulations.gov. A direct link to that docket is available on the TTB website at https://www.ttb.gov/wine/
PART 9—AMERICAN VITICULTURAL AREAS

1. The authority citation for part 9 continues to read as follows:


Subpart C—Approved American Viticultural Areas

2. Add § 9. to read as follows:

§9. San Luis Obispo Coast.

(a) Name. The name of the viticultural area described in this section is “San Luis Obispo Coast”. “SLO Coast” may also be used as the name of the viticultural area described in this section. For purposes of part 4 of this chapter, “San Luis Obispo Coast” and “SLO Coast” are terms of viticultural significance.

(b) Approved maps. The 24 United States Geological Survey (USGS) 1:24,000 scale topographic maps used to determine the boundary of the San Luis Obispo Coast viticultural area are titled:

(1) Burro Mountain, 1995;
(2) Piedras Blancas, 1959; photoinspected 1976;
(3) San Simeon, 1958; photoinspected 1976;
(4) Pebblestone Shut-In, 1959; photoinspected 1976;
(5) Lime Mountain, 1948; photo revised 1979;
(6) Cypress Mountain, 1979;
(7) York Mountain, 1948; photoinspected 1979;
(8) Morro Bay North, 1995;
(9) Atascadero, 1995;
(10) San Luis Obispo, 1968; photoinspected 1978;
(11) Morro Bay South, 1965;
(12) Lopez Mountain, 1995;
(13) Arroyo Grande NE, 1985;
(14) Tar Spring Ridge, 1995;
(15) Nipomo, 1965;
(16) Huasna Peak, 1995;
(17) Twitchell Dam, 1959; photoinspected 1982;
(18) Santa Maria, 1959; photoinspected 1982;
(19) Oceano, 1965; revised 1994;
(20) Pismo Beach, 1998;
(21) Port San Luis, 1965; photoinspected 1979;
(22) Cayucos, 1965; revised 1994;
(23) Cambria, 1959; photoinspected 1979; and

(c) Boundary. The San Luis Obispo Coast viticultural area is located in San Luis Obispo County in California. The boundary of the San Luis Obispo Coast viticultural area is as described below:

(1) The beginning point is on the Burro Mountain map at the intersection of the northern boundary of the Piedra Blanca Grant boundary and the Pacific Ocean. From the beginning point, proceed southeast along the grant boundary to its intersection with the western boundary of Section 15, T25S/R6E; then
(2) Proceed northeast in a straight line to a marked 1,462-foot peak in Section 11, T25S/R6E; then
(3) Proceed southeast in a straight line, crossing onto the Piedras Blancas map, to a marked 2,810-foot peak in Section 19, T25S/R7E; then
(4) Proceed southeast in a straight line, crossing onto the San Simeon map, to the 2,397-foot peak of Garry Peak in the Piedra Blanca Land Grant; then
(5) Proceed east in a straight line to a marked 2,729-foot peak in Section 32, T25S/R8E; then
(6) Proceed southeast in a straight line, crossing onto the Pebblestone Shut-In map, to the 3,432-foot peak of Rocky Butte in Section 24, T26S/R8E; then
(7) Proceed southeast in a straight line to the 2,849-foot peak of Vulture Rock in Section 29, T26S/R9E; then
(8) Proceed southeast in a straight line, crossing over the Lime Mountain map and onto the Cypress Mountain map to the 2,933-foot peak of Cypress Mountain in Section 12, T27S/R9E; then
(9) Proceed southeast in a straight line, crossing onto the York Mountain map, to the intersection of Dover Canyon Road and a jeep trail in Dover Canyon in Section 14, T27S/R10E; then
(10) Proceed southwesterly, then southeasterly along the jeep trail to the point where the jeep trail becomes an unnamed light-duty road, and continuing southeasterly along the road to its intersection Santa Rita Creek in Section 25, T27S/R10E; then
(11) Proceed easterly along Santa Rita Creek to the point where the creek splits into a northern and a southern fork; then
(12) Proceed east in a straight line to Cayucos Templeton Road, then proceed south along Cayucos Templeton Road, crossing onto the Morro Bay North map and continuing along the road as it becomes Santa Rita Road, to the intersection of the road with the northeastern boundary of Section 20, T28S/R11E; then
(13) Proceed southeast along the northeastern boundary of Section 20 to its intersection with the western boundary of the Los Padres National Forest; then
(14) Proceed south, then southeasterly along the western boundary of the Los Padres National Forest, crossing over the Atascadero map and onto the San Luis Obispo map, to the intersection of the forest boundary with the boundary...
of the Camp San Luis Obispo National Guard Reservation at the northeastern corner of Section 32, T29S/R12E; then
(15) Proceed south, then generally southwesterly along the boundary of Camp San Luis Obispo National Guard Reservation, crossing onto the Morro Bay South map and then back onto the San Luis Obispo map, and then continuing generally easterly along the military reservation boundary to the intersection of the boundary with a marked 1,321-foot peak along the northern boundary of the Potrero de San Luis Obispo Land Grant; then
(16) Proceed southeast in a straight line, crossing onto the Lopez Mountain map, to the southeastern corner of Section 18, T30S/R13E; then
(17) Proceed southeasterly in a straight line to the southeast corner of Section 29; then
(18) Proceed southeasterly in a straight line to a marked 2,094-foot peak in Section 2, T31S/R13E; then
(19) Proceed southeasterly in a straight line, crossing onto the Arroyo Grande NE map, to the intersection of the 1,800-foot elevation contour and the western boundary of the Los Padres National Forest, along the eastern boundary of Section 12, T31S/R13E; then
(20) Proceed south along the boundary of the Los Padres National Forest to the southeastern corner of Section 13, T31S/R13E; then
(21) Proceed southeast in a straight line to a marked 1,884-foot peak in Section 19, T31S/R14E; then
(22) Proceed southeast in a straight line to northwesternmost corner of the boundary of the Lopez Lake Recreation Area in Section 19, T31S/R14E; then
(23) Proceed south, then generally east along the boundary of the Lopez Lake Recreation Area, crossing onto the Tar Spring Ridge map, to the intersection of the boundary with an unnamed light-duty road known locally as Lopez Drive west of the Lopez Dam spillway in Section 32, T31S/R14E; then
(24) Proceed east along Lopez Drive to its intersection with an unnamed light-duty road known as Hi Mountain Road in Section 34, T31S/R14E; then
(25) Proceed east along Hi Mountain Drive to its intersection with an unnamed light-duty road known locally as Upper Lopez Canyon Road in the Arroyo Grande Land Grant; then
(26) Proceed north along Upper Lopez Canyon Road to its intersection with an unnamed, unimproved road that runs south to Ranchita Ranch; then
(27) Proceed northeast in a straight line to a marked 1,183-foot peak in Section 19, T31S/R15E; then
(28) Proceed southeast in a straight line to a marked 1,022-foot peak in Section 29, T31S/R15E; then
(29) Proceed southwest in a straight line to a marked 1,310-foot peak in Section 30, T31S/R15E; then
(30) Proceed southeast in a straight line to a marked 1,261-foot peak in Section 32, T31S/R15E; then
(31) Proceed southeast in a straight line to a marked 1,436-foot peak in Section 4, T32S/R15E; then
(32) Proceed southwest in a straight line to a marked 1,308-foot peak in the Huasna Land Grant; then
(33) Proceed westerly in a straight line to a marked 1,070-foot peak in Section 1, T32S/R14E; then
(34) Proceed southeast in a straight line to a marked 1,251-foot peak in the Huasna Land Grant; then
(35) Proceed southwest in a straight line to a marked 1,458-foot peak in the Santa Manuela Land Grant; then
(36) Proceed southeast in a straight line to a marked 1,377-foot peak in the Huasna Land Grant; then
(37) Proceed southwest in a straight line, crossing onto the Nipomo map, to a marked 1,393-foot peak in the Santa Manuela Land Grant; then
(38) Proceed southwest in a straight line to the jeep trail immediately north of a marked 1,3 foot peak in Section 35, T32S/R14E; then
(39) Proceed northwesterly along the jeep trail to its intersection with an unnamed, unimproved road in the Santa Manuela Land Grant; then
(40) Proceed south along the unimproved road to its intersection with Upper Los Berros Road No. 2 in Section 33, T32S/R14E; then
(41) Proceed southeast along Upper Los Berros Road No. 2, crossing onto the Huasna Peak map, to the intersection of the road and State Highway 166; then
(42) Proceed south, then westerly along State Highway 166, crossing over the Twitchell Dam, Santa Maria, and Nipomo maps, then back onto the Santa Maria map, to the intersection of State Highway 166 with U.S. Highway 101 in the Nipomo Land Grant; then
(43) Proceed due south in a straight line to U.S. Highway 101's intersection with the north bank of the Santa Maria River; then
(44) Proceed west along the north bank of the Santa Maria River to its intersection with the 200-foot elevation contour; then
(45) Proceed generally west along the 200-foot elevation contour, crossing over the Nipomo map and onto the Ocean map, to a point north of where the north-south trending 100-foot elevation contour makes a sharp westerly turn in the Guadalupe Land Grant; then
(46) Proceed due south in a straight line to the 100-foot elevation contour; then
(47) Proceed westerly along the 100-foot elevation contour to its intersection with State Highway 1 in the Guadalupe Land Grant; then
(48) Proceed northwesterly in a straight line to the eastern boundary of the Pismo Dunes State Vehicular Recreation Area at Lettuce Lake in the Bolsa de Chami Sal Land Grant; then
(49) Proceed northwesterly along the eastern boundary of the Pismo Dunes State Vehicular Recreation Area to the point where the boundary makes a sharp westerly turn just west of Black Lake in the Bolsa de Chami Sal Land Grant; then
(50) Northerly along the Indefinite Boundary of the Pismo Dunes National Preserve to corner just west of Black Lake in the Bolsa de Chami Sal Land Grant; then
(51) Proceed east in a straight line to an unnamed four wheel drive road east of Black Lake in the Bolsa de Chami Sal Land Grant; then
(52) Proceed north along the western fork of the four wheel drive road as it meanders to the east of White Lake, Big Twin Lake, and Pipeline Lake, to the point where the road intersects an unnamed creek at the southeastern end of Cienega Valley in the Bolsa de Chami Sal Land Grant; then
(53) Proceed northwesterly along the creek to its intersection with an unnamed dirt road known locally as Delta Lane south of the Oceano Airport; then
(54) Proceed northwesterly along Delta Lane to its intersection with an unnamed light-duty road known locally as Ocean Street; then
(55) Proceed east in a straight line to State Highway 1; then
(56) Proceed northerly on State Highway 1, crossing onto the Pismo Beach map, to the highway’s intersection with a light-duty road known locally as Harloe Avenue; then
(57) Proceed west along Harloe Avenue to its intersection with the boundary of Pismo State Beach; then
(58) Proceed northwesterly along the boundary of Pismo State Beach to its intersection with the Pacific Ocean coastline; then
(59) Proceed northwesterly along the Pacific Ocean coastline, crossing over the Pismo Beach, Port San Luis, Morro Bay South, Morro Bay North, Cayucos, Cambria, Pico Creek, San Simeon, and Piedras Blancas maps and onto the Burro Mountain map, and returning to the beginning point.
Summary: The Alcohol and Tobacco Tax and Trade Bureau (TTB) proposes to establish the approximately 5,850-acre "Mount Pisgah, Polk County, Oregon" viticultural area in Polk County, Oregon. The proposed viticultural area lies entirely within the Willamette Valley viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase. TTB invites comments on this proposed addition to its regulations.

Dated: Comments must be received by November 30, 2020.

Addresses: You may electronically submit comments to TTB on this proposal, and view copies of this document, its supporting materials, and any comments TTB receives on it within Docket No. TTB–2020–0008 as posted on Regulations.gov (https://www.regulations.gov), the Federal e-rulemaking portal. Please see the "Public Participation" section of this document below for full details on how to comment on this proposal via Regulations.gov or U.S. mail, and for full details on how to obtain copies of this document, its supporting materials, and any comments related to this proposal.

Definitions: For further Information Contact: Kate M. Bresnahan, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; phone 202–453–1039, ext. 151.

Supplementary Information: Background on viticultural areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated the functions and duties in the administration and enforcement of these provisions to the TTB Administrator through Treasury Order 120–01, dated December 10, 2013 (superseding Treasury Order 120–01, dated January 24, 2003).

Part 4 of the TTB regulations (27 CFR part 4) authorizes TTB to establish definitive viticultural areas and regulate the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) sets forth standards for the preparation and submission of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

Definition

Section 4.25(e)(2) of the TTB regulations (27 CFR 4.25(e)(2)) outlines the procedure for proposing an AVA and provides that any interested party may petition TTB to establish a grape-growing region as an AVA. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes the standards for petitions for the establishment or modification of AVAs. Petitions to establish an AVA must include the following:

- Evidence that the area within the proposed AVA boundary is nationally or locally known by the AVA name specified in the petition;
- An explanation of the basis for defining the boundary of the proposed AVA;
- A narrative description of the features of the proposed AVA affecting viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed AVA distinctive and distinguish it from adjacent areas outside the proposed AVA;
- The appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed AVA, with the boundary of the proposed AVA clearly drawn thereon;
- If the proposed AVA is to be established within, or overlapping, an existing AVA, an explanation that both identifies the attributes of the proposed AVA that are consistent with the existing AVA and explains how the proposed AVA is sufficiently distinct from the existing AVA and therefore appropriate for separate recognition; and
- A detailed narrative description of the proposed AVA boundary based on USGS map markings.

Mount Pisgah, Polk County, Oregon Petition

TTB received a petition from the representatives of the vineyards and wineries within the proposed Mount Pisgah, Polk County, Oregon viticultural area, proposing the establishment of the “Mount Pisgah, Polk County, Oregon” AVA.

The proposed Mount Pisgah, Polk County, Oregon AVA is located within Polk County, Oregon. The proposed AVA lies entirely within the established Willamette Valley AVA (27 CFR 9.90) and does not overlap any other existing or proposed AVA. The proposed Mount Pisgah, Polk County, Oregon AVA contains approximately 5,850 acres, with 10 commercially-producing vineyards covering a total of 531 acres distributed throughout the proposed AVA. The petition states that an additional 164 acres in total will soon
be added to 4 of the existing vineyards. Two wineries are also located within the proposed AVA.

According to the petition, the distinguishing features of the proposed Mount Pisgah, Polk County, Oregon AVA include its climate, geology, soils, and topography. Unless otherwise noted, all information and data pertaining to the proposed AVA contained in this document are from the petition for the proposed Mount Pisgah, Polk County, Oregon AVA and its supporting exhibits.

**Name Evidence**

The petition states that the proposed Mount Pisgah, Polk County, Oregon gets its name from the 835-foot mountain on which the proposed AVA is located. According to the petition, Colonel Cornelius Gilliam named Mount Pisgah, a small mountain near where he settled in Dallas, Oregon in 1845, after the Mount Pisgah near his home in Missouri. The petition included several examples that demonstrate the long-term use of the name “Mount Pisgah” to describe the region of the proposed AVA. For example, in a 1915 account of her journey from Illinois to Polk County and her first years there, Mary Dempsey Bronson recalled her first picnic in Oregon, which was “a May Day picnic on Mount Pisgah” in 1865. An excerpt from the 1927 edition of *Polk County Geographic Names* includes a reference to Mount Pisgah. A Mount Pisgah local chapter of the Oregon Farmers’ Union was active from the 1930s through the 1950s. Mount Pisgah Fruit Farms appeared on Metzger maps of the region as late as 1962, according to the petition.

The petition states that currently, the name “Mount Pisgah” is still used to describe the region. The mountain that forms the majority of the proposed AVA is labeled “Mount Pisgah” on the current United States Geological Survey (USGS) Dallas, Oregon, quadrangle map, as well as on Google Maps, OpenStreetMap, and other map websites, according to the petition. Furthermore, Mt. Pisgah Orchards is a company doing business within the proposed AVA.

**Boundary Evidence**

The boundary of the proposed Mount Pisgah, Polk County, Oregon viticultural area is defined by the shape of the mountain, according to the petition.

Clear divisions of climate, geology, soils, elevation, and topography informed the creation of the boundary. The boundary follows a series of roads and elevation contours to separate the mountain that forms the proposed AVA from the surrounding lower, flatter valley floor, with its alluvial soils and warmer, windier climate.

**Distinguishing Features**

The distinguishing features of the proposed Mount Pisgah, Polk County, Oregon AVA include its temperature, wind speed, geology, soils, elevation, and topography.

**Temperature**

The petitioner collected temperature data from one location within and two locations outside of the proposed Mount Pisgah, Polk County, Oregon AVA. The petitioner collected the data from April through October during the period of 2014–2016 from Croft Vineyard within the proposed AVA; the airport at Salem in the Willamette Valley AVA, 18 miles east of the proposed AVA; and the airport at McMinnville, which is located within the Willamette Valley AVA and adjacent to the McMinnville AVA, 23 miles north-north-east of the proposed AVA. The petition did not include temperature data from the regions to the north, south, or west of the proposed AVA.

The petition states that the proposed Mount Pisgah, Polk County, Oregon AVA is cooler than the surrounding areas, with an average of 2,543 growing degree days over the three years, making it a low region II on the Winkler Scale. The petitioner notes that the 2014–2016 growing seasons for the proposed AVA were warmer than usual, and that a more typical year’s GDD average would place the proposed AVA in the cooler Winkler region 1b. However, the petitioner did not include data to support this claim. Over the same period of time, Salem had an average of 2,903 GDD per year, making it a high region II on the Winkler Scale. McMinnville had an average of 2,661 GDD over the same period of time, making it a mid-region II on the Winkler Scale, according to the petition.

The petition notes that the difference in temperature between the proposed Mount Pisgah, Polk County, Oregon AVA and its surrounding areas has an important impact on viticulture. Winkler identified pinot noir, pinot gris, and chardonnay as grape varietals that are typically grown in regions classified as region 1b. According to the petition, approximately 90 percent of the grapes planted in the proposed AVA are pinot noir, pinot gris, and chardonnay.

**Wind Speed**

According to the petition, to the north of the proposed Mount Pisgah, Polk County, Oregon AVA are the lower-elevation areas near the towns of Dallas, Perrydale, and Rickreall. In these areas, the coastal winds enter the Willamette Valley through the Van Duzer Corridor wind gap in the mountains of the Coast Range. The petition states that the Willamette Valley also experiences north and south winds along the valley floor. The petition states that the proposed AVA is protected from the Pacific coastal winds by the higher elevations of the Coast Range to the west, and from the valley floor winds due to its higher elevations. As a result, the proposed AVA has a much lower average wind speed than the surrounding areas.

The petition included growing season wind speed data from 2014–2016 collected from within the proposed Mount Pisgah, Polk County, Oregon AVA and the regions to the east and north-northeast of the proposed AVA. The data shows that Salem has the highest average wind speed (6.1 mph); McMinnville has a slightly lower average wind speed (5.2 mph); and the proposed AVA has a much lower average wind speed (2.3 mph). According to the Oregon Annual Average Wind Speed map included in the petition, the nearby established Van Duzer Corridor AVA (27 CFR 9.265) to the north and the established Eola-Amity Hills AVA (27 CFR 9.202) to the north-northeast have average wind speeds between 5.0 and 6.0 meters per second (m/s), while the proposed AVA has an average wind speed of 4.5 m/s. The petition quotes climatologist Gregory V. Jones when describing the impact winds have on viticulture: “During the early stages of vegetative growth, high winds can break new shoots, delaying and even reducing the amount of flowering. As the berries


3 See Albert J. Winkler, *General Viticulture* (Berkeley: University of California Press, 1974), pages 61–64. In the Winkler climate classification system, annual heat accumulation during the growing season, measured in annual GDDs, defines climatic regions. One GDD accumulates for each degree Fahrenheit that a day’s mean temperature is above 50 degrees F, the minimum temperature required for grapevine growth.

4 Id. In the Winkler scale, the GDD regions are defined as follows: Region I = less than 2,500 GDDs; Region II = 2,501–3,000 GDDs; Region III = 3,001–3,500 GDDs; Region IV = 3,501–4,000 GDDs; Region V = greater than 4,000 GDDs.

proceed through veraison and into the maturation stage, high winds can be very effective at desiccating the fruit and can result in lower volume

* * *

6 The petition adds that wind affects the composition of berries, humidity in vineyards, susceptibility to fungal infection, the microflora on berries, and the temperature during the ripening period as well as during spring and fall freezes.7

Geology

The petition states that the proposed Mount Pisgah, Polk County, Oregon AVA is bounded topographically around a unique geological formation that occurs only within the proposed AVA. Other Oregon AVAs have sedimentary soils, but they do not have the combination of these soils with an ancient parent material. The parent material of the mountain comes from the Siletz River volcanics of the middle and lower Eocene and Paleocene (approximately 40 to 60 million years ago). The rocks are zeolitized (contain aluminum) and veined with calcite, and were sea floor mountains. The Siletz River volcanics are exposed near the summit of Mount Pisgah, where it directly affects the soils and viticulture. The Siletz River volcanics are the oldest rocks in the Willamette Valley, and occur below marine sediments six miles from the Willamette River, which makes the proposed AVA unique, according to the petition.

According to the petition, 97.2 percent of the soils within the proposed Mount Pisgah, Polk County, Oregon AVA contain colluvium or residuum as parent material, both of which are ancient sedimentary soils that form different soil horizons. The only alluvial parent material in the area is old alluvium coming from the Missoula Flood, which comprises 2.1 percent of the area.

The petition states that the geology of the areas surrounding the proposed Mount Pisgah, Polk County, Oregon AVA are different than that within the proposed AVA. The area to the north of the proposed AVA is comprised of alluvial parent material from the quaternary period, silt, and sand. The area to the west of the proposed AVA is made up of marine siltstone and basalt sandstone. The area to the south of the proposed AVA is alluvial creek beds between formation of siltstone and sandstone. Finally, the area to the east of the proposed AVA is made from alluvial parent material from the quaternary period, silt, and sand, according to the petition.

According to Ted Goldammer’s *Grape Grower’s Handbook*, “The nature of the parent material can have a profound influence on the characteristics of the soil. The mineralogy of the parent material is mirrored in the soil and can determine the weathering process and control the natural vegetation composition.” 8 A research article on grapevine rooting patterns by David R. Smart et al. states, “Grapevines, as a group, appear to have proportionally deeper root distributions * * * compared to many plants in natural ecosystems.” 9 The article also states that in viticulture, mature grape roots may reach 20 feet and may penetrate multiple soil horizons, accessing different minerals. Because the geology of the proposed AVA is different from that of the surrounding regions, grapevine roots within the proposed AVA will have access to a different set of minerals and nutrients than grapevines grown elsewhere.

Soils

The petition states that the weathered soils in the upper layers of the proposed Mount Pisgah, Polk County, Oregon AVA contain coarse to fine sand, silt, and clay. The soils to the south of the proposed AVA are medium textured. Water is available for plants throughout most of the growing season, and soil wetness does not inhibit the growth of roots for significant periods. 10 The USDA defines well drained soils as soils in which water is removed readily, but not rapidly. Well drained soils are commonly medium textured. Water is available for plants throughout most of the growing season, and soil wetness does not inhibit the growth of roots for significant periods. 11 The USDA defines moderately well drained soils as soils in which water is removed somewhat slowly during some periods. 12 Grapes are particularly sensitive to high water levels, according to the petition.

However, grapes do need some water in the summer months, and, according to the petition, available water capacity in the proposed AVA is moderately high. A map of available water capacity of the soils of the proposed AVA and the surrounding regions shows the values of the soils in the proposed AVA range narrowly from 0.16 to 0.12 centimeters (cm) of water to 1 cm of soil, which enables dry farming. Hydraulic conductivity of soil is a linear measurement that describes the ease with which water moves through soil when it is saturated. It is measured in Ksat. According to the petition, a balanced Ksat value allows for root penetration at slow but acceptable rates. According to a map of Ksat values of the soils of the proposed AVA and surrounding regions that was included in the petition, the proposed AVA has Ksat ratings between 3.0 and 4.7, which constitutes a balanced distribution when it comes to hydraulic conductivity.

The petition states that the areas surrounding the proposed Mount Pisgah, Polk County, Oregon AVA have different soil characteristics, as they all contain alluvial deposits from the recent quaternary period, instead of sedimentary deposits. To the north of the proposed AVA, soils are clayey alluvium, have a lower Ksat rating, and are more poorly drained. To the west of the proposed AVA, the soils are alluvial loam, have a lower Ksat rating, and are more poorly drained. To the south of the proposed AVA, soils are silty alluvium and have a lower Ksat rating. According to the petition, soils to the south of the proposed AVA are also not as well drained as the soils of the proposed AVA, even though the differences in soil drainage are not as easily visible on the soil drainage map as they are in

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10 Supra note 8.


12 Id.
other surrounding regions. To the east of the proposed AVA, soils are silty alluvium and alluvial loam, have a higher Ksat rating, and are also more poorly drained.

Elevation and Topography

The petition states that the proposed Mount Pisgah, Polk County, Oregon AVA is located on a small mountain among the hills of the Willamette Valley AVA. The foot of the mountain, which marks the edges of the proposed AVA, is at 260 feet. The top of the Mount Pisgah, at 835 feet, is within the range of elevation for typical wine-grape production in the region. All wine-grape production in the proposed AVA occurs between 750 and 260 feet in elevation, which allows for adequate heat accumulation and cold air drainage. The proposed AVA is also contains several creeks, including Fern Creek, Cooper Creek, and multiple forks of Ash Creek. The elevations and topography of the proposed AVA help protect the vineyards from frost damage in the spring and fall, as cool air drains down the hillsides and creeks to the lower-elevation areas that occur in all directions outside of the proposed AVA.

The petition also states that the proposed Mount Pisgah, Polk County, Oregon AVA has south-facing slopes. By contrast, the region to the south of the proposed AVA, on the slopes of Fishback Hill, faces north. The difference in slope direction has an effect on viticulture. According to the petition, “On a south-facing slope and a north-facing, plants grow differently. Even if the soils are the same, there is different response to temperatures, different emergence times, and different development rates. The temperature variation across the field itself may be on the order of 5°F. In growing degree days over a seven-month season, this could change the total by more than 500 GDDs at 5°F (for only half the day)—very significant considering the yearly totals mentioned earlier in this document.” The petition states that grapes in Oregon are rarely planted on north-facing slopes for that reason.

Summary of Distinguishing Features

In summary, the temperature, wind speed, geology, soils, and elevation and topography of the proposed Mount Pisgah, Polk County, Oregon AVA distinguish it from the surrounding regions. The proposed AVA had an average of 2,543 GDDs and an average wind speed of 2.3 miles per hour between 2014 and 2016. Geologically, the proposed AVA contains Siletz River volcanics parent material that is unique in Oregon AVAs. The majority of the soils in the proposed AVA are silty clay loams. The proposed AVA is a small mountain, where wine grapes grow between 260 and 750 feet in elevation. The following table, derived from the proposed AVA, compares the features of the proposed AVA to the features of the surrounding areas.

<table>
<thead>
<tr>
<th>Distinguishing feature</th>
<th>Direction from proposed AVA</th>
<th>Description of difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature and Growing Degree Days.</td>
<td>North, East</td>
<td>Warmer with higher GDD accumulations.</td>
</tr>
<tr>
<td>Wind</td>
<td>North, East</td>
<td>Higher wind speeds.</td>
</tr>
<tr>
<td>Geology</td>
<td>North, South, East, West</td>
<td>No Siletz River volcanics parent material; alluvial parent material.</td>
</tr>
<tr>
<td>Soils</td>
<td>North, South, East, West</td>
<td>Poorly-drained alluvial soils in each direction; lower Ksat values to north, west, and south, and higher values to the east.</td>
</tr>
<tr>
<td>Elevation</td>
<td>North, East, West</td>
<td>Lower elevations.</td>
</tr>
<tr>
<td>Topography</td>
<td>North, South, East, West</td>
<td>Topography flattens to north, east, and west; rises to a north-facing slope to the south.</td>
</tr>
</tbody>
</table>

Comparison of the Proposed Mount Pisgah, Polk County, Oregon AVA to the Existing Willamette Valley AVA

T.D. ATF–162, which published in the Federal Register on December 1, 1983 (48 FR 54221), established the Willamette Valley AVA in northwest Oregon. The Willamette Valley AVA is one of nine physiographic regions in Oregon and it is described as a “broad alluvial plain” with a unique and homogeneous climate. Temperatures in the Willamette Valley AVA are mild, averaging 40°F in the winter and 75°F in the summer. The area averages 40 inches of rainfall per year. The Willamette Valley AVA contains two basic types of soil—silty loam and clay loam.

The proposed Mount Pisgah, Polk County, Oregon AVA is located 15 miles west of Salem, Oregon, and would be the southermest AVA within the Willamette Valley AVA, and it shares some broad characteristics with the established AVA. Like the established AVA, the proposed AVA does not contain elevations above 1,000 feet above sea level. Additionally, both areas contain mostly silty and clay loam soils. However, the proposed AVA differs from the Willamette Valley AVA because it is located entirely on a small mountain. Thus, it has slightly lower temperatures than other regions within the Willamette Valley AVA. Wind speeds within the proposed AVA are also lower than in other parts of the Willamette Valley AVA, due to its elevation. Lastly, the proposed AVA contains Siletz River volcanics parent material, a unique geological feature which only occurs within the proposed AVA.

TTB Determination

TTB concludes that the petition to establish the approximately 5,850-acre Mount Pisgah, Polk County, Oregon AVA merits consideration and public comment, as invited in this notice of proposed rulemaking.

Boundary Description

See the narrative description of the boundary of the petitioned-for AVA in the proposed regulatory text published at the end of this proposed rule.

Maps

The petitioner provided the required maps, and they are listed below in the proposed regulatory text. You may also view the proposed Mount Pisgah, Polk County, Oregon AVA boundary on the AVA Map Explorer on the TTB website, at https://www.ttb.gov/wine/ava-map-explorer.

Impact on Current Wine Labels

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine’s true place of origin. For a wine to be labeled with an AVA name or with a brand name that includes an AVA name or other term identified as being viticulturally significant in part 9 of the TTB regulations, at least 85

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percent of the wine must be derived from grapes grown within the area represented by that name or other term, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with an AVA name or other viticulturally significant term and that name or term appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the AVA name or other viticulturally significant term appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label. Different rules apply if a wine has a brand name containing an AVA name or other viticulturally significant term that was used as a brand name on a label approved before July 7, 1986. See §4.39(i)(2) of the TTB regulations (27 CFR 4.39(i)(2)) for details.

If TTB establishes this proposed AVA, its name, “Mount Pisgah, Polk County, Oregon,” will be recognized as a name of viticultural significance under § 4.39(i)(3) of the TTB regulations (27 CFR 4.39(i)(3)). TTB also proposes to designate “Mt. Pisgah, Polk County, Oregon” as a term of viticultural significance. The text of the proposed regulation clarifies this point. Consequently, wine bottlers using the name “Mount Pisgah, Polk County, Oregon” in a brand name, including a trademark, or in another label reference as to the origin of the wine, would have to ensure that the product is eligible to use the AVA name as an appellation of origin if this proposed rule is adopted as a final rule. TTB is not proposing to make “Mount Pisgah” a term of viticultural significance due to the number of locations known as “Mount Pisgah” within the United States. Finally, TTB is proposing to allow the word “Mount” to be abbreviated as “Mt.” in the name of the proposed AVA, if the proposed AVA is established.

The approval of the proposed Mount Pisgah, Polk County, Oregon AVA would not affect an existing AVA, and any bottlers using “Willamette Valley” as an appellation of origin or in a brand name for wines made from grapes grown within the Willamette Valley would not be affected by the establishment of this new AVA. The establishment of the proposed Mount Pisgah, Polk County, Oregon AVA would allow vintners to use “Mount Pisgah, Polk County, Oregon” and “Willamette Valley” as appellations of origin for wines made from grapes grown within the proposed Mount Pisgah, Polk County, Oregon AVA, if the wines meet the eligibility requirements for the appellation.

Public Participation

Comments Invited

TTB invites comments from interested members of the public on whether it should establish the proposed AVA. TTB is also interested in receiving comments on the sufficiency and accuracy of the name, boundary, soils, climate, and other required information submitted in support of the petition. In addition, given the proposed Mount Pisgah, Polk County, Oregon AVA’s location within the existing Willamette Valley AVA, TTB is interested in comments on whether the evidence submitted in the petition regarding the distinguishing features of the proposed AVA sufficiently differentiates it from the existing Willamette Valley AVA. TTB is also interested in comments on whether the geographic features of the proposed AVA are so distinguishable from the surrounding Willamette Valley AVA that the proposed Mount Pisgah, Polk County, Oregon AVA should no longer be part of that AVA. Please provide any available specific information in support of your comments.

Because of the potential impact of the establishment of the proposed Mount Pisgah, Polk County, Oregon AVA on wine labels that include the term “Mount Pisgah, Polk County, Oregon” as discussed above under Impact on Current Wine Labels, TTB is particularly interested in comments regarding whether there will be a conflict between the proposed AVA name and currently used brand names. If a commenter believes that a conflict will arise, the comment should describe the nature of that conflict, including any anticipated negative economic impact that approval of the proposed AVA will have on an existing viticultural enterprise. TTB is also interested in receiving suggestions for ways to avoid conflicts, for example, by adopting a modified or different name for the AVA.

Submitting Comments

You may submit comments on this notice by using one of the following two methods:

- **Federal e-Rulemaking Portal:** You may send comments via the online comment form posted with this notice within Docket No. TT–2020–0008 on “Regulations.gov,” the Federal e-rulemaking portal, at https://www.regulations.gov. A direct link to that docket is available on the TTB website at https://www.ttb.gov/wine/wine_rulemaking.shtml under Notice No. 193. You may also reach the relevant docket through the Regulations.gov search page at https://www.regulations.gov. For information on how to use Regulations.gov, click on the site’s “Help” tab.

- **Postal Mail:** You may send comments via postal mail to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005.

Please submit your comments by the closing date shown above in this notice. Your comments must reference Notice No. 193 and include your name and mailing address. Your comments must be made in English, be legible, and be written in language acceptable for public disclosure. TTB does not acknowledge receipt of comments, and TTB considers all comments as original.

In your comment, please clearly state if you are commenting for yourself or on behalf of an association, business, or other entity. If you are commenting on behalf of an entity, your comment must include the entity’s name, as well as your name and position title. If you comment via Regulations.gov, please enter the entity’s name in the “Organization” blank of the online comment form. If you comment via postal mail or hand delivery/courier, please submit your entity’s comment on letterhead.

You may also write to the Administrator before the comment closing date to ask for a public hearing. The Administrator reserves the right to determine whether to hold a public hearing.

Confidentiality

All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

Public Disclosure

TTB will post, and you may view, copies of this notice, selected supporting materials, and any online or mailed comments received about this proposal within Docket No. TT–2020–0008 on the Federal e-rulemaking portal, Regulations.gov, at https://www.regulations.gov. A direct link to that docket is available on the TTB website at https://www.ttb.gov/wine/wine_rulemaking.shtml under Notice No. 193. You may also reach the relevant docket through the Regulations.gov search page at https://www.regulations.gov. For information on how to use Regulations.gov, click on the site’s “Help” tab.

All posted comments will display the commenter's name, organization (if
any), city, and State, and, in the case of mailed comments, all address information, including email addresses. TTB may omit voluminous attachments or material that the Bureau considers unsuitable for posting.

You may also obtain copies of this proposed rule, all related petitions, maps and other supporting materials, and any electronic or mailed comments that TTB receives about this proposal at 20 cents per 8.5 × 11-inch page. Please note that TTB is unable to provide copies of TSB maps or any similarly-sized documents that may be included as part of the AVA petition. Contact TTB’s Regulations and Rulings Division by email using the web form at https://www.ttb.gov/contact-rrd, or by telephone at 202–453–1039, ext. 175, to request copies of comments or other materials.

Regulatory Flexibility Act

TTB certifies that this proposed regulation, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposed regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of an AVA name would be the result of a proprietor’s efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

It has been determined that this proposed rule is not a significant regulatory action as defined by Executive Order 12866 of September 30, 1993. Therefore, no regulatory assessment is required.

Drafting Information

Kate M. Bresnahan of the Regulations and Rulings Division drafted this notice of proposed rulemaking.

List of Subjects in 27 CFR Part 9

Wine.

Proposed Regulatory Amendment

For the reasons discussed in the preamble, TTB proposes to amend title 27, chapter I, part 9, Code of Federal Regulations, as follows:

PART 9—AMERICAN VITICULTURAL AREAS

1. The authority citation for part 9 continues to read as follows:


Subpart C—Approved American Viticultural Areas

2. Subpart C is amended by adding § 9. ___ to read as follows:

§ 9. Mount Pisgah, Polk County, Oregon.

(a) Name. The name of the viticultural area described in this section is “Mount Pisgah, Polk County, Oregon.” For purposes of part 4 of this chapter, “Mount Pisgah, Polk County, Oregon” and “Mt. Pisgah, Polk County, Oregon” are terms of viticultural significance.

(b) Approved maps. The two United States Geological Survey (USGS) 1:24,000 scale topographic maps used to determine the boundary of the Mount Pisgah, Polk County, Oregon viticultural area are titled:

(1) Dallas, OR, 2014; and

(2) Airlie North, OR, 2014.

(c) Boundary. The Mount Pisgah, Polk County, Oregon viticultural area is located in Polk County, Oregon. The boundary of the Mount Pisgah, Polk County, Oregon viticultural area is as described below:

(1) The beginning point is on the Dallas map at the point where the 320-foot elevation contour intersects Mistletoe Road south of the unnamed road known locally as SE Lewis Street. From the beginning point, proceed south along Mistletoe Road for approximately 2 miles to the road’s second intersection with the 740-foot elevation contour; then

(2) Proceed due west approximately 0.5 miles to the 400-foot elevation contour; then

(3) Proceed south along the 400-foot elevation contour, crossing onto the Airlie North map, to the contour’s intersection with Cooper Hollow Road near Fisher Reservoir; then

(4) Proceed southeasterly along Cooper Hollow Road to its intersection with McCaleb Road; then

(5) Proceed east, then northeast, then east along McCaleb Road for approximately 1.6 miles to its intersection with Mistletoe Road and the 260-foot elevation contour; then

(6) Proceed easterly along the 260-foot elevation contour until it intersects again with Mistletoe Road; then

(7) Proceed east along Mistletoe Road for 0.3 mile to its intersection with Matney Road; then

(8) Proceed north along Matney Road for 0.6 mile to its intersection with the 260-foot elevation contour at a 90 degree turn in the road; then

(9) Proceed northwesterly along the 260-foot elevation contour to its intersection with Bursell Road; then

(10) Proceed east along Bursell Road for 0.2 mile to its intersection with the 260-foot elevation contour; then

(11) Proceed north along the 260-foot elevation contour, crossing onto the Dallas map, to the contour’s intersection with Whiteaker Road; then

(12) Proceed southeasterly along Whiteaker Road for 1.0 mile to its intersection with the 260-foot elevation contour at a 90 degree turn in the road; then

(13) Proceed north, then west along the 260-foot elevation contour to its intersection with Ballard Road; then

(14) Proceed south along Ballard Road to its intersection with the 300-foot elevation contour; then

(15) Proceed northwesterly along the 300-foot elevation contour, to its intersection with Cherry Knoll Road; then

(16) Proceed south along Cherry Knoll Road to its intersection with the 320-foot elevation contour; then

(17) Proceed northwesterly along the 320-foot elevation contour, returning to the beginning point.


Mary G. Ryan,
Acting Administrator.

Approved: June 17, 2020.

Timothy E. Skud,
Deputy Assistant Secretary, (Tax, Trade, and Tariff Policy).

Editorial Note: This document was received for publication by the Office of the Federal Register on August 11, 2020.

[FR Doc. 2020–17854 Filed 9–30–20; 8:45 am

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 200902–0231]

RIN 0648–BJ05

Fisheries Off West Coast States; West Coast Salmon Fisheries; Rebuilding Coho Salmon Stocks

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to approve and implement rebuilding plans recommended by the Pacific Fishery Management Council (Council) for three overfished stocks: Juan de Fuca, Queets,
and Snohomish natural coho salmon (collectively, the overfished coho stocks). NMFS determined in June 2018 that these stocks were overfished. NMFS also announces the availability for public review and comment of a draft environmental assessment (EA) analyzing the environmental impacts of implementing these rebuilding plans.

**DATES:** Public comments must be received by November 2, 2020.

**ADDRESSES:** You may submit comments on this document, identified by NOAA–NMFS–2019–0138, by any of the following methods:

- **Electronic Submission:** Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to www.regulations.gov, click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

- **Mail:** Peggy Mundy, NMFS West Coast Region, Sustainable Fisheries Division 7600 Sand Point Way NE, Seattle, WA 98115.

**Instructions:** Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments considered are a part of the public record and will generally be posted for public viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

The Council and NMFS prepared a draft environmental assessment (EA) which includes a regulatory flexibility analysis for each of the three overfished coho stock rebuilding plans. Electronic copies of these documents may be obtained from the West Coast Regional Office website at https://www.fisheries.na.gov/west-coast/laws-and-policies/west-coast-region-national-environmental-policy-act-documents.

**FOR FURTHER INFORMATION CONTACT:**
Peggy Mundy at 206–526–4323.

**SUPPLEMENTARY INFORMATION:**

### Background

The Magnuson-Stevens Fishery Conservation and Management Act (MSA) established a national program for the conservation and management of the fishery resources of the United States to prevent overfishing and to rebuild overfished stocks. To that end, the MSA requires fishery management plans (FMPs) to specify objective and measurable criteria for identifying when the fishery to which the FMP applies is overfished (MSA section 303(a)(10)). The MSA includes national standards which must be followed in any FMP. NMFS has developed guidelines, based on the national standards, to assist in the development and review of FMPs, amendments, and regulations prepared by the Councils and the Secretary (50 CFR 600.305(a)(1)). National Standard 1 (NS1) addresses the need under the MSA for FMPs to specify conservation and management measures that shall prevent overfishing while achieving, on a continuing basis, the optimum yield from each fishery for the U.S. fishing industry (50 CFR 600.310). The NS1 guidelines include status determination criteria (SDC) and other reference points that are used to determine if overfishing has occurred, or if the stock or stock complex is overfished (50 CFR 600.310(e)(2)), and specifies Council actions required to address overfishing and rebuilding for stocks and stock complexes (50 CFR 600.310(j)).

Ocean salmon fisheries in the exclusive economic zone (EEZ) (3 to 200 nautical miles offshore) off Washington, Oregon, and California are managed under the Pacific Fishery Management Council’s (Council) Pacific Coast Salmon FMP (Salmon FMP). The Salmon FMP identifies stocks that are in the fishery and the SDC and reference points that are used to determine when a stock is overfished and when it is rebuilt. For salmon, these metrics are based on the stock’s spawning escapement (i.e., fish that escape the ocean and in-river fisheries to spawn) and the abundance of adult spawners that is expected, on average, to produce maximum sustained yield (MSY), which is expressed as $S_{MSY}$.

The SDC for overfished is defined in the Salmon FMP to be when the three-year geometric mean of a salmon stock’s annual spawning escapements falls below the reference point known as the minimum stock size threshold (MSST), where MSST is generally defined as 0.5$S_{MSY}$ or 0.75$S_{MSY}$—depending on the stock. The default SDC in the Salmon FMP for determining that an overfished stock is rebuilt is when the three-year geometric mean spawning escapement exceeds $S_{MSY}$. Stock-specific values for the $S_{MSY}$ and MSST reference points are listed in Table 3–1 of the Salmon FMP, which is available on the Council’s website (www.pcouncil.org). The status of salmon stocks is assessed annually. When NMFS determines that a stock is overfished, by virtue of meeting the overfished criteria in the Salmon FMP, described above, NMFS notifies the Council. The MSA requires Councils to develop and implement a rebuilding plan within two years of being notified by NMFS that a stock is overfished.

In 2018, NMFS determined that two stocks of Chinook salmon and three stocks of coho salmon were overfished (83 FR 38292, August 6, 2018). NMFS published a proposed rule to approve the Council’s rebuilding plans for the two Chinook salmon stocks and amend 50 CFR part 660 to add § 660.413 Overfished species rebuilding plans (85 FR 6135, February 4, 2020).

**Overfished Determination for Three Coho Stocks**

The annual stock assessments for the three overfished coho stocks in 2018 used escapement data for 2014 through 2016 to determine if the stocks were overfished. The three-year geometric mean spawning escapement for Juan de Fuca coho for the period 2014–2016 was 6,842, which is less than the stock’s MSST of 7,000 (Table 1). The three-year geometric mean spawning escapement for Queets coho for the period 2014–2016 was 4,291, which is less than the stock’s MSST of 4,350 (Table 1). The three-year geometric mean spawning escapement for Snohomish coho for the period 2014–2016 was 29,677, which is less than the stock’s MSST of 31,000. NMFS notified the Council that these stocks were overfished on June 18, 2018, and the overfished determinations were announced in the Federal Register on August 6, 2018 (83 FR 38292). To be determined to be rebuilt, these stocks must achieve a three-year geometric mean escapement of $S_{MSY}$ or greater. $S_{MSY}$ for Juan de Fuca coho is 11,000, $S_{MSY}$ for Queets coho is 5,800, $S_{MSY}$ for Snohomish coho is 50,000.
Fishery Management for the Overfished Coho Stocks

U.S. ocean salmon fisheries impact the three coho stocks in the EEZ north of Cape Falcon, OR. These stocks are also harvested in ocean fisheries off Alaska, British Columbia, and in Washington state waters, including the Strait of Juan de Fuca and Puget Sound. Management of these stocks is subject to the provisions of the Pacific Salmon Treaty Act, which implements the Pacific Salmon Treaty (PST) between the U.S. and Canada, and also must be consistent with Indian tribal treaty fishing rights. The State of Washington and Indian tribes with reserved fishing rights on the Washington Coast and in Puget Sound negotiate annual fisheries through the North of Falcon Process and under the auspices of Hoh v. Baldridge and U.S. v. Washington. Salmon fisheries under the jurisdiction of the Council (Council-managed) are managed to meet agreed upon exploitation rates (i.e., proportion of potential spawners removed by fishing) and escapement goals set under the PST and the North of Falcon Process for several salmon stocks, including the three overfished coho stocks. Total fishing mortality for these coho stocks includes preterminal (i.e., fisheries impacts outside a given stock’s natal river or estuary, including mixed-stock ocean fisheries) and terminal (i.e., fisheries impacts within a given stock’s natal river or estuary). These exploitation rates, or stepped harvest rates, are set annually based on forecast stock abundance, as described below for each stock (see Rebuilding Plans). In addition to these exploitation rates, Council salmon fisheries are also managed to meet conservation objectives and status determination criteria specified in the Salmon FMP under Amendment 16 (76 FR 81851, December 29, 2011). However, annual natural spawning escapement targets for many Washington coast and Puget Sound salmon stocks, including the three overfished coho stocks, may vary from Salmon FMP conservation objectives if agreed to by the Washington tribal and state co-managers, under the provisions of Hoh v. Baldridge, U.S. v. Washington, or subsequent U.S. District Court orders (Table 3–1 of the Salmon FMP).

Juan de Fuca natural coho. The Juan de Fuca coho stock contributes to U.S. ocean salmon fisheries north of Cape Falcon and to ocean salmon fisheries off British Columbia, and to marine and freshwater Puget Sound salmon fisheries. For the period 2004–2017, the total exploitation rate on Juan de Fuca coho averaged 10.5 percent, distributed as follows: Alaskan and Canadian ocean salmon fisheries—23 percent, Council-managed ocean salmon fisheries—23 percent, and other preterminal and terminal salmon fisheries (primarily sport, net, and troll fisheries in the Strait of Juan de Fuca)—54 percent.

Queets natural coho. The Queets coho stock contributes to ocean salmon fisheries off of British Columbia and Washington state, as well as Washington coastal in-river salmon fisheries. For the period 2004–2017, the total exploitation rate on Queets coho averaged 38.5 percent, distributed as follows: Alaskan and Canadian ocean salmon fisheries—8 percent, Council-managed ocean salmon fisheries—20 percent, and other preterminal and terminal salmon fisheries (including freshwater sport and net fisheries in the Quinault, Hoh, and Queets Rivers on the Washington coast)—72 percent.

Snohomish natural coho. The Snohomish coho stock contributes to U.S. ocean salmon fisheries north of Cape Falcon and to ocean salmon fisheries off British Columbia, and to marine and freshwater Puget Sound salmon fisheries. For the period 2004–2017, the total exploitation rate on Snohomish coho averaged 24.4 percent, distributed as follows: Alaskan and Canadian ocean salmon fisheries—5 percent, Council-managed ocean salmon fisheries—9 percent, and other preterminal and terminal salmon fisheries within Puget Sound—86 percent.

Rebuilding Plans

The Council transmitted their recommended rebuilding plans for the three overfished coho stocks to NMFS on October 17, 2019. The plans were developed over the course of several Council meetings in 2018 and 2019 and were informed by the analyses of the Council’s Salmon Technical Team (STT). The STT held public meetings and workshop sessions with state and Federal agencies, tribal governments, and the general public to assess available information on various factors that could impact the productivity of these stocks and lead to the overfished determination. These factors include: Freshwater survival, marine survival, harvest impacts, and assessment and fishery management errors.

Overfishing on the three overfished coho stocks, defined as the exploitation rate on a stock exceeding the maximum fishing mortality threshold (MFMT), did not occur during the years that lead to the overfished determination. The STT’s report concluded that the overfished situation for these stocks was primarily the result of poor marine survival; abundance in 2015 was substantially lower than anticipated in preseason forecasts for many Washington coho stocks. Freshwater habitat conditions and fishery management may have exacerbated the problem caused by low marine survival, but these were not identified in the STT’s report as the proximate cause of the overfished status of any of the three coho stocks. Based on 2015–2017 abundance, Juan de Fuca coho would likely have met the overfished criteria even in the absence of fishing in that time period. The STT’s report is contained within the draft EA (see ADDRESSES).

The Council considered two alternatives for the rebuilding plan for each stock: (1) The existing control rule and (2) a buffered exploitation rate or escapement goal. The Council’s recommendations for rebuilding the overfished coho stocks, which NMFS proposes to approve, are to maintain the existing control rules for Juan de Fuca coho and Queets coho, and to manage for a ten-percent buffer on the S_{MSY} escapement goal for Snohomish coho. Each of the three rebuilding plans

<table>
<thead>
<tr>
<th>Coho stock</th>
<th>Spawning escapement</th>
<th>2014–2016 Geometric mean</th>
<th>MSST (overfished threshold)</th>
<th>S_{MSY} (target for rebuilt)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Juan de Fuca</td>
<td>6,842</td>
<td>7,000</td>
<td>11,000</td>
<td></td>
</tr>
<tr>
<td>Queets</td>
<td>4,291</td>
<td>4,350</td>
<td>5,800</td>
<td></td>
</tr>
<tr>
<td>Snohomish</td>
<td>29,677</td>
<td>31,000</td>
<td>50,000</td>
<td></td>
</tr>
</tbody>
</table>
recommended by the Council meets the MSA requirement to rebuild the stock as quickly as possible, taking into account the status and biology of any overfished stock and the needs of fishing communities (50 CFR 600.310(j)(3)(i)). When a stock or stock complex is overfished, a Council must specify a time period for rebuilding the stock or stock complex based on factors specified in MSA section 304(e)(4). This target time for rebuilding (\(T_{target}\)) shall be as short as possible, taking into account: The status and biology of any overfished stock, the needs of fishing communities, recommendations by international organizations in which the U.S. participates, and interaction of the stock within the marine ecosystem. In addition, the time period shall not exceed 10 years, except where biology of the stock, other environmental conditions, or management measures under an international agreement to which the U.S. participates, dictate otherwise (50 CFR 600.310(j)(3)(i)). The NS1 guidelines also describe the following rebuilding benchmarks: The minimum time to rebuild (\(T_{min}\)) and the maximum time to rebuild (\(T_{max}\)) (50 CFR 600.310(j)(3)(i)). These benchmarks serve to establish the range of target times to rebuild that the Council may consider. Under the NS1 guidelines, \(T_{min}\) is calculated by assuming no fishery mortality, regardless of the source of the mortality. It is not possible, however, for the Council and NMFS to implement a \(T_{min}\) scenario for the overfished coho stocks, because the MSA only provides regulatory authority over fisheries in the EEZ. Therefore, the Council and NMFS have no authority to suspend non-federal fisheries in state waters. However, the Council analyzed a no-fishing scenario to identify \(T_{min}\) and to serve as a bookend in the analysis of rebuilding probabilities.

Table-area salmon fisheries management measures are set annually each April. The Council’s Stock Assessment and Fishery Evaluation Document for the Pacific Coast Salmon Fishery Management Plan (SAFE document) is released annually in February and provides escapement data for previous years. Analyses to determine rebuilding times in the Council’s recommended rebuilding plans used available escapement data in the SAFE document issued February 2019, which included escapement data for the overfished coho stocks through 2017. Year 1 in the STT’s calculations of \(T_{min}\) and \(T_{target}\) was defined as 2018. This convention was adopted due to data availability, as the most recent estimates of ocean abundance and spawning escapement for the three overfished coho stocks were from 2017. Rebuilding times projected by the STT assume the control rules defined in the alternatives were first applied to 2018 fisheries, and each of the nine years thereafter; however, the STT and the Council acknowledged that adopted rebuilding plans were likely be first implemented in 2020.

**Juan de Fuca Natural Coho**

\(T_{min}\): The Council’s analysis determined that, with no fishing mortality, there was a 54 percent probability that Juan de Fuca coho would rebuild in four years. Therefore, \(T_{min} = 4\) years or 2021.

\(T_{max}\): NS1 guidelines state that if \(T_{min}\) for the stock or stock complex is 10 years or less, then \(T_{max}\) is 10 years (50 CFR 600.310(j)(3)(i)(B)(1)). Since \(T_{min}\) for Juan de Fuca coho is four years or 2021, \(T_{max} = 10\) years or 2027.

\(T_{target}\): The Council has recommended the existing control rule to rebuild Juan de Fuca coho. As described above, this stock is managed using a stepped harvest rate control rule which sets annual exploitation rate ceilings based upon forecast stock abundance. Applying that control rule to Juan de Fuca coho results in a matrix of age-3 ocean abundance and total allowable exploitation rates that the Council uses when developing annual management measures (coho salmon from stocks managed under the FMP mature at age 3 years) (Table 2).

<table>
<thead>
<tr>
<th>Abundance category</th>
<th>Age-3 ocean abundance</th>
<th>Total allowable exploitation rate (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Greater than 27,445</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td>Between 11,679 and 27,445</td>
<td>40</td>
</tr>
<tr>
<td>Critical</td>
<td>11,679 or less</td>
<td>20</td>
</tr>
</tbody>
</table>

**MSA consistency.** As mentioned above, the MSA requires overfished stocks to be rebuilt in as short a time as possible, while taking into account the needs of fishing communities. The Council considered an alternative that would limit the annual exploitation rate on Juan de Fuca coho in Southern U.S. salmon fisheries (i.e., ocean and inland salmon fisheries south of the U.S./Canada border, including Council area, State, and tribal fisheries) to 10 percent until the stock is rebuilt. The Council’s analysis of this alternative estimated this would result in an economic loss of $4.34 million over the rebuilding period (in 2016 dollars), not including losses in tribal fisheries, compared to the existing control rule. This alternative would rebuild Juan de Fuca coho one year earlier than under the existing control rule; the Council’s analysis indicates that \(T_{target}\) would be achieved in 2022 under this alternative. Therefore, taking into account the negative economic impacts of the limited exploitation rate alternative and the minimal difference in rebuilding time, the existing control rule meets the MSA requirement to have a rebuilding period that is as short as possible while considering the needs of fishing communities.

**Queets Natural Coho**

\(T_{min}\): The Council’s analysis determined that, with no fishing mortality, there was a 61 percent probability that Queets coho would
The draft EA (see www.pcouncil.org (see ADDRESSES), used 2018 as year one in calculating $T_{\text{target}}$. Under the existing control rule, the Council’s analysis determined there was a 54 percent probability that Queets coho would meet the rebuilt criteria by year two ($T_{\text{target}} = 2019$). This means that the three-year geometric mean of Queets coho escapement for 2017–2019 is expected to meet or exceed $S_{\text{MSY}}$. Because of the timing of coho spawning, there is a delay in the availability of coho escapement data; for example, the Council’s Review of 2019 Ocean Salmon Fisheries (February 2020) included coho spawning escapement through 2018. The 2019 spawning escapement for Queets coho, and the 2017–2019 escapement geometric mean, will be available in February 2021 in the Council’s Review of 2020 Ocean Salmon Fisheries. The Council’s annual reviews of ocean salmon fisheries are available on the Council’s website (www.pcouncil.org).

MSA consistency. As mentioned above, the MSA requires overfished stocks to be rebuilt as short a time as possible, while taking into account the needs of fishing communities. The Council considered an alternative that would buffer the existing control rule for Queets coho by limiting the total exploitation rate at forecast ocean age-3 abundance between 5,800 and 7,250, beginning at 15 percent and ramping linearly to 20 percent. During the preseason process, if spawning escapement is projected to be less than 4,930 (85 percent of $S_{\text{MSY}}$), the non-treaty Council-area fisheries north of Cape Falcon, OR, would be structured to minimize impacts on Queets coho. The Council’s analysis of this alternative estimated this would result in an economic loss of $1.28 million over the rebuilding period (in 2016 dollars), not including losses in tribal fisheries, compared to the existing control rule. This alternative would not improve the rebuilding time compared to the existing control rule; the Council calculated $T_{\text{target}}$ would be achieved in 2019 under the buffered control rule, the same as under the existing control rule. Therefore, due to the negative economic impacts of the buffered control rule alternative and negligible difference in rebuilding time, NMFS and the Council found that the existing control rule meets the MSA requirement to have a rebuilding period that is as short as possible while considering the needs of fishing communities.

**Snohomish Natural Coho**

$T_{\text{min}}$. The Council’s analysis determined that, with no fishing mortality, there was a 78 percent probability that Snohomish coho would rebuild in three years. Therefore, $T_{\text{min}} = 3$ years or 2020.

$T_{\text{max}}$. NS1 guidelines state that if $T_{\text{min}}$ for the stock or stock complex is 10 years or less, then $T_{\text{max}}$ is 10 years (50 CFR 600.310(i)(3)(i)(B)(1)). Since $T_{\text{min}}$ for Snohomish coho is three years or 2020, $T_{\text{max}} = 10$ years or 2027.

$T_{\text{target}}$. The Council has recommended a rebuilding plan that uses a buffered control rule to rebuild Snohomish coho as the preferred alternative. As described above, this stock is managed using a stepped harvest rate control rule which sets annual exploitation rate ceilings based upon forecast stock abundance. Applying that control rule to Queets coho results in a matrix of age-3 ocean abundance and total allowable exploitation rates that the Council uses when developing annual management measures (Table 3).

**TABLE 3—MATRIX INFORMED BY THE CURRENT FMP HARVEST CONTROL RULE APPLIED TO QUEETS COHO**

<table>
<thead>
<tr>
<th>Abundance category</th>
<th>Age-3 ocean abundance</th>
<th>Total allowable exploitation rate (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Greater than 9,667</td>
<td>41–65</td>
</tr>
<tr>
<td></td>
<td>Between 7,250 and 9,667</td>
<td>21–40</td>
</tr>
<tr>
<td>Low</td>
<td>Less than 7,250</td>
<td>Up to 20</td>
</tr>
</tbody>
</table>

In the seven years for which we have escapement data for Queets coho since the implementation of Amendment 16 (2012 through 2018), one of those years had escapement above $S_{\text{MSY}}$. Rebuild in one year. Therefore, $T_{\text{min}} = 1$ year or 2018.

$T_{\text{max}}$. NS1 guidelines state that if $T_{\text{min}}$ for the stock or stock complex is 10 years or less, then $T_{\text{max}}$ is 10 years (50 CFR 600.310(i)(3)(i)(B)(1)). Since $T_{\text{min}}$ for Queets coho is one year or 2018, $T_{\text{max}} = 10$ years or 2027.
The Council’s analysis, contained in the draft EA (see ADDRESSES), used 2018 as year one in calculating $T_{\text{target}}$. Under the Council’s preferred alternative rebuilding plan, there is a 62 percent probability that Snohomish coho will meet the rebuilt criteria by year three ($T_{\text{target}} = 2020$). This means that the three-year geometric mean of Snohomish coho escapement for 2018–2020 is expected to meet or exceed $S_{\text{MSY}}$. The spawning escapement from 2020 will be included in the 2022 stock assessment.

**MSA consistency.** As mentioned above, the MSA requires overfished stocks to be rebuilt in as short a time as possible, while taking into account the needs of fishing communities. The Council considered an alternative that would use the existing control rule for Snohomish coho as well as the preferred alternative. The Council’s analysis of the alternatives estimates that the preferred alternative would result in an economic loss of $432$ thousand over the rebuilding period (in 2016 dollars), not including losses in tribal fisheries, compared to no such loss under the existing control rule. The rebuilding time under both the status quo alternative (existing control rule) and the preferred alternative rebuilding plan would have the same rebuilding time; the Council calculated $T_{\text{target}}$ would be achieved in 2020 under both alternatives. The state and tribal co-managers supported the Council’s preferred alternative rebuilding plan, and the fishing communities did not oppose it. The preferred alternative rebuilding plan has the same $T_{\text{target}}$ as the status quo alternative and is supported by fishery managers and fishing communities, and therefore meets the MSA requirement to have a rebuilding period that is as short as possible while considering the needs of fishing communities.

**National Environmental Policy Act (NEPA)**

The draft EA for this action is an integrated document that includes the Council’s analysis of the overfished stocks, analysis of environmental and socioeconomic effects under NEPA, the regulatory impact review, and regulatory flexibility analysis. The draft EA for this action is posted on the NMFS West Coast Region website (see ADDRESSES).

**Classification**

Pursuant to section 304(b)(1)(A) of the MSA, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Pacific Coast Salmon Fishery Management Plan, other provisions of the MSA, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866. This proposed rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

Using the catch area description in the Pacific States Marine Fisheries Commission Information Network (PacFIN), the most recent year of complete fishing data, 2018, NMFS determined that 357 distinct commercial vessels landed fish caught north of Cape Falcon. The Council’s 2020 SAFE document lists $S_{\text{MSY}}$ target for Snohomish coho. Therefore, this proposed rule to approve and implement the rebuilding plans, consistent with the parameters required under NS1, is largely administrative. This action does not change salmon harvest policy, and economic activity is not expected to change from the baseline at all for Juan de Fuca coho and Queets coho, and is expected to change only minimally, as described above, for Snohomish coho. Therefore, this action is also not expected to significantly reduce profit for the directly regulated small entities. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

This proposed rule was developed after meaningful collaboration with the tribal representative on the Council, and the Council subsequently agreed with the provisions that apply to tribal vessels.

This proposed rule does not include a collection-of-information requirement subject to the Paperwork Reduction Act.

**List of Subjects in 50 CFR Part 660**

Fisheries, Fishing, Recordkeeping and reporting requirements.


Samuel D. Rauch, III,
Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, the National Oceanic and Atmospheric Administration proposes to amend 50 CFR part 660 as follows:

**PART 660—FISHERIES OFF WEST COAST STATES**

1. The authority citation for part 660 continues to read as follows:

2. In §660.413 (proposed to be added at 85 FR 6135), add paragraphs (c) through (e) to read as follows:

§660.413 Overfished species rebuilding plans.

* * * * *

(c) Juan de Fuca coho. The Juan de Fuca coho salmon stock was declared overfished in 2018. The target year for rebuilding Juan de Fuca coho is 2023. The harvest control rule during the rebuilding period for Juan de Fuca coho is the abundance-based stepped harvest rate as shown in table 1 to this paragraph (c).

<table>
<thead>
<tr>
<th>Abundance category</th>
<th>Age-3 ocean abundance</th>
<th>Total allowable exploitation rate (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Greater than 27,445</td>
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</tr>
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<td>40</td>
</tr>
<tr>
<td>Critical</td>
<td>11,679 or less</td>
<td>20</td>
</tr>
</tbody>
</table>

(d) Queets coho. The Queets coho salmon stock was declared overfished in 2018. The target year for rebuilding Queets coho is 2019. The harvest control rule during the rebuilding period for Queets coho is the abundance-based stepped harvest rate as shown in table 2 to this paragraph (d).

<table>
<thead>
<tr>
<th>Abundance category</th>
<th>Age-3 abundance</th>
<th>Total allowable exploitation rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Greater than 9,667</td>
<td>65</td>
</tr>
<tr>
<td>Low</td>
<td>Between 7,250 and 9,667</td>
<td>40</td>
</tr>
<tr>
<td>Critical</td>
<td>Less than 7,250</td>
<td>20</td>
</tr>
</tbody>
</table>

(e) Snohomish coho. (1) The Snohomish coho salmon stock was declared overfished in 2018. The target year for rebuilding Snohomish coho is 2020. The harvest control rule during the rebuilding period for Snohomish coho is the abundance-based stepped harvest rate as shown in table 3 to this paragraph (e).

<table>
<thead>
<tr>
<th>Abundance category</th>
<th>Age-3 abundance</th>
<th>Total allowable exploitation rate (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Greater than 137,000</td>
<td>60</td>
</tr>
<tr>
<td>Low</td>
<td>Between 51,667 and 137,000</td>
<td>40</td>
</tr>
<tr>
<td>Critical</td>
<td>Less than 51,667</td>
<td>20</td>
</tr>
</tbody>
</table>

(2) In years when Snohomish coho abundance is forecast to exceed 137,000, the total allowable exploitation rate will be limited to target achieving a spawning escapement of 55,000 Snohomish coho.

[FR Doc. 2020–19884 Filed 9–30–20; 8:45 am]

BILLING CODE 3510–22–P
This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
[Doc. No. AMS–LP–20–0070]

Notice of Request for Extension of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the Agricultural Marketing Service’s (AMS) intention to request approval from the Office of Management and Budget (OMB) for an extension of the currently approved information collection used to compile and generate the Federally Inspected Estimated Daily Slaughter Report. Upon approval of this information collection, AMS will request approval from the OMB to merge this collection, “Plan for Estimating Daily Livestock Slaughter Under Federal Inspection” (OMB 0581–0050), with the currently approved information collection titled “Livestock, Poultry, and Grain Market News” (OMB 0186–0033). Both collections are directed and authorized by the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), section 203(g), and rely on voluntary cooperation with the livestock industry to collect and disseminate marketing information, utilizing the same information gathering tactics.

DATES: Comments must be received by November 30, 2020.

Additional Information or Comments: Comments should be submitted electronically at http://www.regulations.gov. Comments may also be submitted to Charlie Potts, Officer in Charge, Livestock, Poultry, and Grain Market News Division, Livestock and Poultry Program, Agricultural Marketing Service, U.S. Department of Agriculture; STOP 0252; 1400 Independence Avenue SW.; Room 2619–S; Washington, DC 20250–0252. All comments should reference docket number AMS–LP–20–0070 and note the date and page number of this issue of the Federal Register.

Submitted comments will be available for public inspection at http://www.regulations.gov or at the above address during regular business hours. Comments submitted in response to this Notice will be included in the records and will be made available to the public. All comments received will be posted without change, including any personal information provided.

FOR FURTHER INFORMATION CONTACT:
Charlie Potts, Officer in Charge, Livestock, Poultry, and Grain Market News Division, AMS, USDA, by telephone at (816) 676–7000, or via email at Charlie.Potts@usda.gov.

SUPPLEMENTARY INFORMATION:

Title: Plan for Estimating Daily Livestock Slaughter Under Federal Inspection
OMB Number: 0581–0050.
Expiration Date of Approval: 01–31–2021.
Type of Request: Extension of a currently approved information collection.

Abstract: The Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), section 203(g), directs and authorizes the collection and dissemination of marketing information including adequate outlook information, on a market area basis, for the purpose of anticipating and meeting consumer requirements, aiding in the maintenance of farm income, and to bring about a balance between production and utilization. Under this Market News program, USDA issues a Market News report estimating daily livestock slaughter under Federal inspection. This report is compiled by AMS on a voluntary basis in cooperation with the livestock and meat industry. Market News reporting must be timely, accurate, and continuous if it is to be useful to producers, processors, and the trade in general. The daily livestock slaughter estimates are provided at the request of industry and are used to make production and marketing decisions. The Daily Estimated Livestock Slaughter Under Federal Inspection Report is used by a wide range of industry contacts, including packers, processors, producers, brokers, and retailers of meat and meat products. The livestock and meat industry requested that USDA issue slaughter estimates (daily and weekly), by species, for cattle, calves, hogs, and sheep in order to assist them in making immediate production and marketing decisions and as a guide to the volume of meat in the marketing channel. The information requested from respondents includes their estimation of the current day’s slaughter at their plant(s) and the actual slaughter for the previous day. Also, the Government is a large purchaser of meat and related products and this report assists other Government agencies in providing timely information on the quantity of meat entering the processing channels.

The information must be collected, compiled, and disseminated by an impartial third-party, in a manner which protects the confidentiality of the reporting entity. AMS is in the best position to provide this service.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .0333 hours per response.

Respondents: Business or other for-profit entities, individuals or households, farms, and the Federal Government.

Estimated Number of Respondents: 60.

Estimated Number of Responses: 15,600.

Estimated Number of Responses per Respondent: 260.

Estimated Total Annual Burden on Respondents: 519 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (2) the accuracy of the Agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.
DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service
[Docket No. APHIS–2020–0084]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Importation of Live Swine, Pork and Pork Products, and Swine Semen From the European Union

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service’s intention to request a revision to and extension of approval of an information collection associated with regulations for the importation of live swine, pork and pork products, and swine semen from the European Union.

DATES: We will consider all comments that we receive on or before November 30, 2020.

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

2. Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2020–0084, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at http://www.regulations.gov/#!docketDetail;D=APHIS–2020–0084 or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. If you need someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information regarding the regulations for the importation of live swine, pork and pork products, and swine semen from the European Union, contact Dr. Alexandra MacKenzie, Senior Veterinary Medical Officer, VS Strategy & Policy, Live Animal Imports, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1236; (301) 851–3411. For copies of more detailed information on the information collection, contact Mr. Joseph Moxey, APHIS’ Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Importation of Live Swine, Pork and Pork Products, and Swine Semen from the European Union.

OMB Control Number: 0579–0218.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 et seq.), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture is authorized, among other things, to prohibit or restrict the importation and interstate movement of animals and animal products to prevent the introduction into and dissemination within the United States of livestock diseases and pests. To carry out this mission, APHIS regulates the importation of animals and animal products into the United States.

The regulations in 9 CFR part 94, prohibit or restrict the importation of specified animals and animal products to prevent the introduction of diseases such as classical swine fever (CSF), foot-and-mouth disease, swine vesicular disease, and African swine fever. Among other things, part 94 lists the requirements for the importation of pork and pork products and live swine where these diseases exist. Section 94.31 lists the requirements for the importation of pork, pork products, and breeding swine from the European Union (“the APHIS-defined European CSF region”). In addition, 9 CFR 98.38 lists the requirements for the importation of swine semen from the APHIS-defined European CSF region.

These regulations require information collection activities, such as a certificate for pork and pork products, breeding swine, and swine semen; application for import or in-transit permit; and declaration of importation. Since the last approval, we have decreased the estimates of burden to reflect the decrease in importation of pork and pork products.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning this information collection. These comments will help us:

1. Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;
2. Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

Estimated burden for this collection of information is estimated to average 1 hour per response.

Respondents: Foreign government animal health officials.

Estimated annual number of respondents: 194.

Estimated annual number of responses per respondent: 8.3.

Estimated annual number of responses: 1,611.

Estimated total annual burden on respondents: 1,598 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 28th day of September 2020.

Mark Davidson,
Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2020–21746 Filed 9–30–20; 8:45 am]
BILLING CODE 3410–34–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Pennsylvania Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

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 two meetings of the Pennsylvania Advisory Committee to the Commission will convene by conference calls, as noted below. The purpose of both planning meetings is to discuss any further permutations to the Committee’s draft report on School Discipline and the School-to-Prison Pipeline that the Committee recently voted to submit to the agency’s legal sufficiency review; followed by submission of the final report to the Staff Director for publication.

DATES: The meetings will be held on:
- Tuesday, October 20, 2020, at 11:30 a.m. Eastern Time
- Tuesday, November 17, 2020 at 11:30 a.m. Eastern Time.


FOR FURTHER INFORMATION CONTACT: Ivy Davis at ero@usccr.gov or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 800–367–2403 and conference call ID number: 5859731. 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 landline connections to the toll-free conference call-in number.

Individuals who are deaf, deaf-blind, and hard of hearing may also follow the discussion by first calling the Federal Relay Service at 1–800–877–8339 and providing the operator with the toll-free conference call-in number: 800–367–2403 and conference call ID number: 5859731.

Members of the public are invited to make brief statements during the Public Comment section of the meeting or submit written comments. The written comments must be received in the regional office approximately 30 days after the scheduled meeting. During the COVID–19 Pandemic, written comments may be emailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 300 North Western Street, Suite 2010, Los Angeles, CA 90012 or email Ana Victoria Fortes at afortes@usccr.gov. Written comments may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. 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 Eastern Regional Office at the above phone number, email or street address.

Agenda
Roll call
Welcome
Public Call Information
Project Planning
Other Business
Next Public Meeting
Public Comments
Adjourn


David Mussatt,
Supervisory Chief, Regional Programs Unit.

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the California Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

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 California Advisory Committee (Committee) to the Commission will be held at 2:00 p.m. (Pacific) on Wednesday, October 7, 2020. The purpose of the meeting will be to review their report on immigration enforcement and k–12 children.

DATES: The meeting will be held on Wednesday, October 7, 2020 at 2:00 p.m. PT.

ADDRESSES:

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes, Designated Federal Officer (DFO) at afortes@usccr.gov or by phone at (202) 681–0857.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 800–367–2403, conference ID number: 8294363. Any interested member of the public may call this number and listen to the meeting. 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 landline connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012 or email Ana Victoria Fortes at afortes@usccr.gov. Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at https://www.facadatabase.gov/FACA/FACA/PublicViewCommitteeDetails?id=a100000001gzkUA AQ: 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 meeting. 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 Regional Programs Unit at the above email or street address.

Agenda
I. Welcome
II. Review Report
a. Recommendations
b. Introduction and Background
III. Public Comment
IV. Adjournment

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 circumstances of the COVID crisis and DFO availability.


David Mussatt,
Supervisory Chief, Regional Programs Unit.
COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Hawai‘i Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

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 teleconference meeting of the Hawai‘i Advisory Committee (Committee) to the Commission will be held at 10:00 a.m. on Friday, October 16, 2020 (Hawaiian Time). The purpose of the meeting will be to continue planning for their webhearings on COVID–19 and Pacific Islander communities.

DATES: The meeting will be held on Friday, October 16, 2020 at 10:00 a.m. HST.


FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes, Designated Federal Officer (DFO) at afortes@usccr.gov or by phone at (202) 681–0857.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 800–367–2403, conference ID number: 7622762. Any interested member of the public may call this number and listen to the meeting. 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 landline connections to the toll-free telephone number.

Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Federal Relay Service operator with the conference call-in numbers: 1–800–367–2403; Conference ID: 1644409.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Evelyn Bohor at ero@usccr.gov. Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Maine Advisory Committee link.

Persons interested in the work of this Committee are directed to the Commission’s website, http://www.usccr.gov, or may contact the Eastern Regional Office at the above email or phone number.

Agenda

I. Welcome
II. Post Report
III. Planning for Webhearings
   a. Brainstorm potential speakers
   b. Discuss potential dates/date to avoid
   c. Panel categories/panel themes
   d. Language access
IV. Public Comment
V. Discuss Next Steps
VI. Adjournment


David Mussatt,
Supervisory Chief, Regional Programs Unit.

BILING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Maine Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Maine Advisory Committee (Committee) will hold a meeting on Thursday, October 15, 2020, at 12:00 p.m. (EDT) for the purpose of meeting is to discuss next steps for its digital equity project.

DATES: The meeting will be held on Thursday, October 15, 2020, at 12:00 p.m. EDT.


FOR FURTHER INFORMATION CONTACT: Evelyn Bohor, at ero@usccr.gov or 202–921–2212.

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. This meeting is available to the public through the above listed toll-free number. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over landline connections to the toll-free telephone number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Evelyn Bohor at ero@usccr.gov. Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Maine Advisory Committee link.

Agenda

Thursday, October 15, 2020 at 12:00 p.m. (EDT)

• Welcome/Opening
• Planning Meeting
• Next Steps
• Other Business
• Public Comment
• Adjournment


David Mussatt,
Supervisory Chief, Regional Programs Unit.

BILING CODE P
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 teleconference meeting of the Wyoming Advisory Committee (Committee) to the Commission will be held at 1:00 p.m. (MDT) Thursday, October 22, 2020. The purpose of the meeting will be to vote on their draft of the Op-Ed.

DATES: Thursday, October 22, 2020 at 1:00 p.m. MDT.


FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes, Designated Federal Officer (DFO) at afortes@usccr.gov or by phone at (202) 681–0857.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 800–353–6461, conference ID number: 2231290. Any interested member of the public may call this number and listen to the meeting. 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 landline connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012 or email Ana Victoria Fortes at afortes@usccr.gov.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meetings at https://www.facadatabase.gov/FACA/ FACAPublicViewCommitteeDetails?id=a10t00000001gzJiAAA.

Please click on “Committee Meetings” tab. Records generated from these meetings may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meetings. Persons interested in the work of this Committee are directed to the Commission’s website, https://www.usccr.gov, or may contact the Regional Programs Unit at the above email or street address.

Agenda
I. Welcome
II. Review Draft of Op-Ed
III. Vote
IV. Public Comment
V. Adjournment


David Mussatt,
Supervisory Chief, Regional Programs Unit.

FOR FURTHER INFORMATION CONTACT:
Requests for additional information or specific questions related to collection activities should be directed to Paul Redpath, Office of Civil Rights, Chief, Program Implementation Division, phone (202) 482–2627 or by email at prredpath@doc.gov.

SUPPLEMENTARY INFORMATION:

II. Method of Collection

The Equal Employment Opportunity Commission (EEOC) regulations at 29 CFR 1614.106 require that a Federal employee or applicant for Federal employment alleging discrimination based on race, color, sex, national origin, religion, age, disability, or reprisal for protected activity must submit a signed statement that is sufficiently precise to identify the actions or practices that form the bases of the complaint. The individual completing the form is asked to identify the bureau at which the alleged discrimination took place, and whether the individual worked at that bureau at the time of the alleged discrimination. The individual completing the form is also asked to describe the alleged discriminatory action(s) as clearly as possible and include the date(s) and to articulate the basis or bases of the complaint (race, color, sex, etc.). Further, the individual completing the form is asked to identify the remedy(ies) sought for the alleged discrimination. Although complainants are not required to use the proposed form to file their complaints, the Office of Civil Rights strongly encourages its use to ensure efficient case processing and trend analyses of complaint activity.

III. Data

OMB Control Number: 0690–0015.

Form Number(s): CD–498, CD–498A.

Type of Review: Regular. Extension of a currently approved information collection.

Affected Public: Households and Individuals.

Estimated Number of Respondents: 600.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 300.

Estimated Total Annual Cost to Public: $579.
IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold personal identifying information from public review, we cannot guarantee that we will be able to do so.

Shelleen Dumas,
Department PRA Clearance Officer, Office of the Chief Information Officer, Office of the Secretary.

[FR Doc. 2020–21752 Filed 9–30–20; 8:45 am]
BILLING CODE 3510–BP–P

DEPARTMENT OF COMMERCE
Office of the Secretary
Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Reporting Process for Complaint of Employment Discrimination Based on Sexual Orientation Against the Department of Commerce

AGENCY: Office of Civil Rights, Office of the Secretary, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public’s reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before November 30, 2020.

ADDRESSES: Interested persons are invited to submit comments by email to PRAcomments@doc.gov. Please reference OMB Control Number 0694–0024 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT:
Requests for additional information or specific questions related to collection activities should be directed to Paul Redpath, Office of Civil Rights, Chief, Program Implementation Division, phone (202) 482–2627 or by email at predpath@doc.gov.

SUPPLEMENTARY INFORMATION:
I. Abstract
Pursuant to Executive Order 11478 and Department of Commerce Administrative Order (DAO) 215–11, an employee or applicant for employment with the Department of Commerce who alleges that he or she has been subjected to discriminatory treatment based on sexual orientation by the Department of Commerce or one of its sub-agencies, must submit a signed statement that is sufficiently precise to identify the actions or practices that form the basis of the complaint.

The complainant is also required to provide an address and telephone number where the complainant or his or her representative may be contacted. Through use of the standardized form (CD–545), the Office of Civil Rights proposes to collect the information required by the Executive Order and DAO in a uniform manner that will increase the efficiency of complaint processing and trend analyses of complaint activity.

II. Method of Collection
A paper form, signed by the complainant or his/her designated representative, must be submitted by mail or delivery service, in person, or by facsimile transmission.

III. Data
OMB Control Number: 0690–0024.
Form Number: CD–545.
Type of submission (extension of a currently approved information collection).

Estimated Number of Respondents: 2.
Estimated Time per Response: 30 minutes.
Estimated Total Annual Burden Hours: 1.
Estimated Total Annual Cost to Public: $0.

IV. Request for Comments
We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold personal identifying information from public review, we cannot guarantee that we will be able to do so.

Shelleen Dumas,
Department PRA Clearance Officer, Office of the Chief Information Officer, Office of the Secretary.

[FR Doc. 2020–21724 Filed 9–30–20; 8:45 am]
BILLING CODE 3510–BP–P

DEPARTMENT OF COMMERCE
Bureau of Economic Analysis

RIN 0691–XC114

Request for Comment; Notice of Development of Puerto Rico Gross Domestic Product Statistics

AGENCY: Bureau of Economic Analysis, Department of Commerce.

ACTION: Notice; request for comments.

SUMMARY: The Bureau of Economic Analysis (BEA) is soliciting comments from the public on its new prototype
estimates of Puerto Rico Gross Domestic Product (GDP), which includes statistics for consumer spending, private fixed investment, inventory investment, net exports of goods and services, and government spending for Puerto Rico. BEA seeks comments on the statistics’ data sources, presentation, level of detail, and scope. Following the public comment period, BEA will incorporate feedback, updating the statistics and related materials for Puerto Rico GDP.

DATES: Comments must be received no later than November 2, 2020.

ADDRESSES: You may submit comments by the following methods:
- Email: territories@bea.gov
- Mail: Sabrina Montes, Office of the Director, Bureau of Economic Analysis, Department of Commerce, 4600 Silver Hill Road (BE–40), Washington, DC 20233.

Comments sent by any other method or after the comment period may not be considered. All comments are a part of the public record.

FOR FURTHER INFORMATION CONTACT: Sabrina Montes, Office of the Director, Bureau of Economic Analysis, Department of Commerce, 4600 Silver Hill Road (BE–40), Washington, DC 20233; phone: (301) 278–9268 or email Sabrina.Montes@bea.gov.

SUPPLEMENTARY INFORMATION: In 2018, BEA initiated a project to calculate GDP for Puerto Rico in order to support Puerto Rico’s economic recovery following devastating hurricanes in 2017. This project follows technical collaborations between BEA and the Commonwealth of Puerto Rico dating back to 2010. The project also addresses recommendations from the Congressional Task Force on Economic Growth in Puerto Rico and Government Accountability Office that BEA calculate GDP for Puerto Rico.

The present project—a collaborative effort between the Commonwealth of Puerto Rico and BEA—combines the best available Puerto Rico economic data with BEA’s current national economic accounting methodologies. The project seeks to produce accurate and objective economic statistics for Puerto Rico comparable to data for other U.S. territories, states, and the nation. Prototype statistics of GDP and its components for 2012–2018 were published on September 28, 2020. Methodologies incorporated in the statistics included:
- Using chain-type Fisher indexes to calculate changes in aggregate output and prices;
- expanding the use of economic census data from the U.S. Census Bureau;
- treating expenditures on intangible assets as investment to allow users to understand how these intangible assets drive economic growth; and
- adjusting for inflation at a high level of detail to ensure that the selected price indexes reflect the mix of goods and services produced by the Puerto Rico economy.

BEA is now seeking feedback on these new statistics. BEA will consider this feedback as it continues to refine source data, methodology, and data presentations in preparation for routine production of these data.

BEA invites all comments from the public; private industry; state, local, and territorial governments; non-profit organizations; and other interested parties to assist in improving the prototype statistics. In particular, BEA is interested in feedback regarding the following (with the understanding that BEA will accept and consider all feedback on its new Puerto Rico GDP statistics):
1. How will the statistics on Puerto Rico GDP and its components be used?
2. Given that the statistics are on a calendar year basis, what time of the year should they be published to maximize their usefulness in planning and for other uses?
3. Are the components in the prototype GDP statistics consistent with the data and local information that are available elsewhere on Puerto Rico? If not, please describe the differences.
4. Which would be more useful: Less-detailed product breakdowns, which will result in fewer data suppressions to protect confidentiality, or more-detailed product breakdowns, with the necessary suppressions?
5. BEA is aware that stakeholders may be interested in statistics not included in the present release, such as quarterly measures, GDP by industry, and GNP. What extensions to BEA’s Puerto Rico GDP statistics would be useful and why?

Sabrina Montes,
Economist, Bureau of Economic Analysis.
[FR Doc. 2020–21654 Filed 9–30–20; 8:45 am]

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice and opportunity for public comment.

SUMMARY: The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms’ workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

SUPPLEMENTARY INFORMATION:

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE
[9/19/2020 through 9/24/2020]

<table>
<thead>
<tr>
<th>Firm name</th>
<th>Firm address</th>
<th>Date accepted for investigation</th>
<th>Product(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>George B. Woodcock &amp; Company, Inc.</td>
<td>9667 Canoga Avenue, Chatsworth, CA 91311.</td>
<td>9/21/2020</td>
<td>The firm manufactures shipping containers and packaging supplies.</td>
</tr>
<tr>
<td>New Dimensions Precision Machining, LLC.</td>
<td>6614 South Union Road, Union, IL 60180.</td>
<td>9/22/2020</td>
<td>The firm manufactures miscellaneous metal parts.</td>
</tr>
</tbody>
</table>
Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended. Please follow the requirements set forth in EDA’s regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Bryan Borilk, Director.

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

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


SUPPLEMENTARY INFORMATION:

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (the Act), may request, in accordance with 19 CFR 351.213, that the Department of Commerce (Commerce) conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting date.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review. We intend to release the CBP data under Administrative Protective Order (APO) to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 21 days of publication of the initiation Federal Register notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. Commerce invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, Commerce finds that determinations concerning whether particular companies should be “collapsed” (i.e., treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of a review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (i.e., investigation, administrative review, new shipper review or changed circumstances review). For any company subject to a review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes.

Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete a Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of a proceeding where Commerce considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE—Continued

[9/19/2020 through 9/24/2020]

<table>
<thead>
<tr>
<th>Firm name</th>
<th>Firm address</th>
<th>Date accepted for investigation</th>
<th>Product(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SylvanSport, LLC</td>
<td>235 Commerce Street, Brevard, NC 28712</td>
<td>9/22/2020</td>
<td>The firm manufactures personal trailers for camping and hauling.</td>
</tr>
<tr>
<td>MPP Corporation</td>
<td>82 Airport Drive, Kimball, MI 48074</td>
<td>9/24/2020</td>
<td>The firm manufactures plastic injection molds and tooling.</td>
</tr>
<tr>
<td>MPP Corporation</td>
<td>82 Airport Drive, Kimball, MI 48074</td>
<td>9/24/2020</td>
<td>The firm manufactures plastic injection molds and tooling.</td>
</tr>
</tbody>
</table>

*Listed Firm names and addresses were updated for accuracy.*
Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act. Section 773(e) of the Act states that “if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.” When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial Section D responses.

Opportunity To Request A Review:
Not later than the last day of October 2020, interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in October for the following periods:

### Antidumping Duty Proceedings

<table>
<thead>
<tr>
<th>Country</th>
<th>Description</th>
<th>Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia:</td>
<td>Hot-Rolled Steel Flat Products A–602–809</td>
<td>10/1/19–9/30/20</td>
</tr>
<tr>
<td>Brazil:</td>
<td>Carbon and Certain Alloy Steel Wire Rod A–351–832</td>
<td>10/1/19–9/30/20</td>
</tr>
<tr>
<td></td>
<td>Hot-Rolled Steel Flat Products A–351–845</td>
<td>10/1/19–9/30/20</td>
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<tr>
<td>India:</td>
<td>Stainless Steel Flanges A–533–877</td>
<td>10/1/19–9/30/20</td>
</tr>
<tr>
<td>Indonesia:</td>
<td>Carbon and Certain Alloy Steel Wire Rod A–560–815</td>
<td>10/1/19–9/30/20</td>
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<tr>
<td>Italy:</td>
<td>Pressure Sensitive Plastic Tape A–475–059</td>
<td>10/1/19–9/30/20</td>
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<tr>
<td>Japan:</td>
<td>Hot-Rolled Steel Flat Products A–588–874</td>
<td>10/1/19–9/30/20</td>
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<tr>
<td>Mexico:</td>
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<td>The People’s Republic of China:</td>
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### Countervailing Duty Proceedings

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<tr>
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<td>India:</td>
<td>Stainless Steel Flanges C–533–878</td>
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<td>Iran:</td>
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### Suspension Agreements

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<tr>
<th>Country</th>
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<td>Argentina:</td>
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<tr>
<td>Russia:</td>
<td>Uranium A–821–802</td>
<td>10/1/19–9/30/20</td>
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</table>

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act

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2. Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when Commerce is closed.
must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover. Note that, for any party Commerce was unable to locate in prior segments, Commerce will not accept a request for an administrative review of that party absent new information as to the party’s location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party’s attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties, 68 FR 23954 (May 6, 2003), and Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties, 76 FR 65694 (October 24, 2011), Commerce clarified its practice with respect to the collection of antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders.3 Commerce no longer considers the non-market economy (NME) entity as an exporter conditionally subject to an antidumping duty administrative reviews.4 Accordingly, the NME entity will not be undeclared unless Commerce specifically receives a request for, or self-initiates, a review of the NME entity.5 In administrative reviews of antidumping duty orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, Commerce will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity’s entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity). Following initiation of an antidumping administrative review when there is no review requested of the NME entity, Commerce will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) on Commerce’s ACCESS website at https://access.trade.gov.6 Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.7 Commerce will publish in the Federal Register a notice of “Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation” for requests received by the last day of October 2020. If Commerce does not receive, by the last day of October 2020, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, Commerce will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures “gap” period of the order, if such a gap period is applicable to the period of review. This notice is not required by statute but is published as a service to the international trading community.


James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2020–21728 Filed 9–30–20; 8:45 am]

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Five-Year (Sunset) Reviews

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

SUMMARY: In accordance with the Tariff Act of 1930, as amended (the Act), the Department of Commerce (Commerce) is automatically initiating the five-year reviews (Sunset Reviews) of the antidumping and countervailing duty (AD/CVD) order(s) listed below. The International Trade Commission (the ITC) is publishing concurrently with this notice its notice of Institution of Five-Year Reviews which covers the same order(s).

DATES: Applicable (October 1, 2020).


SUPPLEMENTARY INFORMATION:

Background

Commerce’s procedures for the conduct of Sunset Reviews are set forth in its Procedures for Conducting Five-Year (Sunset) Reviews of Antidumping and Countervailing Duty Orders, 63 FR 13516 (March 20, 1998) and 70 FR 62061 (October 28, 2005). Guidance on methodological or analytical issues

3 See the Enforcement and Compliance website at https://legacy.trade.gov/enforcement/.
5 In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.
7 See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19, 85 FR 41363 (July 10, 2020).

Initiation of Review

In accordance with section 751(c) of the Act and 19 CFR 351.218(c), we are initiating the Sunset Reviews of the following antidumping and countervailing duty order(s):

<table>
<thead>
<tr>
<th>DOC Case No.</th>
<th>ITC Case No.</th>
<th>Country</th>
<th>Product</th>
<th>Commerce Contact</th>
</tr>
</thead>
</table>

Filing Information

As a courtesy, we are making information related to sunset proceedings, including copies of the pertinent statute and Commerce’s regulations, Commerce’s schedule for Sunset Reviews, a listing of past revocations and continuations, and current service lists, available to the public on Commerce’s website at the following address: https://enforcement.trade.gov/sunset/. All submissions in these Sunset Reviews must be filed in accordance with Commerce’s regulations regarding format, translation, and service of documents. These rules, including electronic filing requirements via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), can be found at 19 CFR 351.301.4 Parties are advised to review the final rule, available at https://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt, prior to submitting factual information in these segments. To the extent that other regulations govern the submission of factual information in a segment (such as 19 CFR 351.218), these time limits will continue to be applied. Parties are also advised to review the final rule concerning the extension of time limits for submissions in AD/CVD proceedings, available at https://enforcement.trade.gov/frn/2013/1309frn/2013-22853.txt, prior to submitting factual information in these segments.5

Letters of Appearance and Administrative Protective Orders

Pursuant to 19 CFR 351.103(d), Commerce will maintain and make available a public service list for these proceedings. Parties wishing to participate in any of these five-year reviews must file letters of appearance as discussed at 19 CFR 351.103(d)). To facilitate the timely preparation of the public service list, it is requested that those seeking recognition as interested parties to a proceeding submit an entry of appearance within 10 days of the publication of the Notice of Initiation. Because deadlines in Sunset Reviews can be very short, we urge interested parties who want access to proprietary information under administrative protective order (APO) to file an APO application immediately following publication in the Federal Register of this notice of initiation. Commerce’s regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.6

Information Required From Interested Parties

Domestic interested parties, as defined in section 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b), wishing to participate in a Sunset Review must respond not later than 15 days after the date of publication in the Federal Register of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with Commerce’s regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, Commerce will automatically revoke the order without further review.7

If we receive an order-specific notice of intent to participate from a domestic interested party, Commerce’s regulations provide that all parties wishing to participate in a Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the Federal Register of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that Commerce’s

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2. See section 782(b) of the Act.
5. See Extension of Time Limits, 78 FR 57790 (September 20, 2013).
7. See 19 CFR 351.218(d)(1)(ii).
DEPARTMENT OF COMMERCE
International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Advance Notification of Sunset Review

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

Background
Every five years, pursuant to the Tariff Act of 1930, as amended (the Act), the Department of Commerce (Commerce) and the International Trade Commission automatically initiate and conduct reviews to determine whether revocation of a countervailing or antidumping duty order or termination of an investigation suspended under section 704 or 734 of the Act would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy (as the case may be) and of material injury.

Upcoming Sunset Reviews for November 2020
Pursuant to section 751(c) of the Act, the following Sunset Reviews are scheduled for initiation in November 2020 and will appear in that month’s Notice of Initiation of Five-Year Sunset Reviews (Sunset Review).

Department contact

<table>
<thead>
<tr>
<th>Antidumping Duty Proceedings</th>
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<tbody>
<tr>
<td>Cut-to-Length Carbon Steel Plate from China (A–570–849) (4th Review)</td>
</tr>
<tr>
<td>Melamine from China (A–570–020) (1st Review)</td>
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<tr>
<td>Potassium Phosphate Salts from China (A–570–962) (2nd Review)</td>
</tr>
<tr>
<td>Welded Line Pipe from Republic of Korea (A–580–876) (1st Review)</td>
</tr>
<tr>
<td>Welded Line Pipe from Republic of Turkey (A–489–822) (1st Review)</td>
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<th>Countervailing Duty Proceedings</th>
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<tr>
<td>Melamine from China (C–570–021) (1st Review)</td>
</tr>
<tr>
<td>Potassium Phosphate Salts from China (C–570–963) (2nd Review)</td>
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<tr>
<td>Welded Line Pipe from Republic of Korea (C–580–877) (Review)</td>
</tr>
<tr>
<td>Welded Line Pipe from Turkey (C–489–823) (1st Review)</td>
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<th>Suspended Investigations</th>
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For serving documents containing business proprietary information, until further notice.¹


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

SUMMARY: The Department of Commerce (Commerce) determines that imports of certain hydrofluorocarbon (HFC) blends containing HFC components from India and the People’s Republic of China (China) that are blended in India prior to importation into the United States are circumventing the antidumping duty (AD) order on HFC blends from China.

DATES: Applicable October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Jacob Garten or Benjamin Luberda, AD/
CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3342 or (202) 482–2185, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 10, 2020, Commerce published the Preliminary Determination 1 of circumvention of the antidumping duty order on HFC blends from China with respect to certain HFC blends containing HFC components from India and China that are blended in India prior to importation into the United States.2 We invited parties to comment on the Preliminary Determination.3

We notified the U.S. International Trade Commission (ITC) of our preliminary determination in accordance with section 781(e) of the Tariff Act of 1930, as amended (the Act).4 We received a request for consultations from the ITC and held the consultations on June 11, 2020.5 On July 6, 2020, the ITC notified Commerce that the ITC did not take a position on whether an affirmative circumvention finding for hydrofluorocarbon (HFC) blends produced in India, in whole or in part, from HFC components from China would raise a serious injury issue.6

A summary of the events that occurred since Commerce published the Preliminary Determination, as well as a full discussion of the issues raised by the parties for this final determination, may be found in the Issues and Decision Memorandum.7 The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at http://access.trade.gov. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at http://enforcement.trade.gov/frn/. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Commerce conducted this anti-circumvention inquiry in accordance with section 781(b) of the Act.

Scope of the Order

The products subject to the Order are HFC blends. HFC blends covered by the scope are R–404A, a zeotropic mixture consisting of 52 percent 1,1,1,2-Tetrafluoroethane, 44 percent Trifluoroethane, 44 percent Pentafluoroethane, and 4 percent 1,1,1,2-Tetrafluoroethane; R–407A, a zeotropic mixture of 20 percent Difluoromethane, 40 percent Pentafluoroethane, and 40 percent 1,1,1,2-Tetrafluoroethane; R–407C, a zeotropic mixture of 23 percent Difluoromethane, 25 percent Pentafluoroethane, and 52 percent 1,1,1,2-Tetrafluoroethane; R–410A, a zeotropic mixture of 50 percent Difluoromethane and 50 percent Pentafluoroethane; and R–507A, an azeotropic mixture of 50 percent Pentafluoroethane and 50 percent 1,1,1,2-Trifluoroethane also known as R–507. The foregoing percentages are nominal percentages by weight. Actual percentages of single component refrigerants by weight may vary by plus or minus two percent points from the nominal percentage identified above.8

Any blend that includes an HFC component other than R–32, R–125, R–134a, or R–134a is excluded from the scope of the Order. Excluded from the Order are blends of refrigerant chemicals that include products other than HFCs, such as blends including chlorofluorocarbons (CFCs), hydrochlorofluorocarbons (HCFCs), hydrocarbons (HCs), or hydrofluorolefins (HFOs).

Also excluded from the Order are patented HFC blends, including, but not limited to, ISCEON® blends, including MO99™ (R–438A), MO79 (R–422A), MO59 (R–417A), MO49Plus™ (R–437A) and MO29™ (R–422D), Genetron® Performax™ LT (R–407F), Choice® R–421A, and Choice® R–421B.

HFC blends covered by the scope of the Order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings 3824.78.0020 and 3824.78.0050. Although the HTSUS subheadings are provided for conveniences and customs purposes, the written description of the scope is dispositive.9

Merchandise Subject to the Anti-Circumvention Inquiry


Final Scope Ruling and Final Determination

In the Preliminary Determination, we determined, pursuant to 19 CFR 351.225(k), that, because the scope only covers HFC blends produced in China and the R–410A blend produced and exported by GFL is produced in India, the R–410A blend produced by GFL is not covered by the scope of the Order. We further found that a circumvention analysis and determination is warranted. We then determined that certain HFC blends containing HFC components from India and China that are blended in India prior to importation into the United States (Indian blends) are circumventing the
Order. Specifically, we determined that imports of Indian blends are finished in India and sold in the United States pursuant to the statutory and regulatory criteria laid out in section 781(b) of the Act and 19 CFR 351.225(h). We based our Preliminary Determination upon record evidence submitted by the respondents, the petitioners, and U.S. Customs and Border Protection (CBP).

For a complete discussion of the evidence which led to our preliminary determination, see the Preliminary Determination.

Interested parties submitted comments regarding our Preliminary Determination, and we discuss those comments in the “Discussion of the Issues” section of the Issues and Decision Memorandum. Our final affirmative determination of circumvention remains unchanged from the Preliminary Determination. Accordingly, we determine, pursuant to section 781(b) of the Act, that imports of Indian blends are circumventing the Order. However, we did make certain changes to the certification requirements, as set forth in Appendix II.

Methodology

Commerce is conducting this anti-circumvention inquiry in accordance with section 781(b) of the Act. Given that China is a non-market economy, within the meaning of section 771(18) of the Act, Commerce calculated the value of certain merchandise using factors of production and market economy values, as discussed in section 773(c) of the Act. Further, because Coolmate Refrigerant Pvt. Ltd. did not cooperate to the best of its ability in responding to Commerce’s requests for information, we have based parts of our final determination on the facts available with adverse inferences, as set forth in the Preliminary Decision Memorandum, pursuant to sections 776(a) and (b) of the Act. See the Preliminary Decision Memorandum for a full description of the methodology. We have continued to apply this methodology for our final determination.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this inquiry are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached to this notice as Appendix I. Based on our analysis of the comments received, we have made no changes to the findings in the Preliminary Determination. However, we did make certain changes to the certification requirements, as set forth in Appendix II.

Final Affirmative Determination of Circumvention

We determine that exports to the United States of certain HFC blends containing HFC components from India and China that are blended in India prior to importation into the United States, as described in the “Merchandise Subject to the Anti-Circumvention Inquiry” section, are circumventing the Order. We therefore find it appropriate to determine that this merchandise falls within the Order and to instruct CBP to continue to suspend liquidation of any entries of Indian blends.

Continuation of Suspension of Liquidation

As a result of this determination, and consistent with 19 CFR 351.225(j)(3), we intend to direct CBP to continue to suspend liquidation and to require a cash deposit of estimated antidumping duties at the applicable rate on unliquidated entries of merchandise subject to this inquiry that are entered, or withdrawn from warehouse, for consumption on or after June 18, 2019, the date of initiation of this anti-circumvention inquiry.11 The suspension of liquidation and cash deposit instructions will remain in effect until further notice.

HFC blends R–404A, R–407A, R–407C, R–410A, and R–507A/R–507 produced in India entirely from non-Chinese HFC components are not subject to this inquiry. Therefore, cash deposits are not required for such merchandise. However, imports of such merchandise are subject to the certification requirements, and cash deposits may be required, if the certification requirements are not satisfied. Accordingly if an importer imports HFC blends R–404A, R–407A, R–407C, R–410A, and R–507A/R–507 produced in India and claims that the HFC blend was produced entirely from non-Chinese components, in order not to be subject to AD requirements, the importer and exporter are required to meet the certification and documentation requirements described in Appendices II, III, and IV. The party that made the sale to the United States should fill out the exporter certification. In order to prevent evasion, Commerce will instruct CBP that, in the situation where the parties have not maintained the requisite certification regarding the origin of the HFC components for an entry, CBP should suspend the entry and collect cash deposits at the AD rate established for the China-wide entity (216.37 percent) pursuant to the Order.

Further, for this final determination, we continue to determine that the following company is not eligible for the certification process: Coolmate Refrigerant Pvt. Ltd. Accordingly, exporters of HFC blends from India produced and/or exported by this ineligible company are similarly ineligible for the certification process with regard to imports of HFC blends produced by or sourced from this company. Additionally, exporters are not eligible to certify shipments of merchandise produced by the above-listed company. Accordingly, CBP shall suspend the entry and collect cash deposits for entries of merchandise produced and/or exported by Coolmate Refrigerant Pvt. Ltd. at the AD rate established for the China-wide entity (216.37 percent), pursuant to the Order.

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/ destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with section 781(b) of the Act and 19 CFR 351.225(h).


Joseph A. Laroski Jr.,
Deputy Assistant Secretary for Policy and Negotiations.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary

II. Background

III. Merchandise Subject to the Anti-Circumvention Inquiry

IV. Scope of the Order

V. Discussion of the Issues

Comment 1: Whether Commerce’s Initiation and Preliminary Determination Were Lawful with Respect to the ITC’s Negative Injury Determination

Comment 2: Whether to Use Surrogate Values to Value Chinese-Origin Material Inputs

Comment 3: Whether the Production Process in India is Minor or Insignificant and Whether the Value of Further

Processing in India Represents a Small Portion of the Value of U.S. Merchandise

Comment 4: Validity of the 12 Month Look-Back Provision of the Certification Requirements

Comment 5: Whether the Final Determination Should Be Retroactive to the Date of Initiation

VI. Recommendation

Appendix II

Certification Requirements

If an importer imports HFC blends (i.e., R–404A, R–407A, R–407C, R–410A, and R–507A/R–507) from India and claims that the HFC blends were produced from Chinese components (i.e., Chinese origin R–32, R–125, R–134a, and/or R–143a), the importer is required to complete and maintain the importer certification attached hereto as Appendix II and all supporting documentation. Where the importer uses a broker to facilitate the entry process, it should obtain the entry number from the broker. Agents of the importer, such as brokers, however, are not permitted to make this certification on behalf of the importer. The importer is required to complete and maintain the exporter certification, attached as Appendix IV, and is further required to provide the importer a copy of that certification and all supporting documentation. As explained below, shipments made within one year of purchase of Chinese blends or components are not eligible for the certification process.

For shipments and/or entries on or after June 18, 2019, through April 30, 2020, for which certifications are required, importers and exporters should have completed the required certification no later than 30 days after the publication of the Preliminary Determination in the Federal Register.

Accordingly, where appropriate, the relevant bullet in the certification should reflect that the certification was completed within the time frame specified above. For example, the bullet in the importer certification that reads: “This certification was completed at or prior to the time of shipment,” could be edited as follows: “The shipments/products referenced herein shipped before May 1, 2020. This certification was completed on mm/dd/yyyy, within 30 days of the Federal Register notice publication of the preliminary determination of circumvention.” Similarly, the bullet in the exporter certification that reads, “This certification was completed at or prior to the time of shipment,” could be edited as follows: “The shipments/products referenced herein shipped before May 1, 2020. This certification was completed on mm/dd/yyyy, within 30 days of the Federal Register notice publication of the preliminary determination of circumvention.”

For such entries/shipments, importers and exporters each have the option to complete a blanket certification covering multiple entries/shipments, individual certifications for each entry/shipment, or a combination thereof. For shipments and/or entries on or after May 1, 2020, for which certifications are required, importers should complete the required certification at or prior to the date of entry and exporters should complete the required certification and provide it to the importer at or prior to the date of shipment.

The importer and Indian exporter are also required to maintain sufficient documentation supporting their certifications. The importer will not be required to submit the certifications or supporting documentation to U.S. Customs and Border Protection (CBP) as part of the entry process at this time. However, the importer and the exporter will be required to present the certifications and supporting documentation to Commerce and/or CBP, as applicable, upon request by the respective agency. Additionally, the claims made in the certifications and any supporting documentation are subject to verification by Commerce and/or CBP. The importer and exporter are required to maintain the certifications (the importer must retain both certifications) and supporting documentation for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries.

In the situation where no certification is provided for an entry, and the AD China HFC blends order potentially applies to that entry, a period of three years after the publication of the preliminary determination of circumvention. For shipments made after May 1, 2020, and for entries on or after May 1, 2020, importers and exporters are required to maintain the exporter certification, attached as Appendix IV, and is further required to provide the importer a copy of that certification and all supporting documentation. As explained above, shipments made within one year of purchase of Chinese blends or components are not eligible for the certification process.

If the importer is acting on behalf of the first U.S. customer, complete this paragraph:

• The importer is required to complete and maintain the exporter certification, attached as Appendix IV, and is further required to provide the importer a copy of that certification and all supporting documentation. As explained above, shipments made within one year of purchase of Chinese blends or components are not eligible for the certification process.

For shipments and/or entries on or after June 18, 2019, through April 30, 2020, for which certifications are required, importers and exporters should have completed the required certification no later than 30 days after the publication of the Preliminary Determination in the Federal Register.

Accordingly, where appropriate, the relevant bullet in the certification should reflect that the certification was completed within the time frame specified above. For example, the bullet in the importer certification that reads: “This certification was completed at or prior to the time of shipment,” could be edited as follows: “The shipments/products referenced herein shipped before May 1, 2020. This certification was completed on mm/dd/yyyy, within 30 days of the Federal Register notice publication of the preliminary determination of circumvention.” Similarly, the bullet in the exporter certification that reads, “This certification was completed at or prior to the time of shipment,” could be edited as follows: “The shipments/products referenced herein shipped before May 1, 2020. This certification was completed on mm/dd/yyyy, within 30 days of the Federal Register notice publication of the preliminary determination of circumvention.”

For such entries/shipments, importers and exporters each have the option to complete a blanket certification covering multiple entries/shipments, individual certifications for each entry/shipment, or a combination thereof. For shipments and/or entries on or after May 1, 2020, for which certifications are required, importers should complete the required certification at or prior to the date of entry and exporters should complete the required certification and provide it to the importer at or prior to the date of shipment.

The importer and Indian exporter are also required to maintain sufficient documentation supporting their certifications. The importer will not be required to submit the certifications or supporting documentation to U.S. Customs and Border Protection (CBP) as part of the entry process at this time. However, the importer and the exporter will be required to present the certifications and supporting documentation to Commerce and/or CBP, as applicable, upon request by the respective agency. Additionally, the claims made in the certifications and any supporting documentation are subject to verification by Commerce and/or CBP. The importer and exporter are required to maintain the certifications (the importer must retain both certifications) and supporting documentation for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries.

In the situation where no certification is provided for an entry, and the AD China HFC blends order potentially applies to that entry, a period of three years after the conclusion of any litigation in United States courts regarding such entries.

I hereby certify that:

• My name is (IMPORTING COMPANY OFFICIAL’S NAME) and I am an official of (NAME OF IMPORTING COMPANY), located at (ADDRESS OF IMPORTING COMPANY);

• I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the hydrofluorocarbon (HFC) blends (i.e., R–404A, R–407A, R–407C, R–410A, and/or R–507A/R–507) produced in India that entered under the entry number(s) identified below, and which are covered by this certification.

“Direct personal knowledge” refers to facts the certifying party is expected to have in its own records. For example, the importer should have direct personal knowledge of the importation of the product (e.g., the name of the exporter) in its records.

• The HFC blends covered by this certification were exported by (NAME OF EXPORTING COMPANY), located at (ADDRESS OF EXPORTING COMPANY). If the importer is acting on behalf of the first U.S. customer, complete this paragraph:

• The HFC blends covered by this certification were exported by (NAME OF EXPORTING COMPANY) on behalf of (NAME OF U.S. CUSTOMER), located at (ADDRESS OF U.S. CUSTOMER).

• The HFC blends covered by this certification were shipped to (NAME OF PARTY TO WHOM MERCHANDISE WAS FIRST SHIPPED IN THE UNITED STATES), located at (ADDRESS OF SHIPMENT).

• I have personal knowledge of the facts regarding the production of the imported products covered by this certification.

“Personal knowledge” includes facts obtained from another party, (e.g., correspondence received by the importer (or exporter) from the producer regarding the source of the inputs used to produce the imported products);

• The HFC blends covered by this certification were produced by (NAME OF PRODUCING COMPANY), located at (ADDRESS OF PRODUCING COMPANY); for each additional company, repeat: (NAME OF PRODUCING COMPANY), located at (ADDRESS OF PRODUCING COMPANY).

• The HFC blends covered by this certification do not contain HFC components (i.e., R–32, R–125, R–134a, and/or R–143a) produced in the People’s Republic of China (China);

• This certification applies to the following entries: (Repeat this block as many times as necessary)

<table>
<thead>
<tr>
<th>Producer</th>
<th>Entry summary No.</th>
<th>Entry summary line item No.</th>
<th>Invoice No.</th>
<th>Invoice line item No.</th>
</tr>
</thead>
</table>

• I understand that (NAME OF IMPORTING COMPANY) is required to maintain a copy of this certification and sufficient documentation supporting this certification (i.e., documents maintained in the normal course of business, or documents obtained by the certifying party, for example, product data sheets, chemical testing specifications, production records, invoices, etc.) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries;

• I understand that (NAME OF IMPORTING COMPANY) is required to maintain a copy of this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce);

• I understand that (NAME OF IMPORTING COMPANY) is required to maintain a copy of the exporter’s certification (attesting to the production and/or export of the imported merchandise identified above), and any supporting records provided by the exporter to the importer, for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries;

• I understand that (NAME OF IMPORTING COMPANY) is required to maintain a copy of the exporter’s certification (attesting to the production and/or export of the imported merchandise identified above), and any supporting records provided by the exporter to the importer, for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries;

• I understand that (NAME OF IMPORTING COMPANY) is required to maintain a copy of the exporter’s certification (attesting to the production and/or export of the imported merchandise identified above), and any supporting records provided by the exporter to the importer, for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries;
verify the claims made herein, may result in failure to allow CBP and/or Commerce to substantiate the claims made herein, and/or required certifications, and/or failure to allow CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all sales to which this certification applies are within the scope of the antidumping duty (AD) order on HFC blends from China. I understand that such a finding will result in:

- Suspension of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;
- The requirement that the importer post applicable AD cash deposits equal to the rates as determined by Commerce; and
- The revocation of [NAME OF IMPORTING COMPANY]’s privilege to certify future imports of HFC blends from India as not manufactured using HFC blends and/or components from China.

Exporter Certification

I hereby certify that:

- My name is [COMPANY OFFICIAL’S NAME] and I am an official of [NAME OF EXPORTING COMPANY], located at [ADDRESS OF EXPORTING COMPANY];
- The HFC blends, and the individual components thereof, covered by this certification were produced by [NAME OF PRODUCING COMPANY], located at [ADDRESS OF PRODUCING COMPANY];
- The HFC blends covered by this certification were sold to [NAME OF CUSTOMER], located at [ADDRESS OF CUSTOMER];
- The HFC blends covered by this certification were shipped by [NAME OF EXPORTING COMPANY] to [NAME OF PARTY TO WHOM MERCHANDISE WAS SHIPPED], located at [ADDRESS OF SHIPPED PARTIES];
- The HFC blends covered by this certification were produced at [ADDRESS OF PRODUCING COMPANY] for the later of (1) a period of five years after the conclusion of any litigation in which this certification applies or (2) a period of three years after the certification was completed at or prior to the time of shipment; and
- I am aware that U.S. law (including, but not limited to, 18 U.S.C. Section 1001) imposes criminal sanctions on individuals who knowingly and willfully make materially false statements to the U.S. government.

Signature

[NAME OF COMPANY OFFICIAL]

[ADDRESS OF IMPORTING COMPANY]

[DATE]

Appendix IV

Exporter Certification

I hereby certify that:

- My name is [COMPANY OFFICIAL’S NAME] and I am an official of [NAME OF EXPORTING COMPANY], located at [ADDRESS OF EXPORTING COMPANY];
- The HFC blends, and the individual components thereof, covered by this certification were produced by [NAME OF PRODUCING COMPANY], located at [ADDRESS OF PRODUCING COMPANY];
- The HFC blends covered by this certification were sold to [NAME OF CUSTOMER], located at [ADDRESS OF CUSTOMER];
- The HFC blends covered by this certification were shipped by [NAME OF EXPORTING COMPANY] to [NAME OF PARTY TO WHOM MERCHANDISE WAS SHIPPED], located at [ADDRESS OF SHIPPED PARTIES];
- The HFC blends covered by this certification were produced at [ADDRESS OF PRODUCING COMPANY] for the later of (1) a period of five years after the conclusion of any litigation in which this certification applies or (2) a period of three years after the certification was completed at or prior to the time of shipment; and
- I am aware that U.S. law (including, but not limited to, 18 U.S.C. Section 1001) imposes criminal sanctions on individuals who knowingly and willfully make materially false statements to the U.S. government.

Signature

[NAME OF COMPANY OFFICIAL]

[ADDRESS OF IMPORTING COMPANY]

[DATE]

BILLING CODE 3510–05–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA506]

South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a meeting of its Habitat Protection and Ecosystem-Based Management Advisory Panel (Habitat AP).

DATES: The Habitat AP meet on Wednesday via webinar on October 21, 2020, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m.; and Thursday, October 22, 2020, from 9 a.m. to 12 noon.

ADDRESSES: Meeting address: The meeting will be held via webinar.

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

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571–4306 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: kim.iverson@saufmc.net.
SUPPLEMENTARY INFORMATION: The Habitat AP meeting is open to the public and will be available via webinar as it occurs. Registration is required. Webinar registration information and other meeting materials will be posted to the Council’s website at: http://safmc.net/safmc-meetings/current-advisory-panel-meetings/ as it becomes available.

The Habitat AP meeting agenda includes the following:

- Updates on NOAA Fisheries Ecosystem-Based Fishery Management Activities for the South Atlantic Region including a Draft South Atlantic Ecosystem Status Report and a Draft South Atlantic Climate Vulnerability Analysis; Fishery Ecosystem Plan (FEP) II Implementation Plan Roadmap update; and the South Atlantic Ecopath with Ecosim model, Scientific and Statistical Committee (SSC) Model Workgroup review, model applications and Ecospace development.

- AP members will also receive; a research overview and update on Mapping/Characterization of South Atlantic Deep Water Coral Ecosystems and discuss possible future conservation action. The AP will initiate review of the Council’s Essential Fish Habitat (EFH) Policy Statement on Beach Re-nourishment and Large-Scale Coastal Engineering and receive presentations on: Sand Shoals and Fish Habitat Value project; the Folly Beach Re-nourishment Monitoring Study; and on An Assessment of Fisheries Species to Inform Time-of-Year Restrictions for North Carolina and South Carolina.

The AP will also receive briefings on: Bureau of Ocean Energy Management (BOEM) sponsored research and energy development with a focus on renewable energy and the Kitty Hawk Offshore wind project; the Bahamian oil spill as a result of Hurricane Dorian; and the Southeast Seafloor Mapping Prioritization project.

The AP will develop recommendations as necessary for consideration by the Council’s Habitat Protection and Ecosystem-Based Management Committee.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see ADDRESSES) 3 days prior to the meeting.

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

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

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
Meeting of the Advisory Committee on Commercial Remote Sensing

ACTION: Notice of meeting.

SUMMARY: The Advisory Committee on Commercial Remote Sensing (“ACCRES”) will meet for 2 half-day meetings on October 27 and October 28, 2020.

DATES: The meeting is scheduled as follows: October 27–October 28, 2020 from 10 a.m.–2 p.m. Eastern Daylight Time (EDT) each day.

ADDRESSES: The meeting will be held virtually via Cisco WebEx.

FOR FURTHER INFORMATION CONTACT: Tahara Dawkins, NOAA/NESDIS/CRSRA, 1335 East West Highway, G–101, Silver Spring, Maryland 20910; 301–427–2560 or CRSRA@noaa.gov.

SUPPLEMENTARY INFORMATION: As required by Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (FACA) and its implementing regulations, see 41 CFR 102–3.150, notice is hereby given of the meeting of ACCRES. ACCRES was established by the Secretary of Commerce (Secretary) on May 21, 2002, to advise the Secretary through the Under Secretary of Commerce for Oceans and Atmosphere on matters relating to the U.S. commercial remote sensing space industry and on the National Oceanic and Atmospheric Administration’s activities to carry out the responsibilities of the Department of Commerce set forth in the National and Commercial Space Programs Act of 2010 (51 U.S.C. 60101 et seq.).

Purpose of the Meeting and Matters To Be Considered

The meeting will be open to the public pursuant to Section 10(a)(1) of the FACA. During the meeting, the Committee will hear a report out from the four task groups formed during the 27th meeting of ACCRES and discuss both the U.S. and Global perspectives of the current state of the satellite industry.

Additional Information and Public Comments

The meeting will be held over two half-days and will be conducted via Cisco WebEx. Please RSVP for the meeting through the link: https://forms.gle/HoU7jkRmZQfGs5pv7 or by directly emailing CRSRA@noaa.gov. The agenda, speakers and times are subject to change. For updates, please check online at https://www.nesdis.noaa.gov/CRSRA/accresMeetings.html.

Public comments are encouraged. Individuals or groups who would like to submit advance written comments, please email them to Tahara.Dawkins@noaa.gov, and CRSRA@noaa.gov.

Stephen M. Volz,
Assistant Administrator for Satellite and Information Services.

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

Review of Nomination for Chumash Heritage National Marine Sanctuary

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice.

SUMMARY: In May 2020, the Office of National Marine Sanctuaries (ONMS) of the National Oceanic and Atmospheric Administration (NOAA) requested written comments to facilitate ONMS review of the nomination for Chumash Heritage National Marine Sanctuary (CHNMS). NOAA requested relevant information as it pertains to the 11 national significance criteria and management considerations that NOAA applied to evaluate the CHNMS nomination for inclusion in the national inventory of areas that NOAA may be considered for future designation as a national marine sanctuary. NOAA has synthesized the information gathered through the public process, completed an internal analysis, and the ONMS Director has determined that the CHNMS nomination will remain in the inventory until at least October 5, 2025.

DATES: This determination is effective on October 5, 2020.

ADDRESSES: William Douros Regional Director, ONMS West Coast Region, 99 Pacific Street, Bldg. 100F, Monterey, CA 61935
In 2014, NOAA issued a final rule establishing the sanctuary nomination process (SNP), a process by which communities may submit nominations of areas of the marine and Great Lakes environment for NOAA to consider for designation as a national marine sanctuary (79 FR 33851). The final rule establishing the SNP included a five year limit on any nomination added to the inventory that NOAA does not advance for designation. The nomination for CHNMS was accepted to the national inventory on October 5, 2015, and was scheduled to expire in October 2020.

In November 2019, NOAA issued a notice (84 FR 61546) to clarify procedures for evaluating and updating a nomination as it approaches the five-year mark. The clarified procedure is intended to ensure the inventory contains nominations that remain relevant and responsive to the 11 SNP national significance criteria and management considerations (“SNP Criteria”). The 11 SNP Criteria can be found at https://nominate.noaa.gov. The process to update a nomination about to expire at the five-year mark includes the following steps:

1. ONMS notifies the nominating party at about the four and a half-year mark to give the nominating party an opportunity to provide updates of the nominated area’s relevance to the SNP Criteria.
2. ONMS staff work with partners and the public to gather information on the nomination’s relevance to the SNP Criteria.
3. ONMS staff review information received from the original nominating party, partners, the public and other relevant sources against the SNP Criteria to assess if the nomination is still accurate and relevant.
4. ONMS staff produce a brief synopsis report to the ONMS Director, presenting an analysis of information that has been collected, and a recommendation regarding maintaining the nomination in the inventory, or removing it once the five-year anniversary is reached.

On May 4, 2020, NOAA issued a request for public comments on this nomination (85 FR 26443). NOAA requested relevant information pertaining to the 11 SNP Criteria that NOAA applied to evaluate the CHNMS nomination for inclusion in the national inventory of areas that NOAA may consider for future designation as a national marine sanctuary. NOAA also hosted a virtual public meeting on May 27, 2020. A total of 14,358 public comments were received during this public process. Comments can be found at regulations.gov (search for document number NOAA–NOS–2020–0063–0001). In analyzing these comments, particular attention was given to new scientific information about the national significance of natural and cultural resources, as well as increases or decreases in the threats to resources originally proposed for protection, and changes to the management framework of the area. NOAA also assessed the level of community-based support for the nomination from a broad range of interests.

NOAA reviewed information provided regarding the nomination’s merit for remaining on the inventory after five years, and has determined that new information shows: There are still significant threats to the area; it is still an area of national significance, and there is still broad community support for the nomination remaining on the inventory of possible designations, among other criteria that the nomination still continues to meet. Therefore, the ONMS Director has determined the nomination for the CHNMS should remain on the inventory. NOAA is not proposing to designate CHNMS or any other new national marine sanctuary with this action. This notice serves to inform the public of this decision to extend the nomination on the inventory.

I. Classification

A. National Environmental Policy Act

NOAA determined that because this action is a notice of an administrative nature, and does not designate any new national marine sanctuaries, it meets the definition in Appendix E of the NOAA NEPA Companion Manual under categorical exclusion reference number G7 “Preparation of policy directives, rules, regulations, and guidelines of an administrative, financial, legal, technical, or procedural nature, or for which the environmental effects are too broad, speculative or conjectural to lend themselves to meaningful analysis and will be subject later to the NEPA process, either collectively or on a case-by-case basis.” In considering the list of extraordinary circumstances, NOAA determined that none would be triggered by this action. Therefore, NOAA determined that this action would not result in significant effects to the human environment and is categorically excluded from the need for further review under NEPA. Should NOAA decide to designate a national marine sanctuary, each national marine sanctuary designation will be subject to case-by-case analysis as required under NEPA and section 304(a)(2)(A) of the NMSA. This NEPA determination was prepared using the 2020 CEQ NEPA Regulations. The effective date of the 2020 CEQ NEPA Regulations was September 14, 2020, and reviews begun after this date are required to apply the 2020 regulations unless there is a clear and fundamental conflict with an applicable statute. 85 FR at 43372–73 (§§ 1506.13, 1507.3(a)).

B. Paperwork Reduction Act

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., unless that collection of information displays a currently valid OMB control number. Nominations for national marine sanctuaries discussed in this notice involve a collection-of-information requirement subject to the requirements of the PRA. OMB has approved this collection-of-information requirement under OMB control number 0648–0682.

(Authority: 16 U.S.C. 1431 et seq.)

John Armor,

[FR Doc. 2020–21664 Filed 9–30–20; 8:45 am]

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA324]

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

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

ACTION: Notice of public meeting.
SUMMARY: The SEDAR Steering Committee will meet via webinar to discuss the SEDAR stock assessment process and assessment schedule. See SUPPLEMENTARY INFORMATION.

DATES: The SEDAR Steering Committee will meet via webinar on Friday, October 16, 2020, from 9 a.m. until 12:30 p.m., Eastern.

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

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

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Program Manager, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: julie.neer@safmc.net.

SUPPLEMENTARY INFORMATION: The SEDAR Steering Committee provides guidance and oversight of the SEDAR stock assessment program and manages assessment scheduling. The items of discussion for this meeting are as follows:
1. SEDAR Projects Update
2. SEDAR Projects Schedule
3. SEDAR Process Review and Discussions

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

Special Accommodations
This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SAFMC office (see ADDRESSES) at least 5 business days prior to the meeting.

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

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

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

Supplemental Information: National Marine and Atmospheric Administration (NOMA), Commerce.

ACTION: Notice of vendor to provide fishing year 2021 cage tags.

SUMMARY: NMFS informs surfclam and ocean quahog individual transferable quota allocation holders that they will be required to purchase their fishing year 2021 (January 1, 2021–December 31, 2021) cage tags from the National Band and Tag Company. The intent of this notice is to comply with regulations for the Atlantic surfclam and ocean quahog fisheries and to promote efficient distribution of cage tags.

FOR FURTHER INFORMATION CONTACT: Aimee Ahles, Fishery Management Specialist, (978) 281–9373.

SUPPLEMENTARY INFORMATION: The Federal Atlantic surfclam and ocean quahog fishery regulations at 50 CFR 648.77(b) authorize the Regional Administrator of the Greater Atlantic Region, NMFS, to specify in the Federal Register a vendor from whom cage tags, required under the Atlantic Surfclam and Ocean Quahog Fishery Management Plan (FMP), shall be purchased. Notice is hereby given that National Band and Tag Company of Newport, Kentucky, is the authorized vendor of cage tags required for the fishing year 2021 Federal surfclam and ocean quahog fisheries. Detailed instructions for purchasing these cage tags will be provided in a letter to individual transferable quota allocation holders in these fisheries from NMFS within the next several weeks.

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


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

DEPARTMENT OF COMMERCE
Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comments Request; Patent Petitions Related to Application and Reexamination Processing Fees

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), in accordance with the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0059 (Patent Petitions Related to Application and Reexamination Processing Fees). The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before November 30, 2020.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information:

- Email: InformationCollection@uspto.gov. Include “0651–0059 comment” in the subject line of the message.
- Mail: Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–7728; or by email to raul.tamayo@uspto.gov with “0651–0059 comment” in the subject line. Additional information about this information collection is also available at http://www.reginfo.gov under “Information Collection Review.”

SUPPLEMENTARY INFORMATION:

- Tracey L. Thompson,
  Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
  [FR Doc. 2020–21733 Filed 9–30–20; 8:45 am]
  BILLING CODE 3510–22–P

- Jennifer M. Wallace,
  Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
  [FR Doc. 2020–21666 Filed 9–30–20; 8:45 am]
  BILLING CODE 3510–22–P
I. Abstract

The United States Patent and Trademark Office (USPTO) is required by 35 U.S.C. 131 et seq. to examine an application for patent and, when appropriate, issue a patent. The USPTO also is required to publish patent applications, with certain exceptions, promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought under Title 35, United States Code.

Many actions taken by the USPTO during its examination of an application for patent or reexamination of a patent, are subject to review by an appeal to the Patent Trial and Appeal Board. For other USPTO actions, review is in the form of administrative review obtained via submission of a petition to the USPTO. USPTO petitions practice provides an opportunity for a patent applicant or owner to supply additional information that may be required in order for the USPTO to further process an application or patent.

This information collection covers petitions filed in patent applications and reexamination proceedings, and accompanying fees as set forth in 37 CFR 1.17(f), (g), or (h). This information collection also covers the transmittals for the petition fees.

II. Method of Collection

The items in this information collection can be submitted electronically through Electronic Filing System-Web (EFS-Web), on paper by mail, facsimile, or hand delivery to the USPTO.

III. Data

OMB Number: 0651–0059.

Form Number(s): (SB = Specimen Book; AIA = America Invents Act).

- PTO/SB/28 (EFS-Web only) (Petitions for Make Special Under Accelerated Examination Program)
- PTO/AIA/24a (Petitions for Express Abandonment to Avoid Publication Under 37 CFR 1.138(c))
- PTO/SB/23 (Petition for Extension of Time Under 37 CFR 1.136(b))
- PTO/AIA/17P (Petition Fee Under 37 CFR 1.17(f), (g), and (h) Transmittal)
- PTO/SB/140 (Petition to Withdraw an Application from Issue)

Type of Review: Revision of a currently approved information collection.

Affected Public: Private sector; individuals or households.

Estimated Number of Respondents: 40,922 respondents per year.

Estimated Number of Responses: 40,922 responses per year.

Estimated Time per Response: The USPTO estimates that it will take the public from approximately 5 minutes (0.08 hours) to 12 hours to complete a response, depending on the complexity of the particular item. This includes the time to gather the necessary information, create the documents, and submit the completed request to the USPTO.

Estimated Total Annual Respondent Burden Hours: 72,958 hours.


Table 1—Total Hourly Burden for Private Sector Respondents

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Item</th>
<th>Estimated annual respondents</th>
<th>Estimated annual responses (year)</th>
<th>Estimated time for response (hours)</th>
<th>Estimated annual burden (hour/year)</th>
<th>Rate (^1) ($/hour)</th>
<th>Estimated annual burden</th>
<th>OMB Number</th>
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<tbody>
<tr>
<td>1</td>
<td>Petitions (corresponding to the fee) Under 37 CFR 1.17(f) include:</td>
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<tr>
<td></td>
<td>- Petition to Accord a Filing Date Under 1.57(a).</td>
<td>4,146</td>
<td>4146</td>
<td>4</td>
<td>16,583</td>
<td>$400</td>
<td>$6,633,200</td>
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<td></td>
<td>- Petition to Accord a Filing Date Under 1.53(e).</td>
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<td></td>
<td>- Petition for Decision on a Question Not Specifically Provided For.</td>
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<td></td>
<td>- Petition to Suspend the Rules.</td>
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<td></td>
<td>- Petition Fee Under 37 CFR 1.17(f), (g), and (h) Transmittal.</td>
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<td>2</td>
<td>Petitions (corresponding to the fee) Under 37 CFR 1.17(g) include:</td>
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<tr>
<td></td>
<td>- Petition to Access an Assignment Record.</td>
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<td>10,313</td>
<td>2</td>
<td>20,626</td>
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<td>8,250,400</td>
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<td></td>
<td>- Petition for Access to an Application.</td>
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<td></td>
<td>- Petition for Expungement and Return of Information.</td>
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<td></td>
<td>- Petition to Suspend Action in an Application.</td>
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<td>- Petition Fee Under 37 CFR 1.17(f), (g), and (h) Transmittal.</td>
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<td>3</td>
<td>Petitions (corresponding to the fee) Under 37 CFR 1.17(h) include:</td>
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<td></td>
<td>- Petition for Accepting Color Drawings or Photographs.</td>
<td>23,866</td>
<td>23,866</td>
<td>1</td>
<td>23,866</td>
<td>$400</td>
<td>9,546,400</td>
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<td>- Petition for Entry of a Model or Exhibit.</td>
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<td>- Petition to Withdraw an Application from Issue.</td>
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<td>- Petition to Accord a Filing Date Under 1.57(a).</td>
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<td>- Petition to Suspend the Rules.</td>
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<td>- Petition Fee Under 37 CFR 1.17(f), (g), and (h) Transmittal.</td>
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<td>4</td>
<td>Petitions to Make Special Under Accelerated Examination Program (EFS-Web only).</td>
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<td>798</td>
<td>12</td>
<td>9,576</td>
<td>$400</td>
<td>3,830,400</td>
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<td>5</td>
<td>Petitions for Express Abandonment to Avoid Publication Under 37 CFR 1.138(c).</td>
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<td>570</td>
<td>.2</td>
<td>114</td>
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<td>6</td>
<td>Petition to Withdraw an Application from Issue.</td>
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<td>1</td>
<td>.5</td>
<td>1</td>
<td>$400</td>
<td>400</td>
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</table>

### TABLE 2—TOTAL HOURLY BURDEN FOR INDIVIDUALS AND HOUSEHOLDS RESPONDENTS

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Item</th>
<th>Estimated annual respondents</th>
<th>Estimated annual responses (year) (a)</th>
<th>Estimated time for response (hours) (b)</th>
<th>Estimated annual burden (hour/year) (a) x (b) = c</th>
<th>Rate (d) ($/hour)</th>
<th>Estimated annual burden (c) x (d) = e</th>
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<tbody>
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<td>• Petition to Accord a Filing Date Under 1.57(a).</td>
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<td>• Petition to Accord a Filing Date Under 1.53(e).</td>
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<td>• Petition for Decision on a Question Not Specifically Provided For.</td>
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<td>• Petition to Suspend the Rules.</td>
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<td></td>
<td>• Petition Fee Under 37 CFR 1.17(f), (g), and (h) Transmittal.</td>
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<td>2 .................</td>
<td>Petitions (corresponding to the fee) Under 37 CFR 1.17(g) include:</td>
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<td>• Petition to Access an Assignment Record.</td>
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<td>• Petition for Access to an Application.</td>
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<td>• Petition to Suspend Action in an Application.</td>
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<td>• Petition Fee Under 37 CFR 1.17(f), (g), and (h) Transmittal.</td>
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<td>3 .................</td>
<td>Petitions (corresponding to the fee) Under 37 CFR 1.17(h) include:</td>
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<td>• Petition for Accepting Color Drawings or Photographs.</td>
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<td>• Petition for Entry of a Model or Exhibit.</td>
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<td></td>
<td>• Petition to Withdraw an Application from Issue.</td>
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<tr>
<td></td>
<td>• Petition to Defer Issuance of a Patent.</td>
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<tr>
<td></td>
<td>• Petition Fee Under 37 CFR 1.17(f), (g), and (h) Transmittal.</td>
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<td>5 .................</td>
<td>Petitions to Make Special Under Accelerated Examination Program (EFS-Web only).</td>
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<tr>
<td>6 .................</td>
<td>Petitions for Express Abandonment to Avoid Publication Under 37 CFR 1.138(c).</td>
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<td><strong>Total</strong> .............</td>
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</tbody>
</table>


*Estimated Total Annual Non-Hour Respondent Cost Burden: $3,195,134.
There are no capital start-up, operation, or maintenance costs associated with this information collection. However, this information collection does have annual non-hour costs in the form of postage costs and filing fees.

### TABLE 3—ANNUAL NON-HOUR COST BURDEN

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Item</th>
<th>Estimated annual responses (a)</th>
<th>Estimated cost (b)</th>
<th>Estimated non-hour cost burden (a) x (b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 .................</td>
<td>Petitions requiring the petition fee set forth in 37 CFR 1.17 (f) (Group I) (large entity).</td>
<td>1,089</td>
<td>$420</td>
<td>$457,380</td>
</tr>
<tr>
<td>1 .................</td>
<td>Petitions requiring the petition fee set forth in 37 CFR 1.17 (f) (Group I) (small entity).</td>
<td>840</td>
<td>210</td>
<td>176,400</td>
</tr>
<tr>
<td>1 .................</td>
<td>Petitions requiring the petition fee set forth in 37 CFR 1.17 (f) (Group I) (micro entity).</td>
<td>208</td>
<td>105</td>
<td>21,840</td>
</tr>
<tr>
<td>2 .................</td>
<td>Petitions requiring the petition fee set forth in 37 CFR 1.17 (g) (Group I) (large entity).</td>
<td>4,739</td>
<td>220</td>
<td>1,042,580</td>
</tr>
<tr>
<td>2 .................</td>
<td>Petitions requiring the petition fee set forth in 37 CFR 1.17 (g) (Group I) (small entity).</td>
<td>515</td>
<td>110</td>
<td>56,650</td>
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<tr>
<td>2 .................</td>
<td>Petitions requiring the petition fee set forth in 37 CFR 1.17 (g) (Group I) (micro entity).</td>
<td>62</td>
<td>55</td>
<td>3,410</td>
</tr>
<tr>
<td>3 .................</td>
<td>Petitions requiring the petition fee set forth in 37 CFR 1.17 (h) (Group III) (large entity).</td>
<td>8,310</td>
<td>140</td>
<td>1,163,400</td>
</tr>
<tr>
<td>3 .................</td>
<td>Petitions requiring the petition fee set forth in 37 CFR 1.17 (h) (Group III) (small entity).</td>
<td>3,777</td>
<td>70</td>
<td>264,390</td>
</tr>
<tr>
<td>3 .................</td>
<td>Petitions requiring the petition fee set forth in 37 CFR 1.17 (h) (Group III) (micro entity).</td>
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<td>35</td>
<td>7,490</td>
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<tr>
<td><em>Total</em> .............</td>
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<td>3,193,540</td>
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</table>
Respondents may also incur postage costs when submitting items in this information collection. Although the USPTO prefers that items in this information collection be submitted electronically, items may be submitted to the USPTO by mail through the United States Postal Service. The USPTO expects that approximately 99 percent of the items in this information collection will be submitted electronically, resulting in 198 mailed submissions. The average cost for a four-ounce 2-Day Priority Mail legal flat rate envelope shipped first-class via USPS is $8.05. Therefore, the USPTO estimates that the postage costs for the mailed submissions in this information collection will total $1,594.

**Respondent’s Obligation:** Required to obtain or retain benefits.

**IV. Request for Comments**

The USPTO is soliciting public comments to:

(a) 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;

(b) Evaluate the accuracy of the Agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected; and

(d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personal identifying information in a comment, be aware that the entire comment—including personal identifying information—may be made publicly available at any time. While you may ask in your comment to withhold personal identifying information from public view, USPTO cannot guarantee that it will be able to do so.

**Christopher G. Baker,**

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2020–21799 Filed 9–29–20; 11:15 am]

BILLING CODE 3510–16–P

**DEPARTMENT OF EDUCATION**

[Docket No. ED–2020–SCC–0158]

Agency Information Collection Activities; Comment Request: Implementation Evaluation of the Title III National Professional Development Program

**AGENCY:** Institute for Education Sciences (IES), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

**DATES:** Interested persons are invited to submit comments on or before November 30, 2020.

**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–2020–SCC–0158. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at http://www.regulations.gov by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at ICDocketMgr@ed.gov. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LB3, Room 6W206B, Washington, DC 20202–8240.

**FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Tracy Rimdzius, 202.245–7283.

**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:** Implementation Evaluation of the Title III National Professional Development Program

**OMB Control Number:** 1850–NEW

**Type of Review:** A new information collection.

**Respondents/Affected Public:** Individuals or households.

**Total Estimated Number of Annual Responses:** 939.

**Total Estimated Number of Annual Burden Hours:** 411.

**Abstract:** The data collection described in this submission includes activities for an implementation evaluation of the National Professional Development (NPD) program, authorized by Title III of the Elementary and Secondary Education Act (ESEA), which aims to help educational personnel working with English learners (ELs) meet high professional standards and to improve classroom instruction for ELs. The evaluation is designed to provide a systematic and up-to-date look at the implementation of NPD-supported activities among the programs’ 91 current grantees as well as a representative sample of pre-service and in-service educators who participated in NPD-supported activities. The surveys will collect information on NPD grantees’ goals, strategies used to meet those goals, changes made to teacher education programs, and challenges and successes.
The Commission’s duties are to advise the President and the Secretary on educational and economic opportunities for the Hispanic American community in the following areas: (i) Promoting pathways to in-demand jobs for Hispanic American students, including apprenticeships, internships, fellowships, mentorships, and work-based learning initiatives; (ii) strengthening Hispanic-Serving Institutions (HSIs), as defined by the Higher Education Act of 1965, as amended, and increasing the participation of the Hispanic American community, Hispanic-serving school districts, and HSIs in the programs of the Department and other agencies; (iii) promoting local-based and national private-public partnerships to promote high-quality education, training, and economic opportunities for Hispanic Americans; (iv) promoting awareness of educational opportunities for Hispanic American students, including options to enhance school choice, personalized learning, family engagement, and civics education; (v) promoting public awareness of the educational and training challenges that Hispanic Americans face and the causes of these challenges and; (vi) monitoring changes in Hispanic Americans’ access to educational and economic opportunities.

Meeting Agenda:

The agenda for the Commission meeting is the continuation of the discussion of the strategic plan to meet its duties under its charter.

Members of the public may submit written statements regarding the work of the Commission via Emmanuel.Caudillo@ed.gov (please use the subject line “September 2020 Advisory Commission Meeting Public Comment”), or by letter to Emmanuel Caudillo, White House Hispanic Prosperity Initiative, 400 Maryland Avenue SW, 7E324, Washington, DC 20202, by Tuesday, September 29, 2020.

Instructions for Accessing the Meeting:

Members of the public can access the meeting by registering to obtain dial-in instructions at the below link. Due to technical constraints, registration is limited to 200 participants and will be available on a first-come, first-served basis: https://ems9.intellor.com/?do=register&et=18&p=901941.

Access to Records of the Meeting: The Department will post the official report of the meeting on the Commission’s website within 90 days after the meeting. In addition, pursuant to the FACA, the public may request to inspect records of the meeting at 400 Maryland Avenue SW, Washington, DC, by emailing Emmanuel.Caudillo@ed.gov or by phoning (202) 453–5529 to schedule an appointment.

Reasonable Accommodations: The meeting platform and access code are accessible to individuals with disabilities. If you will need an auxiliary aid or service for the meeting (e.g., interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice not later than Monday, September 28, 2020. Although we will attempt to meet a request received after that date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

Electronic Access to this Document: The official version of this document is the document published in the Federal Register. Free internet access to the official edition of the Federal Register and the Code of Federal Regulations is available via the Federal Digital System at: www.gpo.gov/fdsys. At this site you can view this document, as well as all other documents of this Department published in the Federal Register, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You also may access documents of the Department published in the Federal Register by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: Executive Order 13935 (July 9, 2020)

Elizabeth Hill,

Delegated to perform the duties of the Assistant Secretary, Communications Director, Office of Communications and Outreach.

[FR Doc. 2020–21616 Filed 9–29–20; 4:15 pm]
Federal Advisory Committee Act requires that public notice of this meeting be announced in the Federal Register.

DATES: Thursday, October 22, 2020; 8:30 a.m.–3:00 p.m.

The opportunities for oral public comment are at 10:15 a.m. and 2:45 p.m. MT and written public comment before and after the meeting within seven days. This time is subject to change; please contact the Federal Coordinator (below) for confirmation of times prior to the meeting.

ADRESSES: This hybrid meeting will be open to the public virtually via Zoom only. To attend, please contact Jordan Davies, ICP Citizens Advisory Board (CAB) support staff, by email jdavies@northwindgrp.com or phone (720) 452–7379, no later than 5:00 p.m. MT on Tuesday, October 20, 2020.

Board members, DOE representatives, agency liaisons, and support staff will participate in-person, strictly following COVID-19 precautionary measures, at: Sun Valley Inn, 2 Sun Valley Road, Sun Valley, Idaho 83353.

To Sign Up for Public Comment: Please contact Jordan Davies by email, jdavies@northwindgrp.com, no later than 5:00 p.m. MT on Tuesday, October 20, 2020.

FOR FURTHER INFORMATION CONTACT: Danielle Miller, Federal Coordinator, U.S. Department of Energy, Idaho Operations Office, 1955 Fremont Avenue, MS–1203, Idaho Falls, Idaho 83415. Phone (208) 526–5709; or email: millerd@id.doe.gov or visit the Board’s internet home page at: https://www.energy.gov/em/icp/cab/meetings.

BILING CODE 4550–01–P

DEPARTMENT OF ENERGY


Sabine Pass Liquefaction, LLC; Application To Amend Export Term Through December 31, 2050, for Existing Non-Free Trade Agreement Authorizations

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of application.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice (Notice) of receipt of an application (Application), filed on September 3, 2020, by Sabine Pass Liquefaction, LLC (SPL). SPL seeks to amend the export term set forth in its current authorizations to export liquefied natural gas (LNG) to non-free trade agreement countries, DOE/FE Order Nos. 2961–A, 3669, and 3792, to a term ending on December 31, 2050. SPL filed the Application under the Natural Gas Act (NGA) and DOE’s policy statement entitled, “Extending Natural Gas Export Authorizations to Non-Free Trade Agreement Countries Through the Year 2050” (Policy Statement). Protests, motions to intervene, notices of intervention, and written comments on the requested term extension are invited.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures, and written comments are to be filed using procedures detailed in the Public Comment Procedures section no later than 4:30 p.m., Eastern time, October 16, 2020.

ADDRESSES:

Electronic Filing by email: fergas@hq.doe.gov.


Hand Delivery or Private Delivery Services (e.g., FedEx, UPS, etc.): U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585.


SUPPLEMENTARY INFORMATION: SPL is currently authorized by DOE/FE to export domestically produced LNG in a total volume equivalent to 1,509.3 billion cubic feet per year (Bcf/yr) of natural gas, pursuant to NGA section 3(a), 15 U.S.C. 717b(a), under the following orders and their subsequent amendments:

(i) 803 Bcf/yr under Order No. 2961–A (FE Docket No. 10–111–LNG); 1


meaning an intervenor or protestor may challenge the requested extension but not the existing non-FTA order."  

Accordingly, in reviewing SPL’s Application, DOE/FE will consider any issues required by law or policy under NGA section 3(a), as informed by the Policy Statement. To the extent appropriate, DOE will consider the study entitled, *Macroeconomic Outcomes of Market Determined Levels of U.S. LNG Exports* (2018 LNG Export Study). DOE’s response to public comments received on that Study, and the following environmental documents:

- **Addendum to Environmental Review Documents Concerning Exports of Natural Gas From the United States**, 79 FR 48132 (Aug. 15, 2014);  
- **Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States**, 79 FR 32260 (June 4, 2014);  
- **Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States: 2019 Update**, 84 FR 49278 (Sept. 19, 2019), and DOE/FE’s response to public comments received on that study.

**Public Comment Procedures**

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable, addressing the Application. Interested parties will be provided 15 days from the date of publication of this Notice in which to submit comments, protests, motions to intervene, or notices of intervention. The public previously was given an opportunity to intervene in, protest, and comment on SPL’s long-term non-FTA applications. Therefore, DOE will not consider comments or protests that do not bear directly on the requested term extension.

Any person wishing to become a party to the proceeding must file a motion to intervene or notice of intervention. The filing of comments or a protest with respect to the Application will not serve to make the commenter or protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Application. All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by the regulations in 10 CFR part 590.

Filings may be submitted using one of the following methods: (1) Emailing the filing to fergas@hq.doe.gov, with FE Docket Nos. 10–111–LNG, 13–30–LNG, 13–42–LNG, 13–121–LNG, and 15–63–LNG in the title line; (2) mailing an original and three paper copies of the filing to the Office of Regulation, Analysis, and Engagement at the address listed in ADDRESSES; or (3) hand delivering an original and three paper copies of the filing to the Office of Regulation, Analysis, and Engagement at the address listed in ADDRESSES. All filings must include a reference to FE Docket Nos. 10–111–LNG, 13–30–LNG, 13–42–LNG, 13–121–LNG, and 15–63–LNG. Please Note: If submitting a filing via email, please include all related documents and attachments (e.g., exhibits) in the original email correspondence. Please do not include any active hyperlinks or password protection in any of the documents or attachments related to the filing. All electronic filings submitted to DOE must follow these guidelines to ensure that all documents are filed in a timely manner. Any hardcopy filing submitted greater in length than 50 pages must also include, at the time of the filing, a digital copy on disk of the entire submission.

A decisional record on the Application will be developed through responses to this Notice by parties, including the parties’ written comments and replies thereto. If any party requests additional procedures, a Final Opinion and Order may be issued based on the

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1. See id., 85 FR 52247.
Comment Procedures section no later than 4:30 p.m., Eastern time, October 16, 2020.

**ADDRESSES:**
- Electronic Filing by Email: fergas@hq.doe.gov.
- Hand Delivery or Private Delivery Services (e.g., FedEx, UPS, etc.): U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585.

**FOR FURTHER INFORMATION CONTACT:**
- Benjamin Nussdorf or Amy Sweeney, U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 6D–033, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–7893; (202) 586–2627, benjamin.nussdorf@hq.doe.gov or amy.sweeney@hq.doe.gov
- Cassandra Bernstein or Edward Toyozaki, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, Room 6D–033, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9793; (202) 586–0126, cassandra.bernstein@hq.doe.gov or edward.toyozaki@hq.doe.gov

**SUPPLEMENTARY INFORMATION:** On May 2, 2019, in Order No. 4372, DOE/FE authorized Port Arthur LNG to export domestically produced LNG in a volume equivalent to 698 billion cubic feet per year of natural gas, pursuant to NGA section 3(a), 1 U.S.C. 717b(a). Port Arthur LNG is authorized to export this LNG by vessel from the proposed Port Arthur LNG Project to be located in Port Arthur, Texas, to any country with which the United States has not entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries) for a 20-year term. In the Application, Port Arthur LNG asks DOE to extend its current export term to a term ending on December 31, 2050, as provided in the Policy Statement. Additional details can be found in the Application, posted on the DOE/FE website at: https://www.energy.gov/sites/prod/files/2020/09/f78/Port%20Arthur%20LNG%20LLC-%20Application%20for%20Term%20Extensions.pdf.

**DOE/FE Evaluation**

In the Policy Statement, DOE adopted a term through December 31, 2050 (inclusive of any make-up period), as the standard export term for long-term non-FTA authorizations. As the basis for its decision, DOE considered its obligations under NGA section 3(a), the public comments supporting and opposing the proposed Policy Statement, and a wide range of information bearing on the public interest. DOE explained that, upon receipt of an application under the Policy Statement, it would conduct a public interest analysis of the application under NGA section 3(a).

Accordingly, in reviewing Port Arthur LNG’s Application, DOE/FE will consider any issues required by law or policy under NGA section 3(a), as informed by the Policy Statement. To the extent appropriate, DOE will consider the study entitled, Macroeconomic Outcomes of Market Determined Levels of U.S. LNG Exports (2018 LNG Export Study),7 DOE’s response to public comments received on that Study,8 and the following environmental documents:

- Addendum to Environmental Review Documents Concerning Exports

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4 See id., 85 FR 52247.
5 See id., 85 FR 52247.
6 Id., 85 FR 52247.
8 U.S. Dep’t of Energy, Study on Macroeconomic Outcomes of LNG Exports: Response to Comments Received on Study; Notice of Response to Comments, 83 FR 67251 [Dec. 28, 2018].
of Natural Gas From the United States, 79 FR 48132 (Aug. 15, 2014); 9
• Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States, 79 FR 32260 (June 4, 2014); 10 and
• Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States: 2019 Update, 84 FR 49278 (Sept. 19, 2019), and DOE/FE’s response to public comments received on that study.11

Parties that may oppose the Application should address these issues and documents in their comments and/ or protests, as well as other issues deemed relevant to the Application.

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 et seq., requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its environmental responsibilities.

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable, addressing the Application. Interested parties will be provided 15 days from the date of publication of this Notice in which to submit comments, protests, motions to intervene, or notices of intervention. The public previously was given an opportunity to intervene in, protest, and comment on Port Arthur LNG’s long-term non-FTA application. Therefore, DOE will not consider comments or protests that do not bear directly on the Application. The Application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316. The Application is available for inspection and copying in the Office of Regulation, Analysis, and Engagement docket room, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The Application and any filed protests, motions to intervene or notice of interventions, and comments will also be available electronically by going to the following DOE/FE Web address: http://www.fe.doe.gov/programs/gasregulation/index.html.

Signed in Washington, DC, on September 25, 2020.

Amy Sweeney,
Director, Office of Regulation, Analysis, and Engagement, Office of Fossil Energy.

[FR Doc. 2020–21680 Filed 9–30–20; 8:45 am]

BILLING CODE 6450–01–P
and the Regulations under the Natural Gas Act (18 CFR 157.10). 6

As a matter of practice, the Commission itself generally acts on requests for extensions of time to complete construction for Natural Gas Act facilities when such requests are contested before order issuance. For those extension requests that are contested, 7 the Commission will aim to issue an order acting on the request within 45 days. 8 The Commission will address all arguments relating to whether the applicant has demonstrated there is good cause to grant the extension. 9 The Commission will not consider arguments that re-litigate the issuance of the April 15th Certificate order, including whether the Commission properly found the project to be in the public convenience and necessity and whether the Commission’s environmental analysis for the certificate complied with the National Environmental Policy Act. 10 At the time a pipeline requests an extension of time, orders on certificates of public convenience and necessity are final and the Commission will not re-litigate their issuance. 11 The OEP Director, or his or her designee, will act on those extension requests that are uncontested.

In addition to publishing the full text of this document in the Federal Register, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission’s Home Page (http://ferc.gov) using the “eLibrary” link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission’s Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at FERConlineSupport@ferc.gov or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the “eFile” link at http://www.ferc.gov. Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Time on October 13, 2020.


Kimberly D. Bose, Secretary.

[FR Doc. 2020–21719 Filed 9–30–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–523–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on September 15, 2020, Columbia Gas Transmission, LLC (Columbia), 700 Louisiana Street, Suite 700, Houston, Texas 77002–2700, filed in the above referenced docket a prior notice request pursuant to sections 157.205 and 157.213(b) of the Commission’s regulations under the Natural Gas Act (NGA) and its blanket certificate issued in Docket No. CP83–76–000. Columbia requests authorization to construct and operate one new injection/withdrawal storage well and related appurtenances at Columbia’s Weaver Storage Field in Richland County, Ohio (Weaver 12611 New Well Project). Columbia estimates the cost of the project to be approximately $6 million, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the Federal Register, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission’s Home Page (http://ferc.gov) using the “eLibrary” link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission’s Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at FERConlineSupport@ferc.gov or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this application should be directed to Sorana Linder, Director, Modernization & Certificates, Columbia Gas Transmission, LLC, 700 Louisiana Street, Suite 700, Houston, Texas 77002–2700, by telephone at (832) 320–5209, or by email at sorana.linder@tcenergy.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.

6 Only motions to intervene from entities that were party to the underlying proceeding will be accepted. Algonquin Gas Transmission, LLC, 170 FERC ¶ 61,144, at P 39 (2020).

7 Contested proceedings are those where an intervenor disputes any material issue of the filing. 18 CFR 385.2201(c)(1) (2020).

8 Algonquin Gas Transmission, LLC, 170 FERC ¶ 61,144, at P 40 (2020).

9 Id. P 40.

10 Similarly, the Commission will not re-litigate the issuance of an NGA section 3 authorization, including whether a proposed project is not inconsistent with the public interest and whether the Commission’s environmental analysis for the permit order complied with NEPA.

11 Algonquin Gas Transmission, LLC, 170 FERC ¶ 61,144, at P 40 (2020).
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.


Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.


Kimberly D. Bose,
Secretary.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2150–152]

Puget Sound Energy, Inc.; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. **Type of Application**: Non-Capacity Amendment of License.

b. **Project No.**: 2150–152.

c. **Date Filed**: August 27, 2020, and supplemented on September 24, 2020.

d. **Applicant**: Puget Sound Energy, Inc.

e. **Name of Project**: Baker River Hydroelectric Project.

f. **Location**: The project is located on the Baker River in Skagit and Whatcom counties, Washington. The project occupies federal lands administered by the U.S. Forest Service within the Mt. Baker-Snoqualmie National Forest.

g. **Filed Pursuant to**: Federal Power Act 16 U.S.C. 791a–825r.

h. **Applicant Contact**: Mr. Jory Oppenheimer, Consulting Engineer, Puget Sound Energy, P.O. Box 97034, Bellevue, WA 98009–9734; telephone (425) 462–3556 and email jory.oppenheimer@pse.com.

i. **FERC Contact**: Linda Stewart, (202) 502–8184, linda.stewart@ferc.gov.

j. **Deadline for filing comments, motions to intervene, and protests is 30 days from the issuance date of this notice by the Commission.**

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission’s eFiling system at http://www.ferc.gov/docs-filing/efiling.asp. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at http://www.ferc.gov/docs-filing/ecomment.asp. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426.

Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–2150–152. Comments mailed to Commission staff are not considered part of the Commission record.

The Commission’s Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, it must also serve a copy of the document on that resource agency.

k. **Description of Request**: Puget Sound Energy, Inc. (licensee) proposes to upgrade the turbine generating unit known as Unit 2 at the Upper Baker Development, which has reached the end of its expected life. The proposed upgrade would include installing a new turbine runner, refurbishing the turbine, refurbishing motor poles, replacing the generator stator coils, and replacing the original distributor bushings. The proposal would increase the installed capacity of Unit 2 from 38.3 to 51.0 megawatts and would increase the hydraulic capacity of the Upper Baker Development from 5,030 to 5,140 cubic feet per second. The licensee does not propose any operational changes to the project following the upgrade of Unit 2. The licensee also requests to amend the authorized installed capacities of Unit 3 and Unit 4 at the Lower Baker Development to reflect current as-built conditions. Additionally, the licensee proposes to add to the license as a primary transmission line the existing 0.188-mile-long, 115-kilovolt transmission line connecting the Upper Baker powerhouse to the Shannon substation.

l. **Individuals desiring to be included on the Commission’s mailing list should so indicate by writing to the Secretary of the Commission.**

m. Comments, Protests, or Motions to Intervene: Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 211, and 214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission’s Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified deadline date for the particular application.

n. **Filing and Service of Responsive Documents**: Any filing must (1) bear in all capital letters the title “COMMENTS”, “PROTEST”, or
“MOTION TO INTERVENE” as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting, or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Kimberly D. Bose,
Secretary.

DEPARTMENT OF ENERGY
Federal Energy Regulatory Commission

[Docket No. RP20–1220–000]

Rockies Express Pipeline, LLC; Notice of Initiation of Section 5 Proceeding

On September 25, 2020, the Commission issued an order in Docket No. RP20–1220–000, pursuant to section 5 of the Natural Gas Act, 15 U.S.C. 717d (2012), instituting an investigation into whether the public interest presently requires that the firm transportation service agreements between Rockies Express Pipeline LLC (Rockies Express) and Gulfport Energy Corporation (Gulfport) should be abrogated or modified. Rockies Express Pipeline LLC, 172 FERC ¶ 61,279 (2020).

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the “eFile” link at http://www.ferc.gov. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Kimberly D. Bose,
Secretary.

DEPARTMENT OF ENERGY
Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

- **Docket Numbers:** EC20–104–000.
  **Applicants:** Milligan 1 Wind LLC.
  **Description:** Application for Authorization Under Section 203 of the Federal Power Act, et al. of Milligan 1 Wind LLC.
  **Filed Date:** 9/25/20.
  **Accession Number:** 20200925–5061.
  **Comments Due:** 5 p.m. ET 10/16/20.

- **Docket Numbers:** ER04–835–010.
  **Applicants:** Invenergy Energy Management LLC.
  **Description:** Notice of Change in Facts under Market-Based Rate Authority of Invenergy Energy Management LLC.
  **Filed Date:** 9/24/20.
  **Accession Number:** 20200924–5150.
  **Comments Due:** 5 p.m. ET 10/15/20.
  **Docket Numbers:** ER16–1720–014.
  **Applicants:** Invenergy Energy Management LLC.
  **Description:** Notice of Change in Facts under Market-Based Rate Authority of Invenergy Energy Management LLC.
  **Filed Date:** 9/24/20.
  **Accession Number:** 20200924–5129.
  **Comments Due:** 5 p.m. ET 10/15/20.
  **Docket Numbers:** ER20–2983–000.
  **Applicants:** Midcontinent Independent System Operator, Inc.
  **Description:** Section 205(d) Rate Filing: 2020–09–25, SA 315 Rosewater Wind Farm-NIPSCO GIA 1st Rev (J513) to be effective 9/11/2020.
  **Filed Date:** 9/25/20.
  **Accession Number:** 20200925–5022.
  **Comments Due:** 5 p.m. ET 10/16/20.
  **Docket Numbers:** ER20–2984–000.
  **Applicants:** PJM Interconnection, L.L.C.
  **Description:** Tariff Cancellation: Notice of Cancellation of ICSA, SA No. 2808 to be effective 9/18/2014.
  **Filed Date:** 9/25/20.
  **Accession Number:** 20200925–5040.
  **Comments Due:** 5 p.m. ET 10/16/20.
  **Docket Numbers:** ER20–2985–000.
  **Applicants:** PJM Interconnection, L.L.C.
  **Description:** Tariff Cancellation: Notice of Cancellation of ICSA, SA No.

**DEPARTMENT OF ENERGY**

**Federal Energy Regulatory Commission**

**Combined Notice of Filings #1**

Take notice that the Commission received the following electric corporate filings:

- **Docket Numbers:** EC20–104–000.
  **Applicants:** Milligan 1 Wind LLC.
  **Description:** Application for Authorization Under Section 203 of the Federal Power Act, et al. of Milligan 1 Wind LLC.
  **Filed Date:** 9/25/20.
  **Accession Number:** 20200925–5061.
  **Comments Due:** 5 p.m. ET 10/16/20.

- **Docket Numbers:** ER04–835–010.
  **Applicants:** Invenergy Energy Management LLC.
  **Description:** Notice of Change in Facts under Market-Based Rate Authority of Invenergy Energy Management LLC.
  **Filed Date:** 9/24/20.
  **Accession Number:** 20200924–5150.
  **Comments Due:** 5 p.m. ET 10/15/20.
  **Docket Numbers:** ER16–1720–014.
  **Applicants:** Invenergy Energy Management LLC.
  **Description:** Notice of Change in Facts under Market-Based Rate Authority of Invenergy Energy Management LLC.
  **Filed Date:** 9/24/20.
  **Accession Number:** 20200924–5129.
  **Comments Due:** 5 p.m. ET 10/15/20.
  **Docket Numbers:** ER20–2983–000.
  **Applicants:** Midcontinent Independent System Operator, Inc.
  **Description:** Section 205(d) Rate Filing: 2020–09–25, SA 315 Rosewater Wind Farm-NIPSCO GIA 1st Rev (J513) to be effective 9/11/2020.
  **Filed Date:** 9/25/20.
  **Accession Number:** 20200925–5022.
  **Comments Due:** 5 p.m. ET 10/16/20.
  **Docket Numbers:** ER20–2984–000.
  **Applicants:** PJM Interconnection, L.L.C.
  **Description:** Tariff Cancellation: Notice of Cancellation of ICSA, SA No. 2808 to be effective 9/18/2014.
  **Filed Date:** 9/25/20.
  **Accession Number:** 20200925–5040.
  **Comments Due:** 5 p.m. ET 10/16/20.
  **Docket Numbers:** ER20–2985–000.
  **Applicants:** PJM Interconnection, L.L.C.
  **Description:** Tariff Cancellation: Notice of Cancellation of ICSA, SA No.
DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2622–013]

Turners Falls Hydro, LLC; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission’s (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for license of the Turners Falls Hydroelectric Project No. 2622 (Project No. 2622), located on the Connecticut River, within the power canal of the Turners Falls Hydroelectric Project No. 1889, in Franklin County, Massachusetts, and has prepared an Environmental Assessment (EA) for Project No. 2622.

The EA contains staff’s analysis of the potential environmental impacts of Project No. 2622 and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The Commission provides all interested persons with an opportunity to view and/or print the EA via the internet through the Commission’s Home Page (http://www.ferc.gov) using the “eLibrary” link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. At this time, the Commission has suspended access to the Commission’s Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020.

For assistance, contact FERC Online Support at FERCONlineSupport@ferc.gov or toll-free at (866) 208–3676, or for TTY, (202) 502–8659.

You may also register online at https://ferconline.ferc.gov/eSubscription.aspx to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice.

The Commission strongly encourages electronic filing. Please file comments using the Commission’s eFiling system at https://ferconline.ferc.gov/eFiling.aspx. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the
FARM CREDIT ADMINISTRATION

Sunshine Act Meeting; Farm Credit Administration Board

AGENCY: Farm Credit Administration.

ACTION: Notice, Regular Meeting.

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act, of the forthcoming regular meeting of the Farm Credit Administration Board.

DATES: The regular meeting of the Board will be held October 8, 2020, from 9:00 a.m. until such time as the Board may conclude its business. Note: Because of the COVID–19 pandemic, we will conduct the board meeting virtually. If you would like to observe the open portion of the virtual meeting, see instructions below for board meeting visitors.

Attendance: To observe the open portion of the virtual meeting, go to FCA.gov, select “Newsroom,” then “Events.” There you will find a description of the meeting and a link to “Instructions for board meeting visitors.” See SUPPLEMENTARY INFORMATION for further information about attendance requests.

FOR FURTHER INFORMATION CONTACT: Dale Aultman, Secretary to the Farm Credit Administration Board (703) 883-4009. TTY is (703) 883-4056.

SUPPLEMENTARY INFORMATION: Parts of his meeting of the Board will be open to the public, and parts will be closed. If you wish to observe the open part, follow the instructions above in the “Attendance” section at least 24 hours before the meeting. If you need assistance for accessibility reasons or if you have any questions, contact Dale Aultman, Secretary to the Farm Credit Administration Board, at (703) 883–4009. The matters to be considered at the meeting are as follows:

Open Session

A. Approval of Minutes

• September 10, 2020

B. Reports

• SOFR vs LIBOR: Key Differences and Resulting Challenges for a LIBOR Transition

Closed Session

• Office of Secondary Market Oversight Periodic Report ¹


Kimberly D. Bose,
Secretary.

¹ Session Closed-Exempt provisions to 5 U.S.C. Section 552b(c)(8) and (9).

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Understanding Long-term Respiratory Morbidity in Former Styrene-Exposed Workers: Medical Survey to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on February 28, 2020 to obtain comments from the public and affected agencies. CDC received one public comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-20-201T]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Understanding Long-term Respiratory Morbidity in Former Styrene-Exposed Workers: Medical Survey to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on February 28, 2020 to obtain comments from the public and affected agencies. CDC received one public comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate the need for the collection of the information.
2. Evaluate the appropriateness of the proposed form of information collection.
3. Evaluate whether the information will have practical utility.
4. Evaluate whether the information will have practical utility.
5. Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
6. Enhance the quality, utility, and clarity of the information to be collected.
7. Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
8. Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Understanding Long-term Respiratory Morbidity in Former Styrene-Exposed Workers: Medical Survey—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Styrene is used in the production of automobile parts, boats, computer housings, food containers, wind energy components, and many other products. An estimated 90,000 U.S. workers are potentially exposed to styrene at more than 5,000 U.S. manufacturing plants. Occupational exposure to styrene has been associated with deleterious health effects, including changes in color vision, mucous membrane irritation, hearing loss, and neurocognitive impairment. Workplace exposure to
styrene has also been associated with cases of non-malignant respiratory disease (NMRD), including COPD and obliterator bronchiolitis. However, little is understood about the long-term respiratory effects on styrene-exposed workers.

The goal of this project is to understand the prevalence of long-term respiratory morbidity in styrene-exposed workers. The objectives of the proposed study are: (1) To characterize work exposures by acquiring job histories and comparing with historical exposure levels obtained from a past industrial hygiene survey, (2) to examine prevalence of respiratory morbidity by duration and level of styrene exposure and other characteristics, (3) to apply research biomarkers of lung injury to a styrene-exposed workforce, and (4) to describe the prevalence of color vision impairment with the presence of respiratory morbidity. Our hypothesis is that workers previously exposed to high concentrations of styrene (<5 ppm), even those with short tenure (≤1 year), will have a higher prevalence of respiratory symptoms and lung function abnormalities compared with workers exposed to low concentration of styrene (<5 ppm).

We will conduct face-to-face interviews with members of a cohort of workers from two reinforced plastic boatbuilding plants that closed in 1989 and 1993. The purpose of the interviews is to collect demographic information, detailed job history during and after the worker’s tenure at the boatbuilding plant, upper and lower respiratory symptoms, physician diagnoses of respiratory diseases, cigarette smoking history, and medication use. A NIOSH employee will conduct the interviews.

### Estimated Annualized Burden Hours

<table>
<thead>
<tr>
<th>Type of respondents</th>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
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<tr>
<td>Boatbuilder Cohort Members</td>
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<td>676</td>
<td>1</td>
<td>15/60</td>
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<td>Boatbuilder Cohort Members</td>
<td>Questionnaire</td>
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<td>1</td>
<td>45/60</td>
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<tr>
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<td>Exhaled Nitric Oxide—no form</td>
<td>676</td>
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<td>5/60</td>
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<td>10/60</td>
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<td>10/60</td>
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<td>20/60</td>
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</tbody>
</table>


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20–1278; Docket No. CDC–2020–0101]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperback Reduction Act of 1995. This notice invites comment on a proposed information collection project titled “Online training for law enforcement to reduce risks associated with shift work and long work hours.” This study will develop and pilot test a new, online, interactive training program tailored for the law enforcement community that relays the health and safety risks associated with shift work, long work hours, and related workplace sleep issues, and presents strategies for managers and officers to reduce these risks.

DATES: CDC must receive written comments on or before November 30, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0101 by any of the following methods:

• Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.

• Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and
Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the OMB also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:
1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Online training for law enforcement to reduce risks associated with shift work and long work hours (OMB Control No. 0920–1278, Exp. 12/30/2020)—Extension—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Police often work during the evening, at night, and sometimes irregular and long hours. Shift work and long work hours are linked to many health and safety risks due to disturbances to sleep and circadian rhythms. These work schedules also lead to difficulties with personal relationships due to having less time with family and friends, poor mood from sleep deprivation, and problems balancing work and personal responsibilities. These work schedules and inadequate sleep likely contribute to health problems seen in police: shorter life spans, high occupational injury rates, and burden of chronic illnesses. One strategy to reduce these risks is training programs to inform employers and law enforcement officers about the risks and strategies to reduce their risks.

An extension is being requested due to delays recruiting participants and initiating data collection activities. The delays resulted from the COVID–19 pandemic and the civil unrest after George Floyd’s death on May 25, 2020. Law enforcement leaders requested that the data collection be delayed until the end of June 2020. As a result, NIOSH is requesting a one-year extension for an extension of the data collection end date to May 31, 2021. This pilot study is part of a project awarded National Occupational Research Agenda (NORA) funding. The National Institute for Occupational Safety and Health is authorized to carry out this data collection through Occupational Safety and Health Act of 1970.

The purpose of this project is to develop a training program to relay the risks linked to shift work and long work hours and give workplace strategies for employers and personal strategies for the officers to reduce the risks. Once finalized, the training will be available on the NIOSH website. The training will be pilot tested with 30 recent graduates of a police academy and 30 experienced officers. The study will recruit 60 law enforcement officers during a 30-minute phone call. All respondents will work full-time on fixed night shifts. The pilot test will use a pre-test—post-test design to examine sleep (both duration and quality), worktime sleepiness, and knowledge retained. Pre-test measures will be collected two weeks before the training. Post-test measures will be collected the week of the training (week three of the study), one week after the training (week four) and at eight and nine weeks after the training (weeks 11 and 12 of the study). Additional post-test measures will include feedback about the training and if specific behaviors changed.

Before starting the pretest, the respondent will sign an informed consent form. The pilot pre-test will start with the respondent filling out a 10-minute online survey that includes four short surveys: (1) Demographic information and work experience; (2) the Epworth Sleepiness Scale; (3) the Pittsburgh Sleep Quality Index; and (4) a knowledge test. The respondent will be fitted with a wrist actigraph, which will record activity and estimate the times of sleep. The respondents will keep an online sleep activity diary and wear the actigraph continuously during weeks one to four of the study. The online sleep activity diary takes approximately two minutes a day to complete. The sleep diary and actigraph are being used together to obtain a more accurate timing of respondent’s sleep and activity.

During the third week of the study, the respondent will take the 2.5 hour online training program. Immediately after completing the training, the respondent will take the post-test knowledge test and will provide feedback about the training (including barriers to using the training information and what influential people in their life would want them to do with the training information. At the end of week four, the respondent will return the actigraph. No data collection will occur during weeks five to 10 of the study.

The second post-test period will be weeks 11 and 12 of the study to gather longer-term outcomes. At the beginning of week 11, the respondents will be fitted with an actigraph. The respondent will wear the actigraph and complete the sleep activity diary for the next 14 days. At the end of week 12 of the study, the respondent will complete the Epworth Sleepiness Scale, Pittsburgh Sleep Quality Index, and Changes in Behaviors After Training. The combined response time is five minutes.

The burden table lists three 10-minute meetings during the post-test period when they will return the actigraph at the end of week four, be fitted with an actigraph at the beginning of week 11 and return it at the end of week 12. The total burden hours for the diary is 84.

Study staff will use the findings from the pilot test to make improvements to the training program. The research team will reinforce or expand training content that showed less than desired results on the pilot test. Potential impacts of this project include improvements in management practices such as the design of work schedules and improvements in officers’ personal behaviors for coping with the demands of shift work and long work hours. The total estimated annualized burden hours is 334. There are no costs to respondents other than their time.
was a technical error that is identified

II. Summary of Error

On page 60799, in the DATES section of the notice, the phrase “takes effect October 1, 2020 through October 1, 2024” should be replaced with the phrase “September 28, 2020-September 28, 2024.”

III. Correction of Error

In the Federal Register of September 28, 2020, in FR Doc. 2020–21260, on page 60799, in the 2nd column, in the DATES section, the phrase “takes effect October 1, 2020 through October 1, 2024” is corrected to read “September 28, 2020-September 28, 2024.”


Wilma M. Robinson,
Deputy Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2020–21766 Filed 9–28–20; 4:15 pm]
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA–2020–D–1517]

The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls; 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 guidance for industry entitled “The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls.” This guidance provides general recommendations regarding the development, evaluation, and use of physiologically based pharmacokinetic (PBPK) analyses for biopharmaceutics applications employed by sponsors of investigational new drug applications, new drug applications, or abbreviated new drug applications, and supplements to these applications, for oral drug product development, manufacturing changes, and controls. The guidance covers how to develop, evaluate, and apply PBPK models for biopharmaceutics-related uses, such as establishing clinically relevant dissolution specifications and quality risk assessment for postapproval manufacturing changes.

Jeffrey M. Zirger,

FR Doc. 2020–21731 Filed 9–30–20; 8:45 am
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

[CMS–3386–CN]

Medicare Program; Approval of Application by The Compliance Team for Initial CMS-Approval of Its Home Infusion Therapy Accreditation Program; Correction

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

ACTION: Final notice; correction.

SUMMARY: This document corrects a technical error that appeared in the final notice published in the Federal Register on September 28, 2020 entitled “Medicare Program; Approval of Application by The Compliance Team for Initial CMS-Approval of Its Home Infusion Therapy Accreditation Program.”

DATES: This correction is effective September 28, 2020.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:
I. Background

In FR Doc. 2020–21260 of September 28, 2020 (85 FR 60799–60800), there was a technical error that is identified and corrected in this correcting document. The provision in this correction document is effective as if it had been included in the document published September 28, 2020. Accordingly, the correction is effective September 28, 2020.
DATES: Submit either electronic or written comments on the draft guidance by November 30, 2020 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 wish to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:
• Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2020–D–1517 for “The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.
• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.
Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.
You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).
Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paul Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 1628, Silver Spring, MD 20993–0002, 301–796–4874.

SUPPLEMENTARY INFORMATION:

I. Background
FDA is announcing the availability of a draft guidance for industry entitled “The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls.” This draft guidance provides general recommendations regarding the development, evaluation, and use of PBPK analyses for biopharmaceutics applications employed by sponsors of investigational new drug applications, new drug applications, or abbreviated new drug applications, and supplements to these applications, for oral drug product development, manufacturing changes, and controls. PBPK analyses use models and simulations that combine physiology, population, and drug characteristics to mechanistically describe the pharmacokinetic and/or pharmacodynamic behaviors of a drug product.
Submission of these analyses to FDA is discussed in the guidance for industry entitled “Physiologically Based Pharmacokinetic Analyses—Format and Content” (available at https://www.fda.gov/media/101469/download). However, the application of PBPK modeling in support of drug product development is an evolving field. FDA recognizes this challenge and encourages the development and use of new tools and approaches for linking pharmaceutical quality to clinical performance. Advances in modeling and simulation have enabled the integration of factors such as the physicochemical properties of the active pharmaceutical ingredient, dissolution data, and the physiology of the gastrointestinal tract into the development of PBPK models. As such, PBPK modeling has become a promising tool in predicting systemic drug exposure of oral drug products.
PBPK analyses for biopharmaceutics applications combine dissolution modeling, biopredictive dissolution profiles, or other in vitro testing inputs with PBPK modeling strategies to quantitatively describe the differential and potential interactions of formulation variants with the body and their effect on drug exposure. This guidance describes recommended PBPK model structure, which provides a mechanistic framework of drug oral absorption by representing the in vivo drug absorption process and accounting for the relevant
product quality attributes that affect drug dissolution and absorption, and discusses how to capture and present model assumptions and parameters. Model validation and refinement are also discussed.

In addition, the guidance discusses the major regulatory uses of PBPK modeling for biopharmaceutics applications with respect to supporting product quality. Factors regarding the development of clinically relevant dissolution specifications to aid in biopredictive dissolution method development and to support clinically relevant dissolution acceptance criteria are presented, as well as considerations for conducting virtual bioequivalence studies.

PBPK modeling for biopharmaceutics applications also can be used to establish clinically relevant drug product quality specifications other than dissolution, which can be used to ensure bioequivalence of batches within the specification limits, to the pivotal clinical/bioavailability batches, or to the reference listed drug for generic drugs. Finally, the guidance discusses the use of PBPK analyses for biopharmaceutics applications as an advanced tool for quality risk assessment and management in both the pre- and postapproval stages.

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 “The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either www.regulations.gov or https://www.fda.gov/drugs/ guidances-drugs or https://www.regulations.gov.

Dated; September 23, 2020.

Lauren K. Roth,
Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5743]

Importation of Certain Food and Drug Administration–Approved Human Prescription Drugs, Including Biological Products, and Combination Products Under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

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

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, and Combination Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act.” This guidance describes recommended procedures to obtain a National Drug Code (NDC) for certain FDA-approved prescription drugs that are imported into the United States in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), which would provide an additional avenue through which these drugs could be sold at a lower cost in the U.S. market. This guidance is intended to address certain challenges in the private market faced by manufacturers seeking to sell their drugs at lower costs. This guidance finalizes the draft guidance issued on December 23, 2019.

DATES: The announcement of the guidance is published in the Federal Register on October 1, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2019–D–5743 for “Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, and Combination Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The
Second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, 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 that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:
Lyndsay Hennessey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6180, Silver Spring, MD 20993–0002, 301–796–7605; 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; or the Office of Regulatory Affairs (ORA), Office of Strategic Planning and Operational Policy at ORAPolicyStaffs@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background
FDA is announcing the availability of a guidance for industry entitled “Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, and Combination Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act.” This guidance represents the Agency’s current thinking on the importation of certain FDA-approved drugs, including biological products, and combination products that are the subject of approved new drug applications (NDAs) or biologics license applications (BLAs) and that are also authorized for sale in a foreign country in which the products were originally intended to be marketed. These are referred to in the guidance as “multi-market approved” (“MMA”) products. This guidance describes procedures to obtain an NDC for an FDA-approved drug that is imported into the United States in compliance with section 801 of the FD&C Act (21 U.S.C. 381), which would provide an additional avenue through which drugs could be sold at a lower cost in the U.S. market. In recent years, FDA has become aware that some drug manufacturers may be interested in offering a number of their drugs at lower costs and that obtaining NDCs for their drugs may help them to address certain challenges in the private market. This guidance is not intended to address the applicability of programs administered by the Centers for Medicare & Medicaid Services such as the Medicaid drug rebate program for manufacturers. The Department of Health and Human Services (HHS) may issue further guidance or rulemaking as appropriate. HHS guidance, including relevant Medicaid guidance for drugs imported following the procedures in this guidance, can be found at https://www.hhs.gov/guidance/.

This guidance describes: (1) The process for submitting a supplement to an approved NDA or BLA for an MMA product; (2) the recommended labeling for an MMA product; (3) the process for registration and listing and for obtaining an NDC for the MMA product; (4) the requirements of section 582 of the FD&C Act (21 U.S.C. 360eee–1) as added by the Drug Supply Chain Security Act (Title II of Pub. L. 113–54); (5) recommendations related to procedures for importation of the MMA product; and (6) other requirements applicable to MMA products.

This guidance will help ensure manufacturers are aware of procedures to facilitate manufacturers’ ability to provide access to lower-cost drugs in the United States. The guidance details procedures that will enable manufacturers to obtain an NDC for the MMA product, which could allow manufacturers to offer a drug, biological product, or combination product at a lower cost. The NDC for the MMA product also will support pharmacovigilance, aid in accurate billing and reimbursement, and facilitate clearance of the MMA products through FDA’s admissibility review.

This guidance finalizes the draft guidance entitled “Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act: Draft Guidance for Industry,” issued on December 23, 2019 (84 FR 71961). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: Clarifying the description of MMA products, including combination products; providing additional recommendations for the labeling of MMA products to help ensure that MMA products may be readily identified; and providing a template “Dear Healthcare Provider” letter that manufacturers may use to alert healthcare professionals of the availability of an MMA product.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, and Combination Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995
This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this guidance refers to previously approved collections of information found in the FD&C Act and FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 (NDAs),
have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 (BLAs) have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 207 (domestic and foreign facility registration, including assignment of an NDC) have been approved under OMB control number 0910–0045; the collections of information in 21 CFR part 1 (general enforcement regulations) have been approved under OMB control number 0910–0046; the collections of information in 21 CFR part 201 (labeling) have been approved under OMB control number 0910–0572; the collections of information pertaining to current good manufacturing practice requirements for finished pharmaceuticals and combination products under 21 CFR parts 4, 210, 211, 610, and 680 have been approved under OMB control numbers 0910–0139 and 0910–0834; the collection of information pertaining to Dear Health Care Provider Letters has been approved under OMB control number 0910–0754; and the collections of information pertaining to suspect product identification and notification under section 582 of the FD&C Act have been approved under OMB control number 0910–0806.

III. Electronic Access


Alex M. Azar II,
Secretary, Department of Health and Human Services.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation; Medicaid Reentry Stakeholder Group

AGENCY: Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services.

The Stakeholder Group shall consist of at least 24 members: 2 shall be federal members, appointed by the Secretary or his designee. The federal members shall include designees from federal jail and prison systems, which includes the Federal Bureau of Prisons. Federal members will serve as regular government employees.

The Stakeholder Group shall also consist of 22 non-federal members who are representatives of managed care organizations, Medicaid beneficiaries, health care providers, the National Association of Medicaid Directors, state Medicaid agencies, and representatives from local and state prison systems. The Secretary shall appoint one of the members to serve as the Chair. Non-federal members will serve as Special Government Employees.

The Secretary, or his designee, shall appoint all members of the Stakeholder Group (both federal and non-federal), including one of the members to serve as the Chair. The federal and non-federal members shall be appointed to serve for the duration of the time that the Stakeholder Group is authorized to operate. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term.

Brenda Destro,
Deputy Assistant Secretary for Planning and Evaluation (HSP).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,...
as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Advisory Council.
Date: October 27, 2020.
Closed: 10:00 a.m. to 12:00 p.m.
Agenda: To Review and Evaluate Grant Applications and/or Proposals.
Place: NIH, Bethesda, MD (Virtual Meeting).
Open: 12:30 p.m. to 5:00 p.m.
Agenda: To Discuss Program Policies and Issues.
Place: NIH, Bethesda, MD (Virtual Meeting).

Virtual Access: The meeting will be videocast and can be accessed from the NIH Videocast. https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/advisory-council. Please note, the link to the videocast meeting will be posted within this week of the meeting date.

Contact Person: Laura K. Moon, Ph.D., Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 206–Q, Bethesda, MD 20892, 301–827–5517, moenl@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Any member of the public may submit written comments no later than 15 days after the meeting.

Information is also available on the Institute’s/Center’s home page: www.nhlbi.nih.gov/meetings/nhbac/index.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Ronald J. Livingston, Jr., Program Analyst, Office of Federal Advisory Committee Policy.
[FR Doc. 2020–21673 Filed 9–30–20; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; Advancing Genomic Medicine Research.
Date: December 1, 2020.
Time: 2:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 300, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barbara J. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 300, Bethesda, MD 20892–9306, 301–402–0838, barbara.thomas@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Melanie J. Pantoja, Program Analyst, Office of Federal Advisory Committee Policy.
[FR Doc. 2020–21674 Filed 9–30–20; 8:45 am]
BILLING CODE 4140–01–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 inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing Brian W. Bailey, Ph.D., bbailey@mail.nih.gov, the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579.
A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

Methods To Produce Very Long-Chain Fatty Acids (VLCFA)

Available for licensing and commercial development are patent rights covering methods for synthetically producing highly pure, polyunsaturated very long-chain fatty acids (C20–C40) that are highly scalable, do not require toxic mercury, and are applicable to the synthesis of highly deuterated (≥90%), partially deuterated, and non-deuterated lipids. VLCFAs, while present in very small concentrations in living organisms, nonetheless play vital roles in certain biological processes. The present invention addresses an unmet need for VLCFAs for experimental and therapeutic uses that is currently inadequately met through labor intensive and time consuming extractions from natural sources or technically difficult overexpression in cell cultures, which give very small yields. This invention also includes a method for treating and preventing macular degeneration using VLCFAs. This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:
• Synthesis of very-long chain fatty acids for in vitro and in vivo research purposes
• Synthesis of very-long chain fatty acids for therapeutic purposes
• Treatment and prevention of macular degeneration, inflammatory disorders and other disorders and conditions associated with very long-chain fatty acid deficiencies

Development Stage:
• Preclinical
• Mouse data

Inventors: Rolf Swenson (NHLBI), Zhen-Dan Shi (NHLBI), Zhi-Hong Yang (NHLBI) and Alan Remaley (NHLBI).
The subject invention describes controlling PMN accumulation in the pulmonary disease (COPD).

Although successful arrival of infection travel to the airspace lumen.

neutrophils (PMNs) responding to migration of neutrophils to the airspace is essential for host defense against microbicidal PMNs to the airspace.

incidence of acute lung injury, idiopathic or induced interstitial lung disease.

bronchopulmonary dysplasia.

lung transplant rejection.

Development Stage

EMP2 can selectively target PMN accumulation in the lung, rather than broadly affecting PMN trafficking through all tissues.

Development of EMP2 inhibitor for treatment of neutrophil-dependent lung disorders, such as:

• Acute lung injury

• pneumonia (bacterial, viral, fungal)

• bronchiectasis

• COPD and asthma

• radiation- or chemotherapeutic-induced pneumonitis

• idiopathic or induced interstitial lung disease

• EMP2 membrane protein 2 governs transepithelial migration of neutrophils into the airspace. EMP2 knockout mice have reduced PMN accumulation and exhibit increased survival during bacterial infection. Inhibition of EMP2 can potentially reduce intra airway PMN accumulation and provide a specific treatment for various lung disorders.

Potential Commercial Applications

Development of EMP2 inhibitor for treatment of neutrophil-dependent lung disorders, such as:

Acute lung injury

pneumonia (bacterial, viral, fungal)

bronchiectasis

COPD and asthma

radiation- or chemotherapeutic-induced pneumonitis

idiopathic or induced interstitial lung disease

bronchopulmonary dysplasia

lung transplant rejection

Competitive Advantages

EMP2 can selectively target PMN accumulation in the lung, rather than broadly affecting PMN trafficking through all tissues.

Development Stage

Early stage

In vitro and in vivo (animal) data available

Inventors: Michael Brian Fessler (NIEHS), Carmen J. Williams (NIEHS), and Wan-Chi Lin (NIEHS).


Licensing Contact: Vidita Choudhry, Ph.D.; 301–594–4095; vidita.choudhry@nih.gov. This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404.


Vidita Choudhry,
Technology Development Specialist, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using an Armored Payload and Chimeric Antigen Receptors Targeting GPC3

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Senti Biosciences, Inc. (“Senti”) located in South San Francisco, CA.

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before October 16, 2020 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: David A Lambertson, Ph.D., Senior Technology Transfer Manager at Telephone at 240–276–5530 or Email at david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION: Intellectual Property

The following represents the intellectual property to be licensed under the prospective agreement:


The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the following:

“The development, production and commercialization of a monospecific chimeric antigen receptor (CAR)-based immunotherapy for the prophylaxis and treatment of GPC3-expressing human cancers using unmodified, allogeneic NK cells transduced with a viral vector that expresses a CAR and a gene circuit regulating the expression of one or more armoring payloads, wherein:

(1) The CAR includes:
   a. A single antigen specificity comprising at least the complementary determining region (CDR) sequences of the anti-GPC3 antibody known as YP7, and
   b. an intracellular signaling domain;

(2) the gene circuit includes either (a) a synthetic transcription factor that is stabilized or activated by a small molecule drug or environmental signal, or (b) a promoter element that is responsive to a small molecule drug or environmental signal; and

(3) the armored payload is selected from:
   a. An immune-stimulating cytokine,
   b. a chemokine,
   c. a growth factor,
   d. a co-activation molecule, and
   e. a tumor microenvironment modulator.

The Licensed Field of Use specifically excludes the use of autologous T cells or T cells that have been genetically modified to become allogeneic. For clarity “allogeneic” means the cells are from a donor that is not the recipient and the term “unmodified” means that no genetic engineering with genome editing tools is performed.”

This technology discloses the development of chimeric antigen receptors that recognize the glypican3 (GPC3) cell surface protein. GPC3 is expressed on the cell surface of several solid tumors, including liver cancers (such as hepatocellular cancer (HCC)), certain ovarian cancers, and neuroblastomas. Although the FDA has approved certain therapies for the treatment of liver cancer, those therapies only provide a minimal increase in the life expectancy of patients. The development of a new therapeutic targeting GPC3 will benefit public health by providing an improved and more effective treatment for patients.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Neurosciences Special Review Panel.

Date: November 4, 2020.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neurosciences Center Building, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, Extramural Project Review, Branch Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2116, MSC 6902, Bethesda, MD 20817, (301) 480–8000, bbuzas@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)


Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–21672 Filed 9–30–20; 8:45 am]

BILLING CODE 4140–01–P
Structure-Based Design of SARS-CoV–2 Spike Immunogens Stabilized in the RBD-All Down Conformation

Description of Technology:

SARS-CoV–2 has emerged as a global pathogen, sparking urgent vaccine development efforts. The trimeric SARS-CoV–2 spike appears to be a leading vaccine antigen. However, the inability of antibodies such as CR3022, which binds tightly to a cryptic spike epitope, to neutralize SARS-CoV–2 suggests a spike-based means of neutralization escape.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) sought to understand how antibodies with high affinity fail to neutralize the SARS-CoV–2. To that end, the researchers characterized the SARS-CoV–2 spike protein conformational changes as a function of pH and observed that at endosomal pH the spike protein has a conformation in which all of the receptor binding domains (RBD) are in a down conformation which could explain the virus’ ability to escape neutralization in the endosome.

Hypothesizing that SARS-CoV–2 escapes neutralization through pH-dependent conformational masking, the researchers designed spike proteins with mutations to stabilize the spike in the RBD-all down conformation. Such designs include cavity-filling mutations, disulfides, aspartic acid to asparagine mutations, proline mutations, and other sequence modifications to fix the spike protein in its RBD-all down conformation so that immunization at a physiological pH will elicit antibodies that can recognize the low pH-stabilized all RBD-down conformation of the spike protein and no longer be susceptible to pH-induced neutralization escape.

Immunogenicity studies are underway to determine which of the designs will yield a neutralizing immune response in mice. Pending results in mice, a lead candidate will be selected for studies in nonhuman primates.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications
• An improved stabilized spike immunogen for the development of protective SARS-CoV–2 vaccine.

Competitive Advantages
• Stabilized SARS-CoV–2 spike variants with potential to elicit higher levels of neutralizing antibodies than current related vaccine development.
• Identification of a methodology to screen for improved spike variants (by assessing binding by neutralizing versus non-neutralizing antibodies).

Development Stage: Preclinical Research.

Inventors: Peter Dak-Pin Kwong (NIAID); Tongqing Zhou (NIAID); Yaroslav Trykovec (NCI); Adam Shabbir Olia (NIAID); John R. Mascia (NIAID).


Licensing Contact: To license this technology, please contact Amy F. Petrik, Ph.D., 240–627–3721; amy.petrik@nih.gov.

FOR FURTHER INFORMATION CONTACT: Amy F. Petrik, Ph.D., 240–627–3721; amy.petrik@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION:
Technology description follows.
(Mandatory Guidelines) using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine were first published in the Federal Register on April 11, 1988 (53 FR 11970), and subsequently revised in the Federal Register on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines using Oral Fluid were first published in the Federal Register on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020.

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must meet the minimum standards to conduct drug and specimen validity tests. Other Canadian laboratories that were accredited to conduct forensic urine drug testing as part of the LAPSA program.

HHS-Certified Instrumented Initial Testing Facilities Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

- Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190 (Formerly: Gamma-Dynacare Medical Laboratories)
- Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917
- Cordant Health Solutions, 2617 East L Street, Tacoma, WA 98421, 800–442–0438 (Formerly: Sterling Reference Laboratories)
- DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890
- Dynacare, * 245 Fall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630 (Formerly: Gamma-Dynacare Medical Laboratories)
- ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609
- Laboratory Corporation of America Holdings, 7207 N Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387
- Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.)
- Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)
- LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)
- Legacy Laboratory Services Toxicology, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295
- Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088, Testing for Veterans Affairs (VA) Employees Only
- Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory)
- Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92037, 888–653–5840
- Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432 (Formerly: SmithKline meeting the minimum standards of the Mandatory Guidelines published in the Federal Register on January 23, 2017 (82 FR 7920). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid dated January 23, 2017 (82 FR 7920), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens:

- Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823 (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)
- Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130 (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)
- Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917
- Cordant Health Solutions, 2617 East L Street, Tacoma, WA 98421, 800–442–0438 (Formerly: Sterling Reference Laboratories)
- DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890
- Dynacare, * 245 Fall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630 (Formerly: Gamma-Dynacare Medical Laboratories)
DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2020–0047]

Towing Safety Advisory Committee; October 2020 Teleconference

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Notice of Federal Advisory Committee teleconference meeting.

SUMMARY: The Towing Safety Advisory Committee (Committee) will meet via teleconference to discuss Task 16–01, Subchapter M Implementation. The Committee is expected to receive the final report from the subcommittee tasked with identifying the parameters Coast Guard officials should use to determine whether a vessel inspected under subchapters other than Subchapter M performs occasional towing. Additional items to be discussed are also included as agenda items in the SUPPLEMENTARY INFORMATION section below.

DATES: Meeting: The full Committee will meet by teleconference on Thursday, October 29, 2020, from 1 p.m. until 3 p.m. Eastern Standard Time. Please note that this meeting may close early if the Committee has completed its business.

Comments and supporting documents: To ensure your comments are received by Committee members before the teleconference, submit your written comments no later than October 20, 2020.

AGENCY: Fish and Wildlife Service.

[FR Doc. 2020–21742 Filed 9–30–20; 8:45 am]

BILLING CODE 4160–20–P

SUPPLEMENTARY INFORMATION: The Towing Safety Advisory Committee provides advice and recommendations to the Department of Homeland Security on matters related to shallow-draft inland and coastal waterway navigation and towing safety. It was established by Public Law 96–380 in 1980 and was an active committee on December 3, 2018, the day before the Frank LoBiondo Coast Guard Authorization Act of 2018 (Pub. L. 115–242) was enacted, and operates under provisions of Sec. 601 (d) of that Act.

Agenda

The agenda for the October 29, 2020, teleconference meeting is as follows:


2. Update on the National Towing Safety Advisory Committee and the December 4, 2020 termination date for the Towing Safety Advisory Committee.


4. Awards and recognition.

5. Public Comment period.

A copy of all pre-meeting documentation will be available at https://www.dco.uscg.mil/Our-Organization/Assistant-Commandant-for-Prevention-Policy-CG-5P/Commercial-Regulations-standards-CG-5PS/Office-of-Operating-and-Environmental-Standards/vfos/TSAC/. Alternatively, you may contact Mr. Matthew Layman as noted in the FOR FURTHER INFORMATION CONTACT section above.

During the October 29, 2020 teleconference, a public comment period will be held from approximately 2:45 p.m. to 3 p.m. Eastern Standard Time. Speakers are requested to limit their comments to 3 minutes. Please note that this public comment period may start before 2:45 p.m. if all other agenda items have been covered and may end before 3 p.m. if all of those wishing to comment have done so.

Please contact Mr. Matthew D. Layman, listed in the FOR FURTHER INFORMATION CONTACT section to register as a speaker.


Jeffrey G. Lantz,
Director of Commercial Regulations and Standards.

[FR Doc. 2020–21742 Filed 9–30–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FRS–R5–ES–2020–N128; FXES11130500000–201–FF05E00000]

Endangered Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received
applications for permits to conduct activities intended to enhance the propagation or survival of endangered species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before November 2, 2020.

ADDRESSES: Use one of the following methods to request documents or submit comments. Requests and comments should specify the applicant name and application number (e.g., TE123456):
- Email: permitsR5ES@fws.gov
- U.S. Mail: Abby Gelb, Ecological Services, U.S. Fish and Wildlife Service, 300 Westgate Center Dr., Hadley, MA 01035.

FOR FURTHER INFORMATION CONTACT: Abby Gelb, 413–253–8212 (phone), or permitsR5ES@fws.gov (email). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications for permits under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.). The requested permits would allow the applicants to conduct activities intended to promote recovery of species that are listed as endangered under the ESA.

Background
With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA’s definition of “take” includes such activities as pursuing, harassing, trapping, capturing, or collecting, in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment
We invite local, State, and Federal agencies; Tribes; and the public to comment on the following applications.

### Application Table

<table>
<thead>
<tr>
<th>Application No.</th>
<th>Applicant</th>
<th>Species</th>
<th>Location</th>
<th>Activity</th>
<th>Type of take</th>
<th>Permit action</th>
</tr>
</thead>
</table>

Public Availability of Comments
Written comments we receive become part of the administrative record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps
If we decide to issue any permits to any of the applicants listed in this notice, we will publish a notice in the Federal Register.

Authority
Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.).

Martin Miller,
Chief, Division of Endangered Species, Ecological Services, North Atlantic-Appalachian Region.

[FR Doc. 2020–21650 Filed 9–30–20; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R8–ES–2020–0041; FF08ESMF00–FXES11140800000–201]

Endangered and Threatened Wildlife and Plants; Tracy Hills Project, San Joaquin County, California; Draft Environmental Assessment and Draft Habitat Conservation Plan

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of permit application; request for comment.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of a draft environmental assessment under the National Environmental Policy Act. We also announce receipt of an application for an incidental take permit under the Endangered Species Act (ESA), and receipt of a draft habitat conservation plan. The Tracy Hills Project Owner, LLC (THPO) has applied for an
incidental take permit under the ESA for the Tracy Hills Project in San Joaquin County, California. The permit would authorize the take of three species incidental to the development, construction, and conservation area management of the project. We invite the public and local, State, Tribal, and Federal agencies to comment on the application. Before issuing the requested permit, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before November 2, 2020.

ADDRESSES: Obtaining Documents: The incidental take permit (ITP) application, draft environmental assessment (draft EA), draft habitat conservation plan (HCP), and any comments and other materials that we receive are available for public inspection at http://www.regulations.gov in Docket No. FWS–HQ–ES–2020–0041.

Submitting Comments: To send written comments, please use one of the following methods, and note that your information request or comments are in reference to the draft EA, draft HCP, or both.


For more information, see Public Comments and Public Availability of Comments under SUPPLEMENTARY INFORMATION.


SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), announce the availability of a draft environmental assessment (EA), prepared pursuant to the National Environmental Policy Act of 1969, as amended (NEPA; 42 U.S.C. 4321 et seq.), and its implementing regulations in the Code of Federal Regulations (CFR) at 40 CFR 1506.6. This notice also announces the receipt of an application from the Tracy Hills Project Owner, LLC (applicant), for a 15-year incidental take permit (ITP) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 et seq.). Application for the permit requires the preparation of an HCP with measures to avoid, minimize, and mitigate the impacts of incidental take to the maximum extent practicable. The applicant prepared the draft Tracy Hills Habitat Conservation Plan (draft HCP) pursuant to section 10(a)(1)(B) of the ESA. The purpose of the EA is to assess the effects of issuing the permit and implementing the draft HCP on the natural and human environment.

Background

Section 9 of the ESA (16 U.S.C. 1531–1544 et seq.) prohibits the taking of fish and wildlife species listed as endangered under the ESA; by regulation, take prohibitions are also applied to certain threatened species. Regulations governing permits for endangered and threatened species are at 50 CFR 17.22 and 17.32. For more about the Federal habitat conservation plan (HCP) program, go to http://www.fws.gov/endangered/esa-library/pdf/hcp.pdf.

National Environmental Policy Act Compliance

The proposed permit issuance triggers the need for compliance with the National Environmental Policy Act of 1969, as amended (NEPA; 42 U.S.C. 4321 et seq.). The draft EA was prepared to analyze the impacts of issuing an ITP based on the draft HCP and to inform the public of the proposed action, any alternatives, and associated impacts, and to disclose any irreversible commitments of resources.

Proposed Action Alternative

Under the Proposed Action Alternative, the Service would issue an ITP to the applicant for a period of 15 years for certain covered activities (described below). The applicant has requested an ITP for three covered species (described below), which are listed under the Act.

Habitat Conservation Plan Area

The geographic scope of the draft HCP encompasses 3,876 acres (ac) in western San Joaquin County, California, including the 1,148-ac proposed Development Area and the 2,730-ac Conservation Easement Area that will be used to mitigate impacts from this development.

Covered Activities

The proposed section 10 ITP would allow take of three covered species from covered activities in the proposed HCP area. The applicant is requesting incidental take authorization for covered activities including site preparation, infrastructure development, construction of the proposed project, and management of the conservation easement area. The applicant is proposing to implement a number of project design features, including best management practices, as well as general and species-specific avoidance and minimization measures to minimize the impacts of the take from the covered activities.

Covered Species

The following three federally listed species are proposed to be included as covered species in the proposed HCP:

• San Joaquin kit fox (Vulpes macrotis mutica)—federally listed as endangered;

• California red-legged frog (Rana aurora draytonii)—federally listed as threatened;

• California tiger salamander—Central Valley Distinct Population Segment (Ambystoma californiense)—federally listed as threatened.

No-Action Alternative

Under the No-Action Alternative, the Service would not issue an ITP to the applicant, and the draft HCP would not be implemented. Under this alternative, the applicant may choose not to develop the project, or would do so in a manner designed not to result in the take of ESA-listed species.

Public Comments

We request data, comments, new information, or suggestions from the public, other concerned governmental agencies, the scientific community, Tribes, industry, or any other interested party on this notice, the draft EA, and the draft HCP. We particularly seek comments on the following:

1. Biological information concerning the species;

2. Relevant data concerning the species;

3. Additional information concerning the range, distribution, population size, and population trends of the species;

4. Current or planned activities in the area and their possible impacts on the species;

5. The presence of archeological sites, buildings and structures, historic events, sacred and traditional areas, and other historic preservation concerns, which are required to be considered in project planning by the National Historic Preservation Act; and

6. Any other environmental issues that should be considered with regard to the proposed development and permit action.
Public Availability of Comments

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

Next Steps

Issuance of an incidental take permit is a Federal proposed action subject to compliance with NEPA and section 7 of the ESA. We will evaluate the application, associated documents, and any public comments we receive as part of our NEPA compliance process to determine whether the application meets the requirements of section 10(a) of the Act. If we determine that those requirements are met, we will conduct an intra-Service consultation under section 7 of the ESA for the Federal action for the potential issuance of an ITP. If the intra-Service consultation confirms that issuance of the ITP will not jeopardize the continued existence of any endangered or threatened species, or destroy or adversely modify critical habitat, we will issue a permit to the applicant for the incidental take of the covered species.

Authority

We publish this notice under the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321–4347 et seq.), and its implementing regulations at 40 CFR 1500–1508, as well as in compliance with section 10(c) of the Endangered Species Act (16 U.S.C. 1531–1544 et seq.) and its implementing regulations at 50 CFR 17.22 and 17.32.

Michael Senn,
[FR Doc. 2020–21748 Filed 9–30–20; 8:45 am] BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

201D0102DM/DS6CS00000/DLSN00000.000000/DX6CS25

Statement of Findings: Pechanga Band of Luiseño Mission Indians Water Rights Settlement Act

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of statement of findings.

SUMMARY: The publication by the Secretary of the Interior (Secretary) of this notice causes the settlement agreement executed in accordance with Section 3402 of the Pechanga Band of Luiseño Mission Indians Water Rights Settlement Act (Settlement Act) to become enforceable and causes waivers and releases of claims executed pursuant to Section 3407 of the Settlement Act to take effect.

DATES: This notice takes effect on October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Address all comments and requests for additional information to Douglas Garcia, Chair, Pechanga Settlement Implementation Team, Department of the Interior, Bureau of Indian Affairs, Pacific Regional Office, 2800 Cottage Way, Sacramento, CA 95685, (916) 978–6052, Douglas.Garcia@bia.gov.

SUPPLEMENTARY INFORMATION: Congress enacted the Settlement Act as Title III, Subtitle D of the Water Infrastructure Improvements for the Nation Act, Public Law 114–322. The Settlement Act was enacted to resolve the water right claims of the Pechanga Band of Luiseño Mission Indians (Pechanga Band) subject to an adjudication in the U.S. District Court (Adjudication Court) in United States v. Fullbrook Public Utility District, et al., Case No. 51–01247–GPC–RBB (S.D. Cal.). The Settlement Parties include the Pechanga Band, Rancho California Water District, and the United States. The Eastern Municipal Water District and Metropolitan Water District of Southern California are parties to various sub-agreements to the Pechanga Settlement Agreement (Settlement Agreement).

The Settlement Act and Settlement Agreement quantify and define the Pechanga Band’s rights to water, including surface and groundwater within the Santa Margarita River watershed, that will be satisfied with local groundwater, imported recycled water, and imported potable water. The Settlement Agreement and various sub-agreements include the arrangements and infrastructure necessary to make this water available to the Pechanga Band. The United States contributed funding for imported water and infrastructure development.

Statement of Findings

In accordance with Section 3407(e) of the Settlement Act, I find as follows:

(1) The Adjudication Court has issued a judgment and decree approving the conformity of the Settlement Agreement consistent with the Settlement Act;

(2) All amounts authorized by the Settlement Act have been deposited into the Pechanga Settlement Fund;

(3) The waivers and releases authorized in Section 3407(a) of the Settlement Act have been executed by the Pechanga Band and the Secretary;

(4) The Extension of Service Area Agreement (ESAA) has been executed by the parties to that agreement and takes effect and is enforceable in accordance with its terms; and

(5) The ESAA Water Delivery Agreement has been executed by the parties to that agreement and takes effect and is enforceable in accordance with its terms.


David L. Bernhardt,
Secretary of the Interior.

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

FWS–R4–ES–2020–N002: Deepwater Horizon Oil Spill, Louisiana Trustee Implementation Group; Final Phase 2 Restoration Plan #1.2 and Environmental Assessment: Barataria Basin Ridge and Marsh Creation Project, Spanish Pass Increment and Lake Borgne Marsh Creation Project Increment One; and Finding of No Significant Impact

AGENCY: Department of the Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the Oil Pollution Act of 1990 (OPA), the National Environmental Policy Act of 1969 (NEPA), the Final Programmatic Damage Assessment Restoration Plan/ Final Programmatic Environmental Impact Statement (PDARP/PEIS), and the Consent Decree, the Federal and State natural resource trustee agencies for the Louisiana Trustee Implementation Group (LA TIG) have prepared a Louisiana Trustee Implementation Group Final Restoration Plan/Environmental Assessment #1.2: Barataria Basin Ridge and Marsh Creation Project Spanish Pass Increment and Lake Borgne Marsh Creation Project Increment One (Phase 2 RP/EA #1.2), and Finding of No Significant Impact (FONSI). The Phase 2 RP/EA #1.2 approves construction activities for the restoration of wetlands, coastal, and nearshore habitats injured in the Louisiana Restoration Area as a result of the Deepwater Horizon (DWH) oil spill. The Phase 2 RP/EA #1.2 analyzes restoration project design...
The purpose of this notice is to inform the public of the availability of the final Phase 2 RP/EA #1.2 and FONSI.

**ADDRESSES: Obtaining Documents:** You may obtain a copy of the final Phase 2 RP/EA #1.2 from either of the following websites:

- [https://www.do.gov/deepwaterhorizon](https://www.do.gov/deepwaterhorizon)
- [https://www.gulfspillrestoration.noaa.gov/restoration-areas/loriusiana](https://www.gulfspillrestoration.noaa.gov/restoration-areas/loriusiana)

Alternatively, you may request a CD of the final Phase 2 RP/EA #1.2 (see **FOR FURTHER INFORMATION CONTACT**). A hard copy of the final Phase 2 RP/EA #1.2 is also available to view at 16 repositories located across the region. Locations are listed in the following table.

<table>
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<tr>
<th>Library</th>
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<th>Zip</th>
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<td>St. Tammany Parish Library</td>
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<td>Covington</td>
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<td>Terrebonne Parish Library</td>
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<td>New Orleans Public Library</td>
<td>219 Loyola Avenue</td>
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<td>East Baton Rouge Parish Library</td>
<td>7711 Goodwood Boulevard</td>
<td>Baton Rouge</td>
<td>70806</td>
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<td>2751 Manhattan Boulevard</td>
<td>Harvey</td>
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<td>Plaquemines Parish Library</td>
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<td>Belle Chasse</td>
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<td>St. Bernard Parish Library</td>
<td>201 Porter Street</td>
<td>St. Martinville</td>
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<td>Alex P. Allain Library</td>
<td>206 Iberia Street</td>
<td>Franklin</td>
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<td>Abbeville</td>
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<td>Martha Sowell Utley Memorial Library</td>
<td>314 St. Mary Street</td>
<td>Thibodaux</td>
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<td>South Lafourche Public Library</td>
<td>16241 E Main Street</td>
<td>Cut Off</td>
<td>70345</td>
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<td>Calcasieu Parish Library Central Branch</td>
<td>301 W Claude Street</td>
<td>Lake Charles</td>
<td>70605</td>
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<tr>
<td>Iberia Parish Library</td>
<td>445 E Main Street</td>
<td>New Iberia</td>
<td>70560</td>
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<tr>
<td>Mark Shirley, LSU AgCenter</td>
<td>1105 West Port Street</td>
<td>Abbeville</td>
<td>70510</td>
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**FOR FURTHER INFORMATION CONTACT:**
Nanciann Regalado, via email at nanciann.regalado@fws.gov, via telephone at 678–296–6805, or via the Federal Relay Service at 800–877–8339.

**SUPPLEMENTARY INFORMATION:**

**Introduction**

On April 20, 2010, the mobile offshore drilling unit *Deepwater Horizon*, which was being used to drill a well for BP Exploration and Production, Inc. (BP), in the Macondo prospect (Mississippi Canyon 252—MC252), experienced a significant explosion, fire, and subsequent sinking in the Gulf of Mexico, resulting in an unprecedented volume of oil and other discharges from the rig and from the wellhead on the seabed. The DWH oil spill is the largest offshore oil spill in U.S. history, discharging millions of barrels of oil over a period of 87 days. In addition, well over 1 million gallons of dispersants were applied to the waters of the spill area in an attempt to disperse the spilled oil. An undetermined amount of natural gas was also released into the environment as a result of the spill.

The Trustees conducted the natural resource damage assessment (NRDA) for the DWH oil spill under the Oil Pollution Act 1990 (OPA; 33 U.S.C. 2701 et seq.). Pursuant to OPA, Federal and State agencies act as trustees on behalf of the public to assess natural resource injuries and losses and to determine the actions required to compensate the public for those injuries and losses. The OPA further instructs the designated trustees to develop and implement a plan for the restoration, rehabilitation, replacement, or acquisition of the equivalent of the injured natural resources under their trusteeship to baseline (the resource quality and conditions that would exist if the spill had not occurred). This includes the loss of use and services provided by those resources from the time of injury until the completion of restoration.

The DWH Trustees are:
- U.S. Department of the Interior (DOI), as represented by the National Park Service, U.S. Fish and Wildlife Service, and Bureau of Land Management;  
  - National Oceanic and Atmospheric Administration (NOAA), on behalf of the U.S. Department of Commerce;  
  - U.S. Department of Agriculture (USDA);  
  - U.S. Environmental Protection Agency (EPA);  
- State of Louisiana Coastal Protection and Restoration Authority, Oil Spill Coordinator’s Office, Department of Environmental Quality, Department of Wildlife and Fisheries, and Department of Natural Resources;  
- State of Mississippi Department of Environmental Quality;  
- State of Alabama Department of Conservation and Natural Resources and Geological Survey of Alabama;  
- State of Florida Department of Environmental Protection and Fish and Wildlife Conservation Commission; and  
- State of Texas: Texas Parks and Wildlife Department, Texas General Land Office, and Texas Commission on Environmental Quality.

On April 4, 2016, the United States District Court for the Eastern District of Louisiana entered a Consent Decree resolving civil claims by the Trustees against BP arising from the DWH oil spill: United States vs. BPX et al., Civ. No. 10–4536, centralized in MDL 2179, In re: Oil Spill by the Oil Rig “Deepwater Horizon” in the Gulf of Mexico, on April 20, 2010 (E.D. La.) (http://www.justice.gov/enrd/deepwater-horizon). Pursuant to the Consent Decree, restoration projects in the Louisiana Restoration Area are chosen and managed by the LA TIG. The LA TIG is composed of the following Trustees: State of Louisiana Coastal Protection and Restoration Authority; Oil Spill Coordinator’s Office; Departments of Environmental Quality; Wildlife and Fisheries; and Natural Resources; DOI; NOAA; EPA; and USDA.

**Background**

The Final PDARP/PEIS provides for TIGs to propose phasing restoration projects across multiple restoration plans. A TIG may propose conceptual projects to fund for an information-gathering and planning phase, such as E&D, in a restoration plan (phase 1).
Approval of a Phase 1 restoration plan and projects within, allows the TIG to develop information needed to fully consider design alternatives in a later restoration plan (phase 2). In the final Phase 1 RP #1, the LA TIG selected six conceptual projects for E&D, using funds as provided for in the DWH Consent Decree. Two of those projects selected to undergo E&D were the Barataria Basin Ridge and Marsh Creation Project Spanish Pass Increment (Spanish Pass project) and the Lake Borgne Marsh Creation Project Increment One (Lake Borgne project). Upon development of E&D alternatives for the two projects, a phase 2 restoration plan was drafted and an OPA and NEPA analysis were conducted on the design alternatives. Notice of availability of the draft Phase 2 RP/EA #1.2 was published in the Federal Register on October 18, 2019 (84 FR 55976). Public comment was encouraged and accepted until November 20, 2019. The LA TIG hosted a public webinar on October 28, 2019 to facilitate public review and comment. The LA TIG considered the public comments received and finalized the Phase 2 RP/EA #1.2, selecting construction designs for implementation of both projects. A summary of the public comments received and the LA TIG’s responses to those comments are presented in the final Phase 2 RP/EA #1.2.

Overview of the LA TIG Final Phase 2 RP/EA #1.2

The Phase 2 RP/EA #1.2 is being released in accordance with OPA NRDA regulations found in the Code of Federal Regulations (CFR) at 15 CFR part 990, NEPA and its implementing regulations found at 40 CFR parts 1500–1508, the Final PDARP/PEIS, and the Consent Decree. The Phase 2 RP/EA #1.2 provides OPA and NEPA analyses for a reasonable range of design alternatives for the Spanish Pass and Lake Borgne projects, and identifies the LA TIG’s selected design alternatives, those which the LA TIG believes best meet the objectives of the Spanish Pass and Lake Borgne projects. In accordance with NEPA, as part of the final Phase 2 RP/EA #1.2, the Trustees issued a FONSI. The FONSI is available in Appendix F of the Phase 2 RP/EA #1.2.

The Spanish Pass project is a component of an overall large-scale restoration strategy for the Barataria Basin that would reestablish, through multiple increments, ridge and intertidal marsh habitats degraded due to sea level rise, land subsidence, diminished sediment supply, and storm events. The total construction cost for the Spanish Pass project is $101,359,000 which will be funded from the Wetlands, Coastal, and Nearshore Habitats restoration type allocation provided for in the Consent Decree.

The Lake Borgne project is a component of an overall large-scale restoration strategy for the southwestern shoreline of Lake Borgne that would reestablish, through multiple increments, the bay rim and intertidal marsh habitat. The estimated total construction cost for this increment is $101,823,000 will be funded also from the Wetlands, Coastal, and Nearshore Habitats restoration type allocation. Additional restoration planning for the Louisiana Restoration Area will continue.

Administrative Record

The documents comprising the Administrative Record for the Phase 2 RP/EA #1.2 can be viewed electronically at https://www.do.gov/deepwaterhorizon/adminrecord.

Authority


Mary Josie Blanchard, Director of Gulf of Mexico Restoration, Department of Interior.

[FR Doc. 2020–21750 Filed 9–30–20; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0030957; PWPCRAD00–PCU00RPI4.RS0000]

Notice of Inventory Completion: Santa Barbara Museum of Natural History, Santa Barbara, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Santa Barbara Museum of Natural History has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Santa Barbara Museum of Natural History. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Santa Barbara Museum of Natural History at the address in this notice by November 2, 2020.

ADDRESSES: Luke Swetland, President and CEO, Santa Barbara Museum of Natural History, 2559 Puesta del Sol, Santa Barbara, CA 93105, telephone (805) 682–4711.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Santa Barbara Museum of Natural History, Santa Barbara, CA. The human remains and associated funerary objects were removed from Santa Barbara, Ventura, San Luis Obispo, and Los Angeles Counties, CA.

This notice is published as part of the National Park Service’s administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Santa Barbara Museum of Natural History professional staff in consultation with representatives of the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California and other Chumash representatives of non-federally recognized Indian groups.
History and Description of the Remains

Santa Barbara County

In 1925 and 1988, human remains representing, at minimum two individuals were removed by David Banks Rogers and G. Unzueta from Rincon Point (site CA–SBA–1). The individuals are represented by a partial cranium removed by Rogers and a partial skeleton removed by Unzueta. No known individuals were identified. No associated funerary objects are present. Based on artifact types, the site dates to Phase 2a of the Middle Period (approximately 2,100 to 1,800 years ago).

In 1928 and 1950, human remains representing, at minimum, four individuals were removed by David Banks Rogers and Phil Orr from Rincon Point (CA–SBA–119). The individuals are represented by cranial, mandibles, fragmentary postcranial remains, and a tibia fragment. No known individuals were identified. Two associated funerary objects are one turtle shell and one lot of ochre-stained soil. The site dates to either the late Early Period (approximately 3,000 to 4,000 years ago) or Phase 1 of the Middle Period (approximately 2,500 to 2,100 years ago).

In June 1988, human remains representing, at minimum, seven individuals were removed by SBMNH staff and volunteers from Rincon Point, “Shuku” (site CA–VEN–62A), after trenching for construction behind a private residence. The individuals are represented by one complete skeleton, postcranial elements, a cranial fragment, an ilium fragment and tooth of a subadult, and teeth from one infant and one adult. No known individuals were identified. No associated funerary objects are present.

Sometime before 1935, human remains representing, at minimum, three individuals were removed from Higgins site (CA–SBA–6). L.M. Higgins, a property owner, donated the human remains to the SBMNH in 1935. There is no data on when or by whom the third individual was removed. The individuals are represented by partial sets of human remains. No known individuals were identified. The 10 associated funerary objects are nine beads and one shell fragment.

In 1925 and 1949, human remains representing, at minimum, 34 individuals were removed from Carpinteria (site CA–SBA–7). David Banks Rogers excavated 28 individuals in 1925 and Phil Orr excavated two individuals in 1949, during salvage work. An additional four individuals from this site were discovered during physical examination of the collection. The human remains include 22 individuals represented by cranial elements, including one sub-adult; five individuals represented by partial sets of human remains; one individual represented by a humerus; two individuals represented by a group of cranial and minimal postcranial remains; and four individuals represented by a group of long bones and long bone fragments, including one sub-adult. No known individuals were identified. The seven associated funerary objects are one chert biface fragment; one sandstone bowl; one small pestle; one lot of red pigment; one chert knife; one chert chopper; and one sandstone mano.

Sometime before October of 1926, human remains representing, at minimum, two individuals were removed from “Kolok” (site CA–SBA–13). The individuals are represented by cranial elements. Mr. Kohlsadt, the property owner, donated the human remains to the SBMNH in October 1926. No known individuals were identified. No associated funerary objects are present.

Sometime before October of 1926, human remains representing, at minimum, one individual were removed by Susan Denny from Drake (site CA–SBA–14). Denny, the property owner, donated the human remains to the SBMNH in 1966. The individual is represented by a partial set of remains. No known individuals were identified. No associated funerary objects are present.

In 1924 and sometime before 1935, human remains representing, at minimum, 29 individuals were removed from Fernald Point (CA–SBA–17). David Banks Rogers excavated 28 individuals in 1924, and George Hammond donated one individual to the SBMNH in 1935. The human remains include 18 individuals represented by cranial elements, including one elderly individual; eight individuals represented by postcranial elements, including one sub-adult; and three individuals represented by cranial and postcranial elements. No known individuals were identified. No associated funerary objects are present.

In 1924 and 1992, human remains representing, at minimum, three individuals were removed from “Syuxtun” site (CA–SBA–27). David Banks Rogers excavated one individual in 1924. Further excavations were conducted by Cultural Resources Management professionals in 1989 and 1992. The individuals are represented by cranial and postcranial elements. No known individuals were identified. No associated funerary objects are present.

In 1970 and 1971, human remains representing, at minimum, nine individuals were removed from Burton Mound (site CA–SBA–28). The property owner and a third party removed three of the individuals during development of the site; students from Santa Barbara City College excavated five individuals during a field school; and one additional set of partial human remains were found, reported to police, and turned over to the museum in 2001. The human remains include one individual represented by a partial cranium; one individual represented by postcranial elements; six individuals represented by cranial and postcranial fragments, including one sub-adult; and one individual represented by a single tooth. No known individuals were identified. No associated funerary objects are present.

On various dates, human remains representing, at minimum, 18 individuals were removed from “Mispu” (site CA–SBA–30 and CA–SBA–31). David Banks Rogers, Phil C. Orr, Santa Barbara City college staff and students, and private parties conducted the excavations. The human remains include six individuals represented by cranial elements; two individuals represented by postcranial elements; eight individuals represented by cranial and postcranial elements; and two individuals represented by unidentified fragments. No known individuals were identified. The 185 associated funerary objects are: 23 shell beads; 101 shell fragments; seven shells; 15 shell barrel beads; eight bone fragments; one piece of asphaltum; one steatite tube; 24 visible shell beads (in soil matrix within cranium), four pieces of charcoal; and one fragment of worked bone.

In 1926, human remains representing, at minimum, one individual were removed by David Banks Rogers from Barger No. 1 (site CA–SBA–35). The individual is represented by a mandible fragment. No known individuals were identified. No associated funerary objects are present.

In July 1926, human remains representing, at minimum, one individual were removed from “Ushthaash” (site CA–SBA–37). This
individual is represented by a cranium. No known individuals were identified. No associated funerary objects are present.

In 1924, human remains representing, at minimum, seven individuals were removed by David Banks Rogers from Modoc Road (site CA–SBA–38). Three individuals are represented by cranial elements and four individuals are represented by cranial and postcranial elements. No known individuals were identified. No associated funerary objects are present.

In 1936, human remains representing, at minimum, one individual were removed by Lee Ramirez from Cieneguitas (site CA–SBA–39), and were donated to the SBMNH in 1938. The individual is represented by a partial cranium. No known individuals were identified. The one associated funerary object is a single lead shot.

In June of 1933, human remains representing, at minimum, two individuals were removed by David Banks Rogers from Twin Mounds (site CA–SBA–45). The individuals are represented by phalanges and teeth. No known individuals were identified. The 292 associated funerary objects are: Six steatite disc beads; one fragmented polished bone hairpin; 10 strands of beads; 125 shell beads; 13 shell bead fragments; two tubular steatite beads; 134 shell beads and bangles; and one mother-of-pearl ornament.

In 1926, 1933, and 1941, human remains representing, at minimum, 45 individuals were removed from Mescalitan Island, “Helo” (site CA–SBA–46). Most of the human remains were excavated by Phil C. Orr, and some of the human remains were excavated by Harold E. Childes. The human remains include 15 individuals represented by complete or relatively complete skeletons, including one individual found interred atop an inlaid whale scapula and one individual identified as a child; three individuals represented by skeletons which have been preserved within a plaster jacket, two of whom are infants; 26 individuals represented by incomplete skeletons; and one individual represented by a cranium in which is embedded a projectile point. No known individuals were identified. The 7793 associated funerary objects are: 4807 *Olivella biplicata* beads; 58 *Olivella biplicata* bead fragments; 32 limpet beads; 63 limpet bead fragments; 22 abalone pendants; four cowry beads; 37 fish scales; 2279 shell fragments; 331 bone (faunal) fragments; 16 strands of shell beads; one lump of red ocher; 21 steatite beads; seven steatite ornaments; two steatite pendants; 24 *Megathura crenulata* ornaments; 22 inlaid bone tubes; 11 teeth inlaid with *Olivella biplicata* beads; four steatite bead blanks; 22 projectile points; one abalone ornament; three stone tube beads; 10 bifaces; five abalone beads; one turtle shell rattle; three shell beads; one steatite pipe with bone mouthpiece; one seed; one scraper; one quartz crystal; one grave marker made from whale bone; one steatite bowl; and one sandstone charmstone.

Sometime before the 1930s, human remains representing, at minimum, one individual were removed by Frank Williams and Robert Phelan from the south side of Goleta Slough (site CA–SBA–47). The individual is represented by a fragmented cranium. No known individuals were identified. No associated funerary objects are present.

In 1941, human remains representing, at minimum, two individuals were removed by Phil C. Orr from “Heliyik” (site CA–SBA–48). One individual is represented by an incomplete and fragmentary skeleton, and the second individual is represented by a partial cranium. No known individuals were identified. No associated funerary objects are present.

In 1941, human remains representing, at minimum, one individual were removed by Phil C. Orr from the Bishop site (site CA–SBA–49). The individual is represented by a relatively complete cranium. No known individuals were identified. No associated funerary objects are present.

In 1925, human remains representing, at minimum, 17 individuals were removed by David Banks Rogers from Campbell No. 2 (site CA–SBA–52). The human remains include nine individuals represented by cranial elements; three individuals represented by postcranial elements; and five individuals represented by cranial and postcranial elements. No known individuals were identified. The two associated funerary objects are one Astrea undosa shell and one large Hinnites multirugosus shell.

In 1925, human remains representing, at minimum, one individual were removed by David Banks Rogers from Campbell No. 1 (site CA–SBA–53). The individual is represented by a rib fragment. No known individuals were identified. No associated funerary objects are present.

On an unknown date, human remains representing, at minimum, two individuals were removed from Winchester No. 2 (site CA–SBA–69). One individual is represented by a fragmented mandible and a tibia fragment, and the second individual is represented by a long bone fragment. No known individuals were identified. No associated funerary objects are present.

In 1926, human remains representing, at minimum, eight individuals were removed from Winchester No. 3 (site CA–SBA–71). David Banks Rogers excavated seven human remains in 1926. An additional set of human remains was reported to the police, and...
was turned over to the SBMNH in 2001. The human remains include four individuals represented by cranial elements; two individuals represented by postcranial elements; and two individuals represented by cranial and postcranial elements. No known individuals were identified. The three associated funerary objects are one Olivella biplicata bead; one strand of beads or ornaments made from Haliotis shell; and one chipped stone knife. In 1926 and 1932, human remains representing, at minimum, 23 individuals were removed by David Banks Rogers from Tecolote No. 1 (site CA–SBA–72). The human remains include 11 individuals represented by cranial elements; 11 individuals are represented by postcranial elements; and one individual represented by cranial and postcranial elements. No known individuals were identified. The 504 associated funerary objects are: 15 chert projectile points; 351 Olivella biplicata shell beads; one stone ring; one strand of assorted beads; 68 hair ornaments; 10 hair ornament fragments; 37 asphaltum skirt weights; one bone tube fragment; two bone fragments; 13 limpet ornaments; one perforated Olivella biplicata shell; two fragments of unmodified shell; one strand of Olivella biplicata and stone beads; and one piece of ochre. In 1926, 1929, and the 1980s, human remains representing, at minimum, nine individuals were removed from Tecolote No. 2 (site CA–SBA–73). Five sets of human remains were excavated by David Banks Rogers in 1926; one set of human remains was donated to SBMNH in or around 1926; two sets of human remains were removed by construction workers in 1929; and one set of human remains was removed during unauthorized surface collection in the 1980s. The human remains include six individuals represented by cranial elements; one individual represented by postcranial elements; and two individuals represented by cranial and postcranial elements. No known individuals were identified. Two associated funerary objects are present. Sometime before 1981, human remains representing, at minimum, two individuals were illegally removed by looters from Eagle Canyon (site CA–SBA–76). The Santa Barbara County Sherriff’s Department transferred the human remains to the SBMNH in 1981. Both individuals are represented by cranial and postcranial elements. No known individuals were identified. No associated funerary objects are present. In 1925 and 1926, human remains representing, at minimum, five, five individuals were removed from Mikiw (site CA–SBA–78). Two sets of human remains were excavated by David Banks Rogers in 1925, and three sets of human remains were acquired through private donations in 1936, 1979, and 2001. The human remains include three individuals represented by cranial elements; one individual represented by a few cranial and postcranial elements; and one individual represented by a single long bone fragment. No known individuals were identified. The one associated funerary object is a chert projectile point. In the 1920s, human remains representing, at minimum, two individuals were removed by William A. Edwards from Los Gatos (site CA–SBA–80). The human remains were donated to the SBMNH in 1992. The individuals are represented by numerous fragmentary cranial and postcranial elements. No known individuals were identified. No associated funerary objects are present. Between 1924 and in May 1962, human remains representing, at minimum, 33 individuals were removed by David Banks Rogers and Harold Cocke from Las Llagos No. 1 (site CA–SBA–81). All the individuals are represented by partial sets of remains. No known individuals were identified. The 188 associated funerary objects are: Eight chert projectile points; one strand of Olivella biplicata beads; 13 mother of pearl ornaments; three sandstone bowls; one shell gorget; 12 strands of assorted shell beads; one sandstone pestle; one bone awl; 140 assorted shell beads; one clam shell ornament; one limpet ornament; four large bone beads; one shell necklace; one strands of limpet hair ornaments. In 1926, human remains representing, at minimum, eight individuals were removed by David Banks Rogers from Las Llagos No. 2 (site CA–SBA–82). One individual is represented by cranial elements, five individuals by minimal postcranial elements, and two individuals by a single tooth each, one of which has been identified as a subadult’s tooth. No known individuals were identified. The 543 associated funerary objects are 539 asphaltum skirt weights; two beads; and two shell fragments. Between 1925 and 1926 and on an unknown date, human remains representing, at minimum, six individuals were removed from El Capitan (site CA–SBA–84 and CA–SBA–117). Five sets of human remains were excavated by David Banks Rogers, one set of human remains transferred by The University of California, Davis, and one set of human remains was excavated by an unknown person and transferred to the SBMNH in 1991. Three individuals are represented by cranial elements, two individuals are represented by cranial elements and a single postcranial element, and one individual is represented by a long bone fragment in which is embedded a splinter of chert. No known individuals were identified. The 34 associated funerary objects are one charmstone; three bone whistles; 11 abalone ornaments; 11 shell hair ornaments; one strand of limpet hair ornaments; one strand of assorted beads; one staurorite ornament; four shell ornaments; and one quartz crystal. In 1926, human remains representing, at minimum, three individuals were removed by David Banks Rogers from Refugio No. 1 (site CA–SBA–86). All three individuals are represented by partial sets of human remains. No known individuals were identified. No associated funerary objects are present. In 1926, human remains representing, at minimum, six individuals were removed by David Banks Rogers from Qasil (site CA–SBA–87). All six individuals are represented by partial sets of human remains. No known individuals were identified. No associated funerary objects are present. In the 1950s, human remains representing, at minimum, 12 individuals were removed from Teqepsh (site CA–SBA–477). Based on limited documentation, Albert Mohr and Martin Baumann carried out the excavation for the University of California Archaeological Survey and the Smithsonian Institution. One individual is represented by a cranium, two individuals are represented by fragmented postcranial elements, and nine individuals are represented by partial sets of human remains. No known individuals were identified. No associated funerary objects are present. Sometime before 1927, human remains representing, at minimum, three individuals were removed from Osbi (site CA–SBA–512 and CA–SBA–513). All three individuals are represented by cranial elements. No known individuals were identified. No associated funerary objects are present. In 1950, human remains representing, at minimum, one individual were removed by Mrs. Klein, a private collector, from site CA–SBA–562 in Santa Barbara County, CA. This individual is represented by an incomplete skeleton. No known individuals were identified. No associated funerary objects are present. In 1930, human remains representing, at minimum, five individuals were removed by Henry Abel and J. G. James.
from Salisbury Potrero (site CA–SBA–1279). Three sets of human remains were donated to the SBMNH in 1963 and two sets of human remains were donated by Henry Abel’s daughter, Sally Speers, in 2006. All five individuals are represented by cranial elements. No known individuals were identified. No associated funerary objects are present.

On unknown dates, human remains representing, at minimum, 54 individuals were removed from unknown locations in Santa Barbara County, CA. These human remains lack sufficient provenience information to associate them with a specific site or locality. One set of human remains was discovered by a construction crew near the Education Building on the SBMNH campus on April 21, 2011, during work to improve handicap accessibility. A second set of human remains was collected by C. Otis Miller in 1931, from a burial [at an unidentified site] near the water’s edge on More Ranch, in Goleta. The human remains include 11 individuals represented by cranial elements; 19 individuals represented by postcranial elements; 10 individuals represented by cranial and postcranial elements; and 14 individuals represented by teeth. No known individuals were identified. No associated funerary objects are present.

In May 1927 and sometime before 1960 and 1987, human remains representing, at minimum, 14 individuals were removed from Coches Prietos, Liyam (site CA–SCRI–1), on Santa Cruz Island. Twelve sets of human remains are attributed to excavations conducted by Ronald Olson and David Banks Rogers in May 1927. Two additional sets of human remains were donated to the SBMNH, one in 1960 and one in 1987. Seven individuals are represented by cranial elements and one individual by cranial and minimal postcranial elements. Three individuals are represented by minimal postcranial elements, and three individuals by a single tooth each. No known individuals were identified. The 66 associated funerary objects are: Three pile perch teeth; two stone concretions; two bone fishhooks; two lots of pigment; one small steatite olla; four limpet shell pigment containers; one lot of cordage; one bone whistle; two bone fish bars; one fragment of a bone implement; eight projectile points; 32 Haliotis ornaments; three strands of beads; one large stone drill; one stone scraper; and two canoe planks.

In 1927, human remains representing, at minimum, 10 individuals were removed by David Banks Rogers from Arch Rock (site CA–SCRI–158), on Santa Cruz Island. Two individuals, including one very old individual, are represented by cranial and minimal postcranial elements. Three individuals are represented by a single postcranial element each one element belongs to a sub-adult. Another element has a projectile point embedded in it. No known individuals were identified. The one associated funerary object is a cowry shell lip ornament.

In June 1927, human remains representing, at minimum, five individuals were removed by David Banks Rogers and Ronald Olson from Christie Beach Site 4W, Ch’oloshush (CA–SCRI–236), on Santa Cruz Island. Three of the individuals are represented by cranial elements, and the other two individuals by minimal postcranial elements. No known individuals were identified. The 169 associated funerary objects are: One sample of pigment; one abalone shell containing black pigment; one abalone shell containing red pigment; one chert drill; three plank canoe fragments; 11 fragments of asphaltum basketry impressions; one piece of seagrass cordage; one projectile point; two strands of beads; 147 fragments of shell and shell beads.

In 1936, 1947, and 1950, human remains representing, at minimum, eight individuals were removed by David Banks Rogers and Phil C. Orr from Prisoner’s Harbor, Xaxas (site CA–SCRI–240), on Santa Cruz Island. Seven individuals are represented by cranial elements, and the other individual, a sub-adult, is represented by two teeth. No known individuals were identified. The 1514 associated funerary objects are: Four crystals; four gravers; two seal teeth; nine shell discs; two spiral shell beads; 80 gravers; one stone pipe; two glass beads; one shell container; one abalone ornament; 484 shell beads; two flourite beads; 22 bone tool or ornament fragments; one soap root brush; one steatite bowl fragment; one projectile point; two asphaltum plugs; one asphaltum handle; one stone scraper; 36 tube beads; two musket ramrod thimbles; and 855 glass trade beads.

In 1927, human remains representing, at minimum, four individuals were removed by Ronald Olson and David Banks Rogers from site CA–SCRI–253 (Christy Beach Site 4, Ch’oloshush), on Santa Cruz Island. Two individuals are represented by cranial elements, one individual is represented by a femur, and one individual is represented by three teeth. No known individuals were identified. The 68 associated funerary objects are: One projectile point; one pestle; four strands of shell beads; one stone bowl with shell fragments; 10 shells; 19 shell beads; one bone barb; and 25 fishhook blanks.

In 1927, human remains representing, at minimum, 42 individuals were removed by Ronald Olson and David Banks Rogers from sites CA–SCRI–257 and CA–SCRI–191 (Christy Beach Site 3), on Santa Cruz Island. Eighteen individuals—one is a sub-adult—are represented only by cranial elements. Nineteen individuals—one is a sub-adult—are represented by postcranial elements. Five individuals are represented by cranial and postcranial elements. No known individuals were identified. The 41 associated funerary objects are: two staurotide beads; four bone beads; one claw bead; one fishhook; 15 limpet ornaments; three bone tools; and 15 abalone ornaments.

In August 1932, human remains representing, at minimum, one individual were removed by Dr. Richard Van Valkenburgh from site CA–SCRI–333 (El Montón, Fraser Point, Forney Cove), on Santa Cruz Island. The human remains were donated to the SBMNH by Dr. Roy L. Moodie. The human remains are represented by a complete skeleton. No known individuals were identified. No associated funerary objects are present.

In August 1976, human remains representing, at minimum, one individual were removed by Dr. Carey Stanton from site CA–SCRI–383 (Christy Beach), on Santa Cruz Island. The human remains were donated to the SBMNH in January 1991. The human remains are represented by two teeth and fragments of cranial and postcranial elements. No known individuals were identified. The 15 associated funerary objects are one steatite bowl and 14 pieces of stone debris.

In 1983, human remains representing, at minimum, one individual were removed illegally from site CA–SCRI–436 (West Valdez No. 1), on Santa Cruz Island. The human remains were confiscated by the Santa Barbara County Sheriff’s Department and transferred to the SBMNH in July 1986. The human remains are represented by two teeth. No known individuals were identified. No associated funerary objects are present.

In 1927 and sometime between 1982 and 1986, human remains representing, at minimum, three individuals were removed from site CA–SCRI–437 (West Valdez No. 2), on Santa Cruz Island. One set of human remains was removed by David Banks Rogers. Two additional sets of human remains that had been removed illegally, were confiscated by the Santa Barbara County Sheriff’s Department and transferred to the SBMNH in July 1986. The human remains are represented by postcranial elements. No known individuals were
No associated funerary objects are present.

Around 1984, human remains representing, at minimum, one individual were removed illegally from site CA–SCRI–444 [Hazard’s No. 1], on Santa Cruz Island. The human remains were confiscated by the Santa Barbara County Sheriff’s Department and transferred to the SBMNH in July 1986. The human remains are represented by a single cranial fragment. No known individuals were identified. No associated funerary objects are present.

In July 1927, human remains representing, at minimum, two individuals were removed by David Banks Rogers from site CA–SCRI–445 (Valdez), on Santa Cruz Island. The human remains are represented by cranial elements. No known individuals were identified. No associated funerary objects are present.

In July 1927, human remains representing, at minimum, two individuals were removed by David Banks Rogers and Ronald Olson from site CA–SCRI–496 (Willows), on Santa Cruz Island. The human remains are represented by cranial elements. No known individuals were identified. No associated funerary objects are present.

In July 1927, human remains representing, at minimum, one individual were removed by David Banks Rogers from a site at Baby’s Harbor (SCRI–178), on Santa Cruz Island. The human remains are represented by cranial elements. No known individuals were identified. No associated funerary objects are present.

Around 1929, human remains representing, at minimum, one individual were removed by David Banks Rogers from a site at Albert’s Anchorage, on Santa Cruz Island. The human remains are represented by postcranial elements. No known individuals were identified. No associated funerary objects are present.

In 1981, human remains representing, at minimum, one individual were removed by a ranch worker from a site called Mount Diablo, on Santa Cruz Island. The human remains are represented by a partial cranium. No known individuals were identified. No associated funerary objects are present.

In the early 1980s, human remains representing, at minimum, five individuals were removed illegally from an unrecorded site near Alamos, on Santa Cruz Island. The human remains are represented by cranial elements. They were confiscated by the Santa Barbara County Sheriff’s Department and transferred to the SBMNH in July 1986. No known individuals were identified. No associated funerary objects are present.

Around 1984, human remains representing, at minimum, one individual was removed illegally from site CA–SCRI–455 (Arlington Dunes), on Santa Cruz Island. The human remains are represented by cranial elements. No known individuals were identified. No associated funerary objects are present.

In 1947, human remains representing, at minimum, one individual were removed by Phil C. Orr from CA–SRI–1 (Garañón Point), on Santa Rosa Island. The human remains are represented by a relatively complete skeleton. No known individuals were identified. The 737 associated funerary objects are one shell dish; one shell strand; eight shell beads; three bone fragments; one pearl; 28 faunal remains; 653 shell bead fragments; 23 whale bone implements; and 19 shell ornaments.

Between 1948 and 1958, human remains representing, at minimum, 177 individuals were removed by Phil C. Orr from CA–SRI–2A and CA–SRI–2B (Skull Gulch) and CA–SRI–2 (Unspecified Cemetery) on Santa Cruz Island. Of the 24 individuals removed from CA–SRI–2A: Eight individuals are represented by cranial elements; four individuals are represented by complete skeletons; three individuals are represented by relatively complete skeletons; six individuals which include one subadult and three fetuses—are represented by postcranial elements; two individuals are represented by teeth; and one individual is represented by an infant burial encased in latex. Of the 140 individuals removed from CA–SRI–2B: 96 individuals are represented by cranial elements; four individuals are represented by cranial and postcranial elements; 11 individuals are represented by postcranial elements; three individuals—which include one infant and one subadult—are represented by partial skeletons; five individuals are represented by relatively complete skeletons; 13 individuals are represented by complete skeletons; two individuals are represented by fetal/infant skeletons; one individual is represented by human remains encased in plaster with artifacts; and five individuals are represented by teeth. Of the 13 individuals removed from CA–SRI–2 (Unspecified Cemetery): 11 individuals are represented by postcranial elements; one individual is represented by a vertebral column; and one individual is represented by a long bone fragment. The human remains cannot be associated with a specific cemetery due to insufficient data. No known individuals were identified. The 7584 associated funerary objects are: 5790 beads and bead fragments; 45 bead strands; 13 asphaltum samples; four projectile points; one bone bead; five shell fishhooks; one abalone container; five seed samples; 40 shell fragments; two knives; eight stone beads; six fish vertebrae; four midden samples; one bone bipoint; 25 pendants/ornaments; 818 gravers; 16 bladelets; 26 pieces of ochre; one ochre sample; 18 bone fragments; 480 pieces of charcoal; one charcoal sample; one steatite bowl; one bag of faunal material; two donut stones; one sea mammal tooth; 10 chert drills; one tooth; three pieces of seagrass matting; one seagrass skirt; one bag of skirt weights; one pebble; two bone artifacts; one wood handle; one worked wood piece; one shark tooth; 12 wood fragments; one sandstone pestle; one container; one bone pry bar; one scraper; one piece of seagrass cordage; three shell artifacts; one flake; six chipped stone fragments; 24 Oliva bella biplicata shells; and 196 pieces of charcoal, bone, and shell.

In 1949, 1950, and 1951, human remains representing, at minimum, 64 individuals were removed from CA–SRI–3A and CA–SRI–3B (Tecolote Point), on Santa Rosa Island. 50 individuals are represented by cranial elements; three individuals are represented by complete skeletons; five individuals are represented by partial skeletons; and six individuals are represented by cranial elements with postcranial elements. The 1056 associated with funerary objects are: 654 beads and bead fragments; three bead strands; one bone strigil; five samples of pigment-stained sand; five abalone shells and shell fragments; two shell dishes; 151 Oliva bella biplicata beads with traces of red pigment; five donut stones; 118 asphaltum fragments; one bone hairpin; one abalone dish with pigment-stained sand; one crab claw; three mussel fragments; three limpet shells, 66 pieces of charcoal; one obsidian drill/knife; two bone bipoins; two pieces of modified bone; two awls; three wedges; six chert flakes; one incised gull ulna pin; six bone pry bars; four asphaltum basketry impressions; one shell ornament; five bone tools; one stone tool in asphaltum; one chert bipoins; one hipped stone drill; and one stone tool.

In 1947, human remains representing, at minimum, two individuals were removed by Phil C. Orr from CA–SRI–4 (Arlington Dunes), on Santa Rosa Island. Both individuals are represented by cranial elements. No known individuals were identified. No associated funerary objects are present.
In 1948 and 1949 and in the 1960s, human remains representing, at minimum, 11 individuals were removed by Phil C. Orr from CA–SRI–5A and CA–SRI–5C (Survey Point) and CA–SRI–5 (Unspecified Cemetery), on Santa Rosa Island. Two individuals were collected from an eroding midden at CA–SRI–5 (Unspecified Cemetery), located along the mouth of Arlington Canyon, on Santa Rosa Island. The human remains were brought to the SBMNH in 2010. Eight individuals from CA–SRI–5A are represented by cranial elements. No known individuals were identified. The 614 associated funerary objects are three bone whistles; 37 shell ornaments; 474 shell beads and bead fragments; 64 shell beads and ornaments; seven bead strands; three bead and ornament strands; one bird bone fragment; one chipped stone knife; one bone awl; 19 ornaments; one bone whistle; two pendants; and one donut stone.

At an unknown date, human remains representing, at minimum, three individuals were removed from CA–SRI–6 (Arlington Point), on Santa Rosa Island. One individual is represented by postcranial fragments and two individuals are represented by a relatively complete postcranial skeleton and a second right femur fragment. The human remains were donated to the SBMNH by Mrs. Margaret Wooley in 1994. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, 11 individuals were removed from CA–SRI–9A (Arlington Cave), on Santa Rosa Island. Three individuals—which include one sub-adult—are represented by cranial elements; one individual is represented by a postcranial fragment; three individuals are represented by relatively complete skeletons; and four individuals—which include one skeleton incased in plaster and two infant skeletons incased in plaster and matrix are represented by complete skeletons. The 66 associated funerary objects are two doughnut stones, 56 shell beads, three Haliotis dishes, four unmodified shells, and one basket holding the infant burial that is encased in plaster.

In 1948, human remains representing, at minimum, one individual were removed by Phil C. Orr from CA–SRI–24, on Santa Rosa Island. This individual is represented by a partial skeleton. The 11 associated funerary objects are: Two shell bead strands; one abalone ornament; six shell beads; and two small stones.

In 1948, 1949, 1951, 1957, and 1961, human remains representing, at minimum, 108 individuals were removed by Phil C. Orr from CA–SRI–41A (Cañada Verde Dunes), on Santa Rosa Island. 63 individuals—which include 13 sub-adults—are represented by cranial elements; seven individuals—which include one infant and one sub-adult—are represented by post-cranial elements; 13 individuals—which include two sub-adults—are represented by cranial elements with post-cranial elements; one individual is represented by a tooth and postcranial elements; six individuals are represented by complete skeletons; four individuals—which include two sub-adults—are represented by a relatively complete skeleton; 13 individuals—which include one infant and one sub-adult—are represented by a partial skeleton; and one individual is represented by several undifferentiated fragments. The 13053 associated funerary objects are: 11925 shell beads and bead fragments; 12 incised bone fragments; three bone bipoints; 99 clam shell pendants; one piece of red pigment; 112 abalone pendants/ornaments; two bone tools; three samples of charcoal; five shell bead strands; five bone whistles; 10 abalone shell rings; 24 shell pendants; 14 bone awls; four unmodified land snails; 26 bone pendants/ornaments; 128 stone beads; 10 steatite pendants; 383 bone beads and bead fragments; one decorated pendant with ochre staining; 20 charcoal pieces; 16 chert projectile points and point fragments; nine pieces of asphaltum; two bone whittle fragments; four steatite rings; two abalone shell fragments; three steatite elbow pipes; one abalone spangle; 10 animal bone tools; one steatite charmstone; one Olivella bead headband (in fragments); one projectile point hafted in elk antler; two bone tubes; one stone bead strand; one serpentine pendant; two tarring pebbles; 13 fragments of engraved bone tools; one donut stone; nine shell fragments; one shell with ochre; 18 bone fragments with ochre staining; one flaked chert tool; three pieces of unworked chert; one crab claw; 28 abalone shell beads and ornaments inlaid into asphaltum; 31 limpet shell ornaments; one bone disc; three ochre samples; 15 bird bones with asphaltum; two perforated stones; one striated pebble; one chipped stone hammer; one chert drill; one abrader; one chert knife/scrap; one unsorted midden sample; one Thais shell; one bone pin; seven abalone dishes/containers; 15 quartz crystals; one chert flake; 28 charcoal/asphaltum fragments; and 24 pieces of shell, stone, bone, and charcoal.

In 1957, human remains representing, at minimum, one individual were removed by Phil C. Orr from CA–SRI–41B (Cañada Verde), on Santa Rosa Island. This individual is represented by a partial cranium. The eight associated funerary objects are one bone bead, one clam shell bead, one unmodified Olivella biplicata shell bead, one spire-ground Olivella biplicata shell bead, one Olivella biplicata shell disc bead, and three Olivella biplicata shell barrel beads.

In 1951, human remains representing, at minimum, one individual were removed by Phil C. Orr from CA–SRI–41C (Cañada Verde, Cemetery C), on Santa Rosa Island. This individual is represented by a cranium and mandible. No known individuals were identified. No associated funerary objects are present.

In 1951, human remains representing, at minimum, one individual were removed by Phil C. Orr from CA–SRI–41X (Cañada Verde, Cemetery X), on Santa Rosa Island. This individual is represented by a relatively complete skeleton. The 268 associated funerary objects are 205 shell artifacts, 13 awls, one bone tool, five fragments of unmodified bone, 10 cores, 24 projectile points, one knife, one steatite cup, one doughnut stone, one asphaltum cake, four samples of pigment-stained sand, and two bone hairpins.

In 1957, human remains representing, at minimum, six individuals were removed by Phil C. Orr from CA–SRI–43A (Fox), on Santa Rosa Island. Two individuals—which include one sub-adult—are represented by cranial and postcranial elements; one individual is represented by postcranial remains; and three individuals are represented by complete skeletons. The 10 associated funerary objects are one abalone shell, two projectile points, one doughnut stone, one swordfish sword with carved handle, three tarring pebbles, and two bone tools.

In August 1927, human remains representing, at minimum, 20 individuals were removed by David Banks Rogers from CA–SRI–60 (Rancho House Canyon, Hichimin), on Santa Rosa Island. 11 individuals—which include one sub-adult—are represented by cranial elements; seven individuals—which include one sub-adult—are represented by postcranial elements, one of which has an arrowhead embedded in it; and two individuals—a sub-adult and an infant—are represented by teeth. The 1550 associated funerary objects are 851 Olivella beads and bead fragments/
blanks; one asphaltum skirt weight; two biface fragments; two chert flakes; 34 drills; two clam shell ornaments; 45 abalone ornament fragments; two Megathura crenulata ornaments; one worked abalone rim fragment; one bone bipoint; two bone artifacts; three abalone tube beads; one dentalium tube bead; one unworked shell fragment; four chert knives; one arrowhead; two fishhook blanks; 296 bladelet drills; one bone pin; one bone whistle; one piece of twisted cordage; eight large clam tube beads; one strand of abalone beads; 226 shell bead fragments; seven fragments of eel grass matting; four bone tools; one abalone fishhook; one pierced piece of steatite; one rim fragment of a cup; one strand of stone and shell beads; two limpet ornaments; one abalone ornament; one bone awl; five chert points; one piece of hand forged metal; and 36 pendants and ornaments.

At an unknown date, human remains representing, at minimum, one individual were removed from CA–SRI–61 (Skunk Point), on Santa Rosa Island. The human remains were given to Harold J. Bell of Camarillo by the then foreman of the Vail and Vickers Ranch, and were subsequently donated to the SBMNH by Patricia Bell in 1987. The human remains are represented by a cranial and mandible. No known individuals were identified. No associated funerary objects are present.

In 1927 and 1950, human remains representing, at minimum, 11 individuals were removed by David Banks Rogers (1927) and Phil C. Orr (1950) from CA–SRI–62 (Johnson’s Lee, “Nilalu’y”), on Santa Rosa Island. Three individuals—which include two subadults—are represented by cranial elements; three individuals—which include one infant—are represented by postcranial elements; one individual, a subadult, is represented by cranial elements with postcranial elements; and four individuals—which include one subadult—are represented by complete skeletons. No known individuals were identified. The 176 associated funerary objects are one fragment of a pear-shaped donut stone; one glass bead; one abalone fishhook; one maul; four worked bone artifacts; two unworked bone artifacts; one donut stone; four pieces of unwoven eel grass which were wrapped around the burials; 96 shell beads and bead blanks/fragments; one charcoal sample; one sandstone basket mortar; one abalone shell fragment; one abalone pendant; one Mitra ideae shell; one abalone shell; one fishhook fragment; one pestle; one fish jaw ornament; 55 bone tube fragments; and one stone ornament.

At an unknown date, human remains representing, at minimum, four individuals were removed from CA–SRI–63 (Johnson’s East), on Santa Rosa Island. Beginning in 1950, the site was heavily impacted by the construction of a U.S. Air Force base. The remains were possibly recovered by Air Force personnel; however, there were no field notes from this salvage work that could be located. The four individuals are represented by partial crania, one of which is burned. No known individuals were identified. No associated funerary objects are present.

On October 4, 1952, human remains representing, at minimum, one individual were removed by Phil C. Orr from CA–SRI–72 (South of SE Anchorage), on Santa Rosa Island. This individual is represented by cranial elements. No known individuals were identified. No associated funerary objects are present.

In 1927, human remains representing, at minimum, three individuals were removed by Rogers from CA–SRI–78 (Water Canyon), Santa Rosa Island. One very old individual is represented by a mandible; one individual is represented by cranial elements and 13 teeth; and one individual is represented by a phalanx. The eight associated funerary objects are one strand of shell, bone, and stone beads and seven shell bead fragments.

In 1949, human remains representing, at minimum, three individuals were removed by Phil C. Orr from CA–SRI–128 (Pemberton No. 1 Well), on Santa Rosa Island. Two sets of human remains are attributed to Orr’s excavations in 1949 and one set of human remains was likely salvaged by oil drilling crews. The three individuals are represented by partial crania. No known individuals were identified. No associated funerary objects are present.

In 1959, human remains representing, at minimum, one individual were removed by Phil C. Orr from CA–SRI–168 (Moss Cave), on Santa Rosa Island. This individual is represented by six rib fragments and strands of human hair. No known individuals were identified. No associated funerary objects are present.

In late 1960, human remains representing, at minimum, four individuals were removed from CA–SRI–173 (Arlington Springs), Santa Rosa Island. This individual is represented by two partial femora, including one encased in a soil matrix. No known individuals were identified. No associated funerary objects are present.

In 1958, human remains representing, at minimum, 22 individuals were removed by W. Banning Vail from an unknown location a few miles west of Ranch House, on Santa Rosa Island. These human remains were donated by Vail to the SBMNH in 1983. The human remains include cranial elements, teeth, postcranial elements, and additional unidentified fragments of bone. The minimum number of individuals was determined by the presence of 22 right scapulae. No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, two individuals were removed from unknown sites on Santa Rosa Island (NA–CA–SRI–XX–12–1 through NA–CA–SRI–XX–12–5). One set of remains was donated by Margaret Wooley in 1994. One set of remains was donated to the SBMNH in 2001 by Ed McGowan, who had obtained them from the estate of geologist Holmut Ehrenspeck, in the 1970s. One set of remains was donated to the SBMNH in 2008 by E.R. Blakley. One set of remains was discovered by Raymond Winters’s uncle in the 1940s and was later donated to the Museum by Mr. Winters in 2007. Four individuals are represented by cranial elements and one individual is represented by cranial and postcranial elements. No known individuals were identified. The 82 associated funerary objects are one Olivella bisplicata barrel bead, one strand of shell beads, 77 bead fragments, one Halolithus pendant, one Tivola stultorum ornament, and one worked ground stone artifact.

Ventura County

On a date prior to 1998, human remains representing, at minimum, four individuals were removed from Simomo (site CA–VEN–24). The human remains were donated to the SBMNH in 1998 by Ed Mercurio. The individuals are represented by cranial and postcranial elements. No known individuals were identified. No associated funerary objects are present.

Sometime between May 7 and June 26, 1942, human remains representing, at minimum, 16 individuals were removed by Phil C. Orr from Soule Ranch (site CA–VEN–61). The individuals are represented by cranial and postcranial elements. No known individuals were identified. The 110 associated funerary objects are one bone awl, one bone tube bead, three abalone beads, two stone bowls, 14 decorated bone tube fragments, 5 Olivella beads, one biface, one stone weight, one perforated tooth, one strand of shell.
beads with a tooth, five whistle fragments, one bone implement, 20 bone tube fragments, one stone sphere, one steatite mortar, one Trivia californiana shell, one Cerithidea sp. horn shell, one turtle shell in fragments, and one bone hairpin.

Sometime in the 1960s, human remains representing, at minimum, 12 individuals were removed by Robert O. Browne from the Browne site (CA–VEN–150). The human remains were transferred to the SBMNH in 2005. The individuals—which include one subadult—are represented by cranial and postcranial elements. No known individuals were identified. No associated funerary objects are present.

On an unknown date before 1998, human remains representing, at minimum, one individual were removed from Chumash Park (site CA–VEN–165). The human remains were donated to the SBMNH by Ed Mercurio in 1998. The individual is represented by a fragmented mandible with fragmented postcranial elements. No known individuals were identified. No associated funerary objects are present.

In 1937, human remains representing, at minimum, one individual were removed by John G. Dalton from an unknown location near Ojai. The individual is represented by cranial and postcranial elements. No known individuals were identified. No associated funerary objects are present.

In August 1931, human remains representing, at minimum, one individual were removed by C. Otis Miller from Lake Sherwood. The individual is represented by cranial elements. No known individuals were identified. No associated funerary objects are present.

In 1983, human remains representing, at minimum, one individual were removed by Ken Ritzi from an unknown location in Oxnard. The human remains were donated to the SBMNH by Ken Ritzi in 2012. The individual is represented by a femur fragment. No known individuals were identified. No associated funerary objects are present.

San Luis Obispo County

In late October or early November 1968, human remains representing, at minimum, one individual were removed from Shell Beach (site CA–SLO–58). The human remains were donated to the SBMNH by Gregory Garman of Contraflaga College. The individual is represented by a fragmentary cranium and mandible with minimal postcranial elements. No known individuals were identified. No associated funerary objects are present.

On an unknown date, human remains representing, at minimum, one individual were removed from Morro Bay Mesa. The human remains were labeled with “N. of Main St., Moro Bay Mesa, Overlooking Moro Rock.” The individual is represented by a cranium and mandible. No known individuals were identified. No associated funerary objects are present.

Sometime before 1998, human remains representing, at minimum, one individual were removed from site CA–SLO–834, one mile east at Atascadero, San Luis Obispo County, CA. The human remains were donated to the SBMNH by Major George Mansfield in 1954. The individual is represented by a vertebra. No known individuals were identified. No associated funerary objects are present.

Los Angeles County

On an unknown date, human remains representing, at minimum, one individual were removed from Solstice Canyon. The human remains were found in Phil Orr’s personal collection, and were donated to the SBMNH. The individual is represented by a cranium and a mandible. No known individuals were identified. No associated funerary objects are present.

Sometime prior to 1998, human remains representing, at minimum, two individuals were removed from unknown locations in Los Angeles County. According to the labeling, the origin of the human remains is, variously, “Agoura” and the “Santa Monica Mtns. Coast, west of Zuma Beach.” The human remains were donated to the SBMNH by Ed Mercurio in 1998. One individual is represented by teeth, and the other individual is represented by a fragmentary cranium. No known individuals were identified. No associated funerary objects are present.

San Luis Obispo County

The majority of the human remains and associated funerary objects listed in this notice date to three periods in prehistory recognized by archeologists working the Santa Barbara Channel region: Early Period (9,000 to 3,000 years ago), Middle Period (3,000 to 800 years ago), and Late Period (800 to 200 years ago). Linguistic, archeological, and biological evidence demonstrate many millennia of Chumash cultural presence in the Santa Barbara region, beginning in the Early Period. A cultural affiliation study completed for the National Park Service in 1999 demonstrated that Chumash communities in the twentieth century possess continuity with identifiable earlier groups that inhabited the Santa Barbara Channel region at the time of European contact and settlement. The only federally recognized tribe of Chumash Indians today is the Santa Ynez Band of Mission Indians. Some individual members of the federally recognized Tejon Indian Tribe also possess Chumash ancestry.

Determination Made by the Santa Barbara Museum of Natural History

Officials of the Santa Barbara Museum of Natural History have determined that:

Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 1,011 individuals of Native American ancestry.

Pursuant to 25 U.S.C. 3001(3)(A), the 36,943 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Luke Sweetland, President and CEO, Santa Barbara Museum of Natural History, 2559 Puesta del Sol, Santa Barbara, CA 93105, telephone (805) 682–4711, by November 2, 2020. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Santa Ynez Band of Chumash Mission Indians.
of the Santa Ynez Reservation, California may proceed.

The Santa Barbara Museum of Natural History is responsible for notifying the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California that this notice has been published.

Melanie O’Brien,
Manager, National NAGPRA Program.

* [FR Doc. 2020–21705 Filed 9–30–20; 8:45 am] BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–432 and 731–TA–1024–1028 (Third Review) and AA1921–188 (Fifth Review)]

Prestressed Concrete Steel Wire Strand From Brazil, India, Japan, Korea, Mexico, and Thailand;
Scheduling of Expedited Five-Year Reviews

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (“the Act”) to determine whether revocation of the antidumping duty orders on prestressed concrete steel wire strand (“PC strand”) from Brazil, India, Korea, Mexico, and Thailand, and the antidumping finding on PC strand from Japan, as well as revocation of the countervailing duty order on PC strand from India, would be likely to lead to continuation or recurrence of material injury.

DATES: June 5, 2020.


SUPPLEMENTARY INFORMATION: Background.—On June 5, 2020, the Commission determined that the domestic interested party group response to its notice of institution (85 FR 12331, March 2, 2020) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews. Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews and rules of general application, consult the Commission’s Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary’s Office will accept only electronic filings at this time. Filings must be made through the Commission’s Electronic Document Information System (EDIS, https://edis.usitc.gov). No-in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Staff report.—A staff report containing information concerning the subject matter of the reviews will be placed in the nonpublic record on September 28, 2020, and made available to persons on the Administrative Protective Order service list for these reviews. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission’s rules.

Written submissions.—As provided in section 207.62(d) of the Commission’s rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,2 and any party other than an interested party to the reviews may file written comments with the Secretary on what determinations the Commission should reach in the reviews. Comments are due on or before October 5, 2020. However, should the Department of Commerce (“Commerce”) extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce’s final results is three business days after the issuance of Commerce’s results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s Handbook on Filing Procedures, available on the Commission’s website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission’s procedures with respect to filings.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission’s rules.

By order of the Commission.
Lisa Barton,
Secretary to the Commission.

* [FR Doc. 2020–21737 Filed 9–30–20; 8:45 am] BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION


Carbazole Violet Pigment 23 From China and India; Institution of Five-Year Reviews


ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to the Tariff Act of 1930 (“the Act”), as amended, to determine whether revocation of the countervailing duty order on carbazole
violet pigment 23 from India and the antidumping duty orders on carbazole violet pigment 23 from China and India would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted October 1, 2020. To be assured of consideration, the deadline for responses is November 2, 2020. Comments on the adequacy of responses may be filed with the Commission by December 14, 2020.


General information concerning the Commission may also be obtained by accessing its internet server (https://www.usitc.gov). The public record for this proceeding may be viewed on the Commission’s electronic docket (EDIS) at https://edis.usitc.gov.

SUPPLEMENTARY INFORMATION:

Background.—On December 29, 2004, the Department of Commerce (“Commerce”) issued a countervailing duty order on carbazole violet pigment 23 from India (69 FR 77995) and antidumping duty orders on carbazole violet pigment 23 from China (69 FR 77987) and India (69 FR 77988). Following first five-year reviews by Commerce and the Commission, effective May 27, 2010, Commerce issued a continuation of the countervailing duty order on imports of carbazole violet pigment 23 from India (75 FR 29719) and antidumping duty orders on imports of carbazole violet pigment 23 from China and India (75 FR 29718). Following second five-year reviews by Commerce and the Commission, effective November 17, 2015, Commerce issued a continuation of the countervailing duty order on imports of carbazole violet pigment 23 from India and antidumping duty orders on imports of carbazole violet pigment 23 from China and India (80 FR 71773). The Commission is now conducting third reviews pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission’s Rules of Practice and Procedure at 19 CFR part 201, subparts A and B, and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct full or expedited reviews. The Commission’s determinations in any expedited reviews will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to these reviews:

(1) Subject Merchandise is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by Commerce.

(2) The Subject Countries in these reviews are China and India.

(3) The Domestic Like Product is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the Subject Merchandise. In its original determinations and its expedited first and second five-year review determinations, the Commission found a single Domestic Like Product comprised of both crude and finished carbazole violet pigment 23 that corresponds to Commerce’s scope.

(4) The Domestic Industry is the U.S. producers as a whole of the Domestic Like Product, or those producers whose collective output of the Domestic Like Product constitutes a major proportion of the total domestic production of the product. In its original determinations and its expedited first and second five-year determinations, the Commission defined the Domestic Industry to include all producers of crude and finished carbazole violet pigment 23.

(5) An Importer is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the Subject Merchandise into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the Subject Merchandise and, if the merchandise is sold to the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in 19 CFR 201.15(a). The Commission will determine whether to permit persons to appear in a review under Commission rule 19 CFR 201.15(b), even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission’s designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post-employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008).

Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to §207.7(a) of the Commission’s rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the Federal Register. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to §207.3 of the Commission’s rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter’s knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding may be
disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to § 207.61 of the Commission’s rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is November 2, 2020. Pursuant to § 207.62(b) of the Commission’s rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is December 14, 2020. All written submissions must conform with the provisions of § 201.8 of the Commission’s rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s Handbook on Filing Procedures, available on the Commission’s website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission’s procedures with respect to filings. Also, in accordance with §§ 201.16(c) and 207.3 of the Commission’s rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Please note the Secretary’s Office will accept only electronic filings at this time. Filings must be made through the Commission’s Electronic Document Information System (EDIS, https://edis.usitc.gov). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

No response to this request for information is required if a currently valid Office of Management and Budget (“OMB”) number is not displayed; the OMB number is 3117 0016/USITC No. 20–5–472, expiration date June 30, 2023. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to § 207.61(c) of the Commission’s rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to § 776(b) of the Act (19 U.S.C. 1677b(b)) in making its determinations in the reviews.

Information to be Provided in Response to This Notice of Institution: If you are a domestic producer, union/worker group, or trade/business association; import/export Subject Merchandise from more than one Subject Country; or produce Subject Merchandise in more than one Subject Country, you may file a single response. If you do so, please ensure that your response to each question includes the information requested for each pertinent Subject Country. As used below, the term “firm” includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1673(i) and (b) capacity (quantity) of your firm to produce the Domestic Like Product. Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(3) A list of all known and currently operating U.S. importers of the Domestic Like Product. Identify any known related parties and the nature of the relationship as defined in each Subject Country that currently export or have exported Subject Merchandise to the United States or other countries after 2014.

(4) A list of 3–5 leading purchasers in the U.S. market for the Domestic Like Product and the Subject Merchandise (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(5) A list of known sources of information on national or regional prices for the Domestic Like Product or the Subject Merchandise in the U.S. or other markets.

(6) If you are a U.S. producer of the Domestic Like Product, provide the following information on your firm’s operations on that product during calendar year 2019, except as noted (report quantity data in pounds and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the Domestic Like Product accounted for by your firm’s(s’) production;

(b) Capacity (quantity) of your firm to produce the Domestic Like Product (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime,
(a) Production (quantity and, if known, an estimate of the percentage of total production of Subject Merchandise in each Subject Country accounted for by your firm’s(s’) production;
(b) Capacity (quantity) of your firm(s) to produce the Subject Merchandise in each Subject Country (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and
(c) the quantity and value of your firm(s’) exports to the United States of Subject Merchandise and, if known, an estimate of the percentage of total exports to the United States of Subject Merchandise from each Subject Country accounted for by your firm’s(s’) exports.
(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the Domestic Like Product that have occurred in the United States or in the market for the Subject Merchandise in each Subject Country after 2014, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the Domestic Like Product produced in the United States, Subject Merchandise produced in each Subject Country, and such merchandise from other countries.
(13) (OPTIONAL) A statement of whether you agree with the above definitions of the Domestic Like Product and Domestic Industry; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission’s Rules of Practice and Procedure filed on behalf of Pictos Technologies, Inc. on September 25, 2020. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital imaging devices and products containing the same and
components thereof. The complaint names as respondents: Samsung Electronics Co., Ltd. of Korea; Samsung Electronics America, Inc. of Ridgefield Park, NJ; and Samsung Semiconductor, Inc. of San Jose, CA. The complainant requests that the Commission issue a limited exclusion order and cease and desist orders.

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant’s licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the Federal Register. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the Federal Register. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (“Docket No. 3494”) in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures 

Please note the Secretary’s Office will accept only electronic filings during this time. Filings must be made through the Commission’s Electronic Document Information System (EDIS, https://edis.usitc.gov). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at EDISHelp@usitc.gov.

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, solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission’s Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.


William Bishop,
Supervisory Hearings and Information Officer.

[PR Doc. 2020–21671 Filed 9–30–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–465 and 731–TA–1161 (Second Review)]

Certain Steel Grating From China; Institution of Five-Year Reviews


ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to the Tariff Act of 1930 (“the Act”), as amended, to determine whether revocation of the antidumping and countervailing duty orders on certain steel grating from China would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted October 1, 2020. To be assured of consideration, the deadline for responses is November 2, 2020. Comments on the adequacy of responses may be filed with the Commission by December 14, 2020.


SUPPLEMENTARY INFORMATION: Background.—On July 23, 2010, the Department of Commerce (“Commerce”) issued antidumping and countervailing duty orders on imports of certain steel grating from China (75 FR 43143–
the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the Subject Merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in §201.11(b)(4) of the Commission’s rules, no later than 21 days after publication of this notice in the Federal Register. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission’s designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post-employment statute for Federal employees, and Commission rule 201.15(b), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to §207.7(a) of the Commission’s rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the Federal Register. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to §207.3 of the Commission’s rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter’s knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to §207.61 of the Commission’s rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is November 2, 2020. Pursuant to §207.62(b) of the Commission’s rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is December 14, 2020. All written submissions must conform with the provisions of §201.8 of the Commission’s rules; any submissions that contain BPI must also conform with the requirements of §§201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s Handbook on Filing Procedures, available on the Commission’s website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission’s procedures with respect to filings. Also, in accordance with §§201.16(c) and 207.3 of the Commission’s rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany every document (if you are not a party to the proceeding you do not need to serve your response).
Please note the Secretary’s Office will accept only electronic filings at this time. Filings must be made through the Commission’s Electronic Document Information System (EDIS, https://edis.usitc.gov). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

No response to this request for information is required if a currently valid Office of Management and Budget (“OMB”) number is not displayed; the OMB number is 3117 0016/USITC No. 20–5–473, expiration date June 30, 2023. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to § 207.61(c) of the Commission’s rules, any interested party may fail to provide the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to § 776(b) of the Act (19 U.S.C. 1677b(b)) in making its determinations in the reviews.

Information to be Provided in Response to This Notice of Institution: As used below, the term “firm” includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how, including whether your firm/entity is a U.S. producer of the Domestic Like Product, a U.S. union or worker group, a U.S. importer of the Subject Merchandise, a foreign producer or exporter of the Subject Merchandise, a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or a foreign producer or exporter of the Subject Merchandise (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping and countervailing duty orders on the Domestic Industry in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of Subject Merchandise on the Domestic Industry.

(5) A list of all known and currently operating U.S. producers of the Domestic Like Product. Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the Subject Merchandise and producers of the Subject Merchandise in the Subject Country that currently export or have exported Subject Merchandise to the United States or other countries after 2014.

(7) A list of 3–5 leading purchasers in the U.S. market for the Domestic Like Product and the Subject Merchandise (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the Domestic Like Product or the Subject Merchandise in the U.S. or other markets.

(9) If you are a U.S. producer of the Domestic Like Product, provide the following information on your firm’s operations on that product during calendar year 2019, except as noted (report quantity data in kilograms and value data in U.S. dollars; f.o.b. plant).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the Subject Merchandise from the Subject Country, provide the following information on your firm’s(s’) operations on that product during calendar year 2019 (report quantity data in kilogram and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of Subject Merchandise from the Subject Country accounted for by your firm’s(s’) imports;

(b) The quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of Subject Merchandise imported from the Subject Country; and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of Subject Merchandise imported from the Subject Country.

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the Subject Merchandise in the Subject Country, provide the following information on your firm’s(s’) operations on that product during calendar year 2019 (report quantity data in kilograms and value data in U.S. dollars, landed and duty-paid at the U.S. port but not expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the Domestic Like Product produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the Domestic Like Product produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the Domestic Like Product produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).
including antidumping or countervailing duties. If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of Subject Merchandise in the Subject Country accounted for by your firm’s(s’) production;

(b) Capacity (quantity) of your firm(s) to produce the Subject Merchandise in the Subject Country (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm’s(s’) exports to the United States of Subject Merchandise and, if known, an estimate of the percentage of total exports to the United States of Subject Merchandise from the Subject Country accounted for by your firm’s(s’) exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the Domestic Like Product that have occurred in the United States or in the market for the Subject Merchandise in the Subject Country after 2014, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation from foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the Domestic Like Product produced in the United States, Subject Merchandise produced in the Subject Country, and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the Domestic Like Product and Domestic Industry; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission’s rules.

By order of the Commission.


William Bishop,
Hearings and Information Officer.
[FR Doc. 2020–21668 Filed 9–30–20; 8:45 am]
BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION
[Investigation No. 731–TA–149 (Fifth Review)]

Barium Chloride From China; Institution of a Five-Year Review


ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to the Tariff Act of 1930 (‘‘the Act’’), as amended, to determine whether revocation of the antidumping duty order on barium chloride from China would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted October 1, 2020. To be assured of consideration, the deadline for responses is November 2, 2020. Comments on the adequacy of responses may be filed with the Commission by December 14, 2020.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

Background.—On October 17, 1984, the Department of Commerce (‘‘Commerce’’) issued an antidumping duty order on imports of barium chloride from China (49 FR 40635). Commerce issued a continuation of the antidumping duty order on imports of barium chloride from China following the first five-year review (64 FR 42654, August 5, 1999), second five-year review (69 FR 47405, August 5, 2004), third five-year review (75 FR 36629, June 28, 2010), and fourth five-year review (80 FR 68511, November 5, 2015). The Commission is now conducting a fifth review pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time.

Provisions concerning the conduct of this proceeding may be found in the Commission’s Rules of Practice and Procedure at 19 CFR part 201, subparts A and B, and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct a full review or an expedited review. The Commission’s determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to this review:

(1) Subject Merchandise is the class or kind of merchandise that is within the scope of the five-year review, as defined by Commerce.

(2) The Subject Country in this review is China.

(3) The Domestic Like Product is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the Subject Merchandise. In its original determination, the Commission defined the Domestic Like Product as crystalline and anhydrous barium chloride, excluding high purity barium chloride. In its expedited first and second five-year review determinations, its full third five-year review determination, and its expedited fourth five-year review determination, the Commission found one Domestic Like Product coextensive with Commerce’s scope: All forms of barium chloride, including crystalline, anhydrous, and high purity. For purposes of responses to this notice, the Domestic Like Product is all forms of barium chloride, including crystalline, anhydrous, and high purity.

(4) The Domestic Industry is the U.S. producers as a whole of the Domestic Like Product, or those producers whose collective output of the Domestic Like Product constitutes a major proportion...
of the total domestic production of the product. In its original determination, its expedited first and second five-year review determinations, its full third five-year review determination, and its expedited fourth five-year review determination, the Commission defined the Domestic Industry as all domestic producers of the Domestic Like Product.

(5) An Importer is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the Subject Merchandise into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the Subject Merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in §201.11(b)(4) of the Commission’s rules, no later than 21 days after publication of this notice in the Federal Register. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission’s designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post-employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008).

Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to §207.7(a) of the Commission’s rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the Federal Register. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to §207.3 of the Commission’s rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter’s knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding may be disclosed and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to §207.61 of the Commission’s rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is November 2, 2020. Pursuant to §207.62(b) of the Commission’s rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is December 14, 2020. All written submissions must conform with the provisions of §201.8 of the Commission’s rules; any submissions that contain BPI must also conform with the requirements of §§201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s Handbook on Filing Procedures, available on the Commission’s website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission’s procedures with respect to filings. Also, in accordance with §§201.16(c) and 207.3 of the Commission’s rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Please note the Secretary’s Office will accept only electronic filings at this time. Filings must be made through the Commission’s Electronic Document Information System (EDIS, https://edis.usitc.gov). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

No response to this request for information is required if a currently valid Office of Management and Budget (“OMB”) number is not displayed; the OMB number is 3117 0016/USITC No. 20–4–471, expiration date June 30, 2023. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to §207.61(c) of the Commission’s rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to §2(6)(b) of the Act (19 U.S.C. 1677e(b)) in making its determination in the review.

Information to be Provided in Response to This Notice of Institution: As used below, the term “firm” includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how,
including whether your firm/entity is a U.S. producer of the Domestic Like Product, a U.S. union or worker group, a U.S. importer of the Subject Merchandise, a foreign producer or exporter of the Subject Merchandise, a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty order on the Domestic Industry in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 755(a)(5) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of Subject Merchandise on the Domestic Industry.

(5) A list of all known and currently operating U.S. producers of the Domestic Like Product. Identify any known related parties and the nature of the relationship as defined in §771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the Subject Merchandise and producers of the Subject Merchandise in the Subject Country that currently export or have exported Subject Merchandise to the United States or other countries after 2014.

(7) A list of 3–5 leading purchasers in the U.S. market for the Domestic Like Product and the Subject Merchandise (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the Domestic Like Product or the Subject Merchandise in the U.S. or other markets.

(9) If you are a U.S. producer of the Domestic Like Product, provide the following information on your firm’s operations on that product during calendar year 2019, except as noted (report quantity data in pounds and value data in U.S. dollars, f.o.b. plant).

If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the Domestic Like Product accounted for by your firm(s)’ production;

(b) Capacity (quantity) of your firm to produce the Domestic Like Product (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the Domestic Like Product produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of Domestic Like Product produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG& A) expenses, and (v) operating income of the Domestic Like Product produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the Subject Merchandise from the Subject Country, provide the following information on your firm’s(s’) operations on that product during calendar year 2019 (report quantity data in pounds and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of Subject Merchandise from the Subject Country accounted for by your firm’s(s’) imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. commercial shipments of Subject Merchandise imported from the Subject Country; and

(c) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. internal consumption/company transfers of Subject Merchandise imported from the Subject Country.

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the Subject Merchandise in the Subject Country, provide the following information on your firm’s(s’) operations on that product during calendar year 2019 (report quantity data in pounds and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of Subject Merchandise in the Subject Country accounted for by your firm’s(s’) production;

(b) Capacity (quantity) of your firm(s) to produce the Subject Merchandise in the Subject Country (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm’s(s’) exports to the United States of Subject Merchandise and, if known, an estimate of the percentage of total exports to the United States of Subject Merchandise from the Subject Country accounted for by your firm’s(s’) exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the Domestic Like Product that have occurred in the United States or in the market for the Subject Merchandise in the Subject Country after 2014, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the Domestic Like Product produced in the United States, Subject Merchandise produced in the Subject
Country, and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the Domestic Like Product and Domestic Industry; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

By order of the Commission.


William Bishop,
Supervisory Hearings and Information Officer.

[FR Doc. 2020–21667 Filed 9–30–20; 8:45 am]
BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE
[OMB Number 1140–0058]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Investigator Integrity Questionnaire—ATF Form 8620.7

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice

ACTION: 30-day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for an additional 30 days until November 2, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

1. Type of Information Collection: Revision of a currently approved collection.

2. The Title of the Form/Collection: Investigator Integrity Questionnaire.

3. The agency form number, if any, and the applicable component of the Department sponsoring the collection: Form number: ATF Form 8620.7. Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. Affected public who will be asked or required to respond, as well as a brief abstract:

Primary: Individuals or households.
Other: None.

Abstract: Persons interviewed by ATF contract investigators are randomly selected to complete the Investigator Integrity Questionnaire—ATF Form 8620.7, which measures the effectiveness, efficiency and professionalism of investigators while conducting interviews for a Federal background investigation. Individuals may voluntarily participate in this survey by providing an email address during their interview.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: An estimated 2,500 respondents will utilize the survey annually, and it will take each respondent approximately 5 minutes to complete each response.

(6) An estimate of the total public burden (in hours) associated with the collection: The estimated annual public burden associated with this collection is 208 hours, which is equal to 2,500 (# of respondents) * .083 (5 minutes or the time taken to complete each response).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.


Melody Braswell,
Department Clearance Officer for PRA, U. S. Department of Justice.

[FR Doc. 2020–21722 Filed 9–30–20; 8:45 am]
BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under The Clean Water Act

On September 25, 2020, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern of Texas in the lawsuit entitled United States and State of Texas v. City of Corpus Christi, Civil Action No. 2:20–cv–00235.

The United States and the State of Texas filed a joint Complaint against the City, pursuant to Section 309(b) of the Clean Water Act, 33 U.S.C. 1319(b), and provisions of the Texas Water Code. The Complaint seeks, inter alia, injunctive relief to address and eliminate illegal discharges, namely sanitary sewer overflows, occurring from the City’s wastewater collection and transmission system and discharges of pollutants from wastewater treatment plants that exceed effluent limits established in state-issued permits. Under the proposed Consent Decree, the City will implement comprehensive injunctive relief measures to eliminate and prevent such violations. The City will pay a civil penalty of $1.136 million, which amount will be shared equally by the United States and the State.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to United States and State of Texas v. City of Corpus Christi, D.J. Ref. No. 90–5–1–10396. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments: Send them to:

By email: pubcomment-ees.enrd@usdoj.gov
DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA")

On September 28, 2020, the Department of Justice lodged a proposed consent decree with the United States District Court for the District of New Jersey in the lawsuit entitled United States of America, New Jersey Department of Environmental Protection, and Administrator of the New Jersey Spill Compensation Fund v. Hercules LLC, Civil Action No. 1:20-cv-13377, D.J. Ref. No. 90–11–3–12075. All comments must be submitted no later than sixty (60) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments: Send them to:

By email .......... pubcomment-ees.enrd@usdoj.gov
By mail .......... Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the consent decree may be examined and downloaded at this Justice Department website: https://www.justice.gov/enrd/consent-decrees. We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $38.00 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $19.75.

Kenneth Long,
Acting Assistant Section Chief,
Environmental Enforcement Section,
Environment and Natural Resources Division.

[FR Doc. 2020–21732 Filed 9–30–20; 8:45 am]
BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Hercules LLC ("Hercules") agrees to perform the remedial action for OU1 and OU2 that is identified in the United States Environmental Protection Agency's ("EPA") Record of Decision relating to the Site, dated September 25, 2018. The proposed consent decree requires Hercules to fully reimburse the United States for $143,943 in past response costs and to pay New Jersey's past response costs of approximately $129,036. The proposed consent decree also requires Hercules to reimburse the United States and New Jersey for their future Site-related response costs.

The publication of this notice opens a period for public comment on the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, Environmental Enforcement Section, and should refer to United States of America, New Jersey Department of Environmental Protection, and Administrator of the New Jersey Spill Compensation Fund v. Hercules LLC, Civil Action No. 1:20-cv-13377, D.J. Ref. No. 90–11–3–12075. All comments must be submitted no later than sixty (60) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments: Send them to:

By email .......... pubcomment-ees.enrd@usdoj.gov
By mail .......... Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the consent decree may be examined and downloaded at this Justice Department website: https://www.justice.gov/enrd/consent-decrees. We will provide a paper copy of the consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $76.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Henry S. Friedman,
Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2020–21740 Filed 9–30–20; 8:45 am]
BILLING CODE 4410–15–P

This notice announces a forthcoming virtual meeting of the National Institute of Corrections (NIC) Advisory Board. The meeting will be open to the public.

Name of the Committee: NIC Advisory Board.

General Function of the Committee: To aid the National Institute of Corrections in developing long-range plans, advise on program development, and recommend guidance to assist NIC’s efforts in the areas of training, technical assistance, information services, and policy/program development assistance to Federal, state, and local corrections agencies.

Date and Time: 1–4 p.m. EDT on Monday, October 26, 2020; 1–4 p.m. EDT on Tuesday, October 27, 2020; 1–4 p.m. EDT on Thursday, October 29, 2020 (approximate times each day).

Location: Virtual Platform.

Contact Person: Scott Weygandt, Executive Assistant, National Institute of Corrections, 320 First Street NW, Room 901–3, Washington, DC 20534. To contact Mr. Weygandt, please call (303) 338–6626.

Date and Time: 1–4 p.m. EDT on Monday, October 26, 2020; 1–4 p.m. EDT on Tuesday, October 27, 2020; 1–4 p.m. EDT on Thursday, October 29, 2020 (approximate times each day).

Location: Virtual Platform.

Contact Person: Scott Weygandt, Executive Assistant, National Institute of Corrections, 320 First Street NW, Room 901–3, Washington, DC 20534. To contact Mr. Weygandt, please call (303) 338–6626.

Agenda: Over the course of three days (October 26, 27, and 29, 2020), the Advisory Board will receive an (1) Agency Report from the NIC Acting Director and (2) overviews/updates from the agency’s programmatic divisions (jails, prisons, community services, and academy divisions). Time for questions and counsel is built in to the agenda. Initial planning for FY21 Advisory Board meeting(s) will also occur.

Procedure: On October 26, 27, and 29, 2020, the meetings are open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 15, 2020. Oral presentations from the public will be scheduled between approximately 3:00 p.m. to 3:15 p.m. each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 15, 2020.

General Information: NIC welcomes the attendance of the public at its
of the Trade Act of 1974 ("the Act") and
are identified in the Appendix to this
notice. Upon receipt of these petitions,
the Administrator of the Office of Trade
Adjustment Assistance, Employment
and Training Administration, has
instituted investigations pursuant to
Section 221(a) of the Act.

The purpose of each of the
investigations is to determine whether
the workers are eligible to apply for
adjustment assistance under Title II,
Chapter 2, of the Act. The investigations
will further relate, as appropriate, to the
determination of the date on which total
or partial separations began or
threatened to begin and the subdivision
of the firm involved.

The petitioners or any other persons
showing a substantial interest in the
subject matter of the investigations may
request a public hearing provided such request is filed in writing with the
Administrator, Office of Trade
Adjustment Assistance, at the address
shown below, no later than October 13,
2020.

Interested persons are invited to
submit written comments regarding the
subject matter of the investigations to
the Administrator, Office of Trade
Adjustment Assistance, at the address
shown below, not later than October 13,
2020.

The petitions filed in this case are
available for inspection at the Office of
the Administrator, Office of Trade
Adjustment Assistance, Employment
and Training Administration, U.S.
Department of Labor, Room N–5428,
200 Constitution Avenue NW,
Washington, DC 20210.

Signed at Washington, DC this 16th day of
September 2020.

Hope D. Kinglock,
Certifying Officer, Office of Trade Adjustment
Assistance.

Appendix

52 TAA Petitions Instituted Between 8/1/20 and 8/31/20

<table>
<thead>
<tr>
<th>TA-W</th>
<th>Subject firm (petitioners)</th>
<th>Location</th>
<th>Date of institution</th>
<th>Date of petition</th>
</tr>
</thead>
<tbody>
<tr>
<td>96116</td>
<td>Motorola Mobility LLC (Workers)</td>
<td>Chicago, IL</td>
<td>08/03/20</td>
<td>07/31/20</td>
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<tr>
<td>96117</td>
<td>Secure Contact Solutions, LLC (Company)</td>
<td>Alpharetta, GA</td>
<td>08/03/20</td>
<td>07/31/20</td>
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<tr>
<td>96118</td>
<td>Johnson Controls Inc. (Workers)</td>
<td>Marinette, WI</td>
<td>08/04/20</td>
<td>08/02/20</td>
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<tr>
<td>96119</td>
<td>CSS Corporation (State/One-Stop)</td>
<td>Draper, UT</td>
<td>08/05/20</td>
<td>08/04/20</td>
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<tr>
<td>96120</td>
<td>Glen Raven Custom Fabrics (State/One-Stop)</td>
<td>Sunbury, PA</td>
<td>08/05/20</td>
<td>08/04/20</td>
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<tr>
<td>96121</td>
<td>Hewlett-Packard Enterprise (State/One-Stop)</td>
<td>Fort Collins, CO</td>
<td>08/05/20</td>
<td>08/04/20</td>
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<tr>
<td>96122</td>
<td>Ran-Tech Engineering &amp; Aerospace, Inc. (State/One-Stop)</td>
<td>Clackamas, OR</td>
<td>08/05/20</td>
<td>08/05/20</td>
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<td>96123</td>
<td>SECO Warwick Corporation (Company)</td>
<td>Meadville, PA</td>
<td>08/05/20</td>
<td>08/04/20</td>
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<td>96124</td>
<td>PECO, Inc. an Astronics Company (State/One-Stop)</td>
<td>Clackamas, OR</td>
<td>08/06/20</td>
<td>08/05/20</td>
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<td>96125</td>
<td>Indiana’s Goodwill Ambassador Inc. (Company)</td>
<td>Indianapolis, IN</td>
<td>08/06/20</td>
<td>08/06/20</td>
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<td>96126</td>
<td>NMG LLC (State/One-Stop)</td>
<td>Norfolk, NE</td>
<td>08/06/20</td>
<td>08/05/20</td>
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<td>96127</td>
<td>Levi Strauss &amp; Company (State/One-Stop)</td>
<td>Eugene, OR</td>
<td>08/07/20</td>
<td>08/06/20</td>
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<td>96128</td>
<td>Southwick LLC (Union)</td>
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<td>08/07/20</td>
<td>08/06/20</td>
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<td>96129</td>
<td>Molinlycke (State/One-Stop)</td>
<td>Indianapolis, IN</td>
<td>08/10/20</td>
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<td>96130</td>
<td>Lands’ End, Inc. (Company)</td>
<td>Dodgeville, WI</td>
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<td>Mid Continent Controls, Inc. (State/One-Stop)</td>
<td>Derby, KS</td>
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<td>96132</td>
<td>Southwick/Brooks Brothers/Golden Fleece (State/One-Stop)</td>
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<td>Toray Composite Materials America, Inc. (State/One-Stop)</td>
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<td>08/08/20</td>
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<td>96134</td>
<td>Trulife Engineered Solutions (State/One-Stop)</td>
<td>Bellingham, WA</td>
<td>08/11/20</td>
<td>08/08/20</td>
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<tr>
<td>96135</td>
<td>Allegheny Technologies Inc. Specialty Alloys &amp; Components (Union).</td>
<td>Albany, OR</td>
<td>08/13/20</td>
<td>08/12/20</td>
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<tr>
<td>96136</td>
<td>Cooper Standard (Company)</td>
<td>Surgoinsville, TN</td>
<td>08/13/20</td>
<td>08/12/20</td>
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<tr>
<td>96137</td>
<td>Jones &amp; Vining, Inc. (State/One-Stop)</td>
<td>Walnut Ridge, AR</td>
<td>08/13/20</td>
<td>08/12/20</td>
</tr>
<tr>
<td>96138</td>
<td>Mosey Manufacturing (State/One-Stop)</td>
<td>Richmond, IN</td>
<td>08/13/20</td>
<td>08/12/20</td>
</tr>
<tr>
<td>96139</td>
<td>Wauapaca Foundry, Inc. (State/One-Stop)</td>
<td>Lawrenceville, PA</td>
<td>08/13/20</td>
<td>08/12/20</td>
</tr>
<tr>
<td>96140</td>
<td>Maxion Wheels Akron LLC (State/One-Stop)</td>
<td>Akron, OH</td>
<td>08/14/20</td>
<td>08/13/20</td>
</tr>
<tr>
<td>96141</td>
<td>Boeing Distribution Services Inc. (Company)</td>
<td>Miami, FL</td>
<td>08/17/20</td>
<td>08/14/20</td>
</tr>
<tr>
<td>96142</td>
<td>Libbey Glass (Company)</td>
<td>Shreveport, LA</td>
<td>08/18/20</td>
<td>08/17/20</td>
</tr>
<tr>
<td>96143</td>
<td>Nokia (State/One-Stop)</td>
<td>Naperville, IL</td>
<td>08/18/20</td>
<td>08/17/20</td>
</tr>
<tr>
<td>96144</td>
<td>Signify North America Corporation (State/One-Stop)</td>
<td>Salina, KS</td>
<td>08/18/20</td>
<td>08/17/20</td>
</tr>
<tr>
<td>96145</td>
<td>TECT Aerospace (State/One-Stop)</td>
<td>Wichita, KS</td>
<td>08/18/20</td>
<td>08/17/20</td>
</tr>
<tr>
<td>96146</td>
<td>James Counts (Company)</td>
<td>Surprise, AZ</td>
<td>08/19/20</td>
<td>08/18/20</td>
</tr>
<tr>
<td>96147</td>
<td>Pittsburgh Glass Works, LLC (Company)</td>
<td>Pittsburgh, PA</td>
<td>08/19/20</td>
<td>08/19/20</td>
</tr>
<tr>
<td>96148</td>
<td>SRG Global (State/One-Stop)</td>
<td>Newbern &amp; Ripley, TN</td>
<td>08/19/20</td>
<td>08/18/20</td>
</tr>
<tr>
<td>96149</td>
<td>Titanium Metals Corporation (TIMET) (Union)</td>
<td>Toronto, OH</td>
<td>08/19/20</td>
<td>08/17/20</td>
</tr>
<tr>
<td>96150</td>
<td>United States Steel Corporation (State/One-Stop)</td>
<td>Boysers, PA</td>
<td>08/20/20</td>
<td>08/17/20</td>
</tr>
<tr>
<td>96151</td>
<td>United States Gypsum (State/One-Stop)</td>
<td>Norfolk, VA</td>
<td>08/20/20</td>
<td>08/18/20</td>
</tr>
<tr>
<td>96152</td>
<td>Comcast Technology Solutions, LLC (State/One-Stop)</td>
<td>Battle, WA</td>
<td>08/21/20</td>
<td>08/19/20</td>
</tr>
<tr>
<td>96153</td>
<td>Therm-O-Disc (State/One-Stop)</td>
<td>Mansfield, OH</td>
<td>08/21/20</td>
<td>08/20/20</td>
</tr>
</tbody>
</table>
DEPARTMENT OF LABOR
Employment and Training Administration

Post-Initial Determinations Regarding Eligibility To Apply for Trade Adjustment Assistance

In accordance with Sections 223 and 284 (19 U.S.C. 2273 and 2395) of the Trade Act of 1974 (19 U.S.C. 2271, et seq.) (“Act”), as amended, the Department of Labor herein presents the following revised determinations regarding eligibility to apply for trade adjustment assistance under Chapter 2 of the Act (“TAA”) for workers by (TA–W) number issued during the period of August 1st, 2020 through August 31st, 2020. These determinations are available on the Department’s website https://

<table>
<thead>
<tr>
<th>TA–W No.</th>
<th>Subject firm</th>
<th>Location</th>
<th>Impact date</th>
<th>Reason(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>95,014</td>
<td>Delphi Technologies Services, LLC</td>
<td>West Henrietta, NY</td>
<td>7/21/2018</td>
<td>Worker Group Clarification.</td>
</tr>
<tr>
<td>95,421</td>
<td>Dun &amp; Bradstreet, Inc. (D &amp; B)</td>
<td>Tucson, AZ</td>
<td>11/5/2018</td>
<td>Worker Group Clarification.</td>
</tr>
<tr>
<td>95,970</td>
<td>Dun &amp; Bradstreet, Inc. (D &amp; B)</td>
<td>Waltham, MA</td>
<td>11/5/2018</td>
<td>Worker Group Clarification.</td>
</tr>
<tr>
<td>95,421A</td>
<td>Pittsburgh Glass Works, LLC</td>
<td>Evansville, IN</td>
<td>6/5/2019</td>
<td>Worker Group Clarification.</td>
</tr>
<tr>
<td>95,970A</td>
<td>Pittsburgh Glass Works, LLC</td>
<td>Pittsburgh, PA</td>
<td>6/5/2019</td>
<td>Worker Group Clarification.</td>
</tr>
<tr>
<td>95,970B</td>
<td>Pittsburgh Glass Works, LLC</td>
<td>Rochester Hills, MI</td>
<td>6/5/2019</td>
<td>Worker Group Clarification.</td>
</tr>
</tbody>
</table>

I hereby certify that the aforementioned determinations were issued during the period of August 1st, 2020 through August 31st. These determinations are available on the Department’s website https://
www.doleta.gov/tradeact/petitioners/taa_search_form.cfm under the searchable listing determinations or by calling the Office of Trade Adjustment Assistance toll free at 888-365-6822.

Signed at Washington, DC this 16th day of September, 2020.

Hope D. Kinglock,
Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2020-21713 Filed 9-30-20; 8:45 am]
BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Trade Adjustment Assistance

In accordance with the Section 223 (19 U.S.C. 2273) of the Trade Act of 1974 (19 U.S.C. 2271, et seq.) ("Act"), as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance under Chapter 2 of the Act ("TAA") for workers by (TA–W) number issued during the period of August 1, 2020 through August 31, 2020. (This Notice primarily follows the language of the Trade Act. In some places however, changes such as the inclusion of subheadings, a reorganization of language, or "and," "or," or other words are added for clarification.)

Section 222(a)—Workers of a Primary Firm

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for TAA, the group eligibility requirements under Section 222(a) of the Act (19 U.S.C. 2272(a)) must be met, as follows:

(1) The first criterion (set forth in Section 222(a)(1) of the Act, 19 U.S.C. 2272(a)(1)) is that a significant number or proportion of the workers in such workers’ firm (or “such firm”) have become totally or partially separated, or are threatened to become totally or partially separated; AND (ii and iii below)

(2) The second criterion (set forth in Section 222(a)(2) of the Act, 19 U.S.C. 2272(a)(2)) may be satisfied by either (A) the Increased Imports Path, or (B) the Shift in Production or Services to a Foreign Country Path/Acquisition of Articles or Services from a Foreign Country Path, as follows:

(A) Increased Imports Path:

(i) the sales or production, or both, of such firm, have decreased absolutely; AND (ii and iii below)

(ii) (I) imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased; OR

(II) (aa) imports of articles like or directly competitive with articles incorporated, have increased; OR

(ii) (bb) imports of articles like or directly competitive with articles which are produced directly using the services supplied by such firm, have increased; OR

(iii) imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased; AND

(iv) the increase in imports described in clause (ii) contributed importantly to such workers’ separation or threat of separation and to the decline in the sales or production of such firm; OR

(B) Shift in Production or Services to a Foreign Country Path OR Acquisition of Articles or Services From a Foreign Country Path:

(i) (I) there has been a shift by such workers’ firm to a foreign country in the production of articles or the supply of services like or directly competitive with articles which are produced or services which are supplied by such firm; OR

(ii) such workers’ firm has acquired from a foreign country articles or services that are like or directly competitive with articles which are produced or services which are supplied by such firm; OR

(ii) the petition is filed during the 1-year period beginning on the date on which—

(A) an affirmative determination of serious injury or threat thereof under section 202(b)(1) of the Act (19 U.S.C. 2252(b)(1)); OR

(B) an affirmative determination of market disruption or threat thereof under section 421(b)(1) of the Act (19 U.S.C. 2436(b)(1)); OR

(C) an affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A)); AND

(i) (I) there has been a shift by such workers’ firm to a foreign country in the production of articles or the supply of services like or directly competitive with articles which are produced or services which are supplied by such firm; OR

(ii) the petition is filed during the 1-year period beginning on the date on which—

(A) a summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) of the Trade Act (19 U.S.C. 2252(f)(1)) with respect to the affirmative determination described in paragraph (1)(A) is published in the Federal Register under section 202(f)(3) (19 U.S.C. 2252(f)(3)); OR

Section 222(e)—Firms identified by the International Trade Commission

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for TAA, the group eligibility requirements of Section 222(e) of the Act (19 U.S.C. 2272(e)) must be met, by following criteria (1), (2), and (3) as follows:

(1) The workers’ firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) an affirmative determination of serious injury or threat thereof under section 202(b)(1) of the Act (19 U.S.C. 2252(b)(1)); OR

(B) an affirmative determination of market disruption or threat thereof under section 421(b)(1) of the Act (19 U.S.C. 2436(b)(1)); OR

(C) an affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A)); AND

(ii) the petition is filed during the 1-year period beginning on the date on which—

(A) a summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) of the Trade Act (19 U.S.C. 2252(f)(1)) with respect to the affirmative determination described in paragraph (1)(A) is published in the Federal Register under section 202(f)(3) (19 U.S.C. 2252(f)(3)); OR

Section 222(b)—Adversely Affected Secondary Workers

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for TAA, the group eligibility requirements of Section 222(b) of the Act (19 U.S.C. 2272(b)) must be met, as follows:

(1) A significant number or proportion of the workers in the workers’ firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated; AND

(2) the workers’ firm is a supplier or downstream producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act (19 U.S.C. 2272(a)), and such supply or production is related to the article or service that was the basis for such certification (as defined in subsection 222(c)(3) and (4) of the Act (19 U.S.C. 2272(c)(3) and (4))); AND

(3) either—

(A) the workers’ firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers’ firm; OR

(B) a loss of business by the workers’ firm with the firm described in paragraph (2) contributed importantly to the workers’ separation or threat of separation determined under paragraph (1).

Section 222(e)—Firms identified by the International Trade Commission

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for TAA, the group eligibility requirements of Section 222(e) of the Act (19 U.S.C. 2272(e)) must be met, by following criteria (1), (2), and (3) as follows:

(1) The workers’ firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) an affirmative determination of serious injury or threat thereof under section 202(b)(1) of the Act (19 U.S.C. 2252(b)(1)); OR

(B) an affirmative determination of market disruption or threat thereof under section 421(b)(1) of the Act (19 U.S.C. 2436(b)(1)); OR

(C) an affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A)); AND

(ii) the petition is filed during the 1-year period beginning on the date on which—

(A) a summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) of the Trade Act (19 U.S.C. 2252(f)(1)) with respect to the affirmative determination described in paragraph (1)(A) is published in the Federal Register under section 202(f)(3) (19 U.S.C. 2252(f)(3)); OR
The following certifications have been issued. The requirements of Section 222(a)(2)(B) (Shift in Production or Acquisition of Articles or Services from a Foreign Country Path) of the Trade Act have been met.

<table>
<thead>
<tr>
<th>TA-W No.</th>
<th>Subject firm</th>
<th>Location</th>
<th>Impact date</th>
</tr>
</thead>
<tbody>
<tr>
<td>95,375</td>
<td>Henkel Corporation, Henkel Aireight Unit, Agile One</td>
<td>Chanhassen, MN</td>
<td>November 13, 2018.</td>
</tr>
<tr>
<td>95,418</td>
<td>SAP America, Inc., Data Center, SAP Product Engineering, 1F Technology, 23K Studios, etc.</td>
<td>Newtown Square, PA</td>
<td>November 24, 2018.</td>
</tr>
<tr>
<td>95,876</td>
<td>Novares US, LLC, Novares, Accounts Payable Accounts Receivable Group, AMBP Division.</td>
<td>Livonia, MI</td>
<td>April 7, 2019.</td>
</tr>
<tr>
<td>95,929</td>
<td>9380–3955 Quebec Inc., EZIP TECHNOLOGIES USA, TECHNOLOGIES EZIP, E219 TECHNOLOGIES, etc.</td>
<td>Bigfork, MN</td>
<td>May 21, 2019.</td>
</tr>
<tr>
<td>95,989</td>
<td>Capgemini America, Inc., Capgemini North America, Cloud Infrastructure Services Division (INFRA).</td>
<td>Burbank, CA</td>
<td>June 15, 2019.</td>
</tr>
<tr>
<td>95,994</td>
<td>Seagate Technology, Research &amp; Development, Pilot Line, Manpower, Accounting Principals, etc.</td>
<td>Shakopee, MN</td>
<td>June 16, 2019.</td>
</tr>
<tr>
<td>95,996</td>
<td>Georgica Pine Clothiers, LLC, Sea Island Clothiers, BAPA Enterprises, Atrium Staffing, Michael Page, etc.</td>
<td>Brooklyn, NY</td>
<td>June 17, 2019.</td>
</tr>
<tr>
<td>96,001</td>
<td>ACP Products, Inc., Cabinetworks Group</td>
<td>Mt. Union, PA</td>
<td>June 18, 2019.</td>
</tr>
<tr>
<td>96,024</td>
<td>Winoa USA, Inc.</td>
<td>Bedford, VA</td>
<td>June 29, 2019.</td>
</tr>
</tbody>
</table>
The following certifications have been issued. The requirements of Section 222(b) of the Trade Act have been met.

<table>
<thead>
<tr>
<th>TA–W No.</th>
<th>Subject firm</th>
<th>Location</th>
<th>Impact date</th>
</tr>
</thead>
<tbody>
<tr>
<td>96,065</td>
<td>NTT Data Services, LLC, Service Desk Support, Next Level Business Services Inc., Randstad USA.</td>
<td>Lincoln, NE</td>
<td>July 16, 2019.</td>
</tr>
<tr>
<td>96,126</td>
<td>NMG LLC</td>
<td>Norfolk, NE</td>
<td>August 5, 2019.</td>
</tr>
<tr>
<td>96,142</td>
<td>Libbey Glass, Libbey Inc., Jean Simpson Inc</td>
<td>Shreveport, LA</td>
<td>August 17, 2019.</td>
</tr>
</tbody>
</table>

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

<table>
<thead>
<tr>
<th>TA–W No.</th>
<th>Subject firm</th>
<th>Location</th>
<th>Impact date</th>
</tr>
</thead>
<tbody>
<tr>
<td>95,901</td>
<td>Larco, Inc</td>
<td>Crossett, AR</td>
<td>April 27, 2019.</td>
</tr>
<tr>
<td>96,063</td>
<td>Kaiser Aluminum Corporation, Flat Rolled Products Division</td>
<td>Spokane Valley, WA</td>
<td>July 8, 2019.</td>
</tr>
<tr>
<td>96,083B</td>
<td>AIM Group USA, Inc., Sekisui Aerospace Division</td>
<td>Sumner, WA</td>
<td>July 22, 2019.</td>
</tr>
</tbody>
</table>

The following certifications have been issued. The requirements of Section 222(e) (firms identified by the International Trade Commission) of the Trade Act have been met.

<table>
<thead>
<tr>
<th>TA–W No.</th>
<th>Subject firm</th>
<th>Location</th>
<th>Impact date</th>
</tr>
</thead>
<tbody>
<tr>
<td>95,960</td>
<td>Western Cabinets Inc., Woodmont Cabinetry, Link Staffing Services Corp., Johnston's Service, etc.</td>
<td>Dallas, TX</td>
<td>April 17, 2019.</td>
</tr>
</tbody>
</table>
### Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for TAA have not been met for the reasons specified.

<table>
<thead>
<tr>
<th>TA–W No.</th>
<th>Subject firm</th>
<th>Location</th>
<th>Impact date</th>
</tr>
</thead>
<tbody>
<tr>
<td>95,521</td>
<td>Frank’s International, LLC, Gulf of Mexico, Frank’s International N.V., Spherion Staffing, etc.</td>
<td>Lafayette, LA</td>
<td>.................</td>
</tr>
<tr>
<td>95,681</td>
<td>Elster American Meter Company, Research and Development Engineering, Smart Energy, Honeywell International.</td>
<td>Nebraska City, NE</td>
<td>.................</td>
</tr>
<tr>
<td>95,719</td>
<td>Meggitt Aircraft Braking Systems Corporation, Meggitt-USA, Inc</td>
<td>Akron, OH</td>
<td>.................</td>
</tr>
<tr>
<td>95,994A</td>
<td>Seagate Technology, Manpower, Accounting Principals, Experis, Global Technical Talent, etc.</td>
<td>Bloomington, MN</td>
<td>.................</td>
</tr>
</tbody>
</table>

The investigation revealed that the criteria under paragraphs (a)(2)(A) (increased imports), (a)(2)(B) (shift in production or services to a foreign country or acquisition of articles or services from a foreign country), (b)(2) (supplier to a firm whose workers are certified eligible to apply for TAA or downstream producer to a firm whose workers are certified eligible to apply for TAA), and (e) (International Trade Commission) of section 222 have not been met.

<table>
<thead>
<tr>
<th>TA–W No.</th>
<th>Subject firm</th>
<th>Location</th>
<th>Impact date</th>
</tr>
</thead>
<tbody>
<tr>
<td>95,367</td>
<td>Flambeau River Papers, Flambeau River Biofuel Company</td>
<td>Park Falls, WI</td>
<td>.................</td>
</tr>
<tr>
<td>95,515</td>
<td>IPSCO Tubulars (KY) LLC, IPSCO Tubulars Inc., Tenaris S.A., Resource Manufacturing, etc.</td>
<td>Catoosa, OK</td>
<td>.................</td>
</tr>
<tr>
<td>95,517</td>
<td>Buchanan Minerals, LLC, Coronado Global Resources Inc</td>
<td>Raven, VA</td>
<td>.................</td>
</tr>
<tr>
<td>95,841</td>
<td>Pier 1 Imports (U.S.) Inc., Pier 1 Imports Inc</td>
<td>Little Rock, AR</td>
<td>.................</td>
</tr>
<tr>
<td>95,841A</td>
<td>Pier 1 Imports (U.S.) Inc., Pier 1 Imports Inc</td>
<td>Jonesboro, AR</td>
<td>.................</td>
</tr>
<tr>
<td>95,842</td>
<td>Pier 1 Imports (U.S.) Inc., Pier 1 Imports Inc</td>
<td>Kansas City, MO</td>
<td>.................</td>
</tr>
<tr>
<td>95,842A</td>
<td>Pier 1 Imports (U.S.) Inc., Pier 1 Imports Inc</td>
<td>Shawnee, KS</td>
<td>.................</td>
</tr>
<tr>
<td>95,842B</td>
<td>Pier 1 Imports (U.S.) Inc., Pier 1 Imports Inc</td>
<td>Olathe, KS</td>
<td>.................</td>
</tr>
<tr>
<td>95,846</td>
<td>Denver Plastics Nebraska</td>
<td>Wahoo, NE</td>
<td>.................</td>
</tr>
<tr>
<td>95,861</td>
<td>Philips Neuro, Philips NA LLC, Randstad, Ensunet</td>
<td>Eugene, OR</td>
<td>.................</td>
</tr>
<tr>
<td>95,874</td>
<td>Paramount Industrial Companies, Inc., ECN Staffing</td>
<td>Norfolk, VA</td>
<td>.................</td>
</tr>
<tr>
<td>95,917</td>
<td>United States Steel Corporation, Minnesota Ore Operations, G4S Secure Solutions and Cleaning Specialist.</td>
<td>Keewatin, MN</td>
<td>.................</td>
</tr>
<tr>
<td>95,930</td>
<td>Halliburton Energy Services Inc., Halliburton Company, Human Resources Service Center</td>
<td>Duncan, OK</td>
<td>.................</td>
</tr>
<tr>
<td>95,955</td>
<td>Gerdau Ameristeel US Inc., Gerdau Ameristeel, BARR, Rumpca, G4S, First Class Mill, Wal-Zon, IMS, etc.</td>
<td>Saint Paul, MN</td>
<td>.................</td>
</tr>
<tr>
<td>95,992</td>
<td>NorTech Graphics Inc., Pennmac, Synergy HR</td>
<td>Lead Hill, AR</td>
<td>.................</td>
</tr>
<tr>
<td>96,062</td>
<td>Horizon Terra, Inc., idX Louisville, UFP Industries, Inc., idX Corporation</td>
<td>Jeffersonville, IN</td>
<td>.................</td>
</tr>
<tr>
<td>96,092</td>
<td>Lear Corporation, Advanced Assembly, LLC</td>
<td>Columbia City, IN</td>
<td>.................</td>
</tr>
</tbody>
</table>

### Determinations Terminating Investigations of Petitions for Trade Adjustment Assistance

After notice of the petitions was published in the Federal Register and on the Department’s website, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

<table>
<thead>
<tr>
<th>TA–W No.</th>
<th>Subject firm</th>
<th>Location</th>
<th>Impact date</th>
</tr>
</thead>
<tbody>
<tr>
<td>95,308</td>
<td>Bucher &amp; Christian Consulting, Inc., BCforward</td>
<td>Andover, MA</td>
<td>.................</td>
</tr>
<tr>
<td>95,702</td>
<td>Galesburg Castings, Inc</td>
<td>Galesburg, IL</td>
<td>.................</td>
</tr>
<tr>
<td>96,070</td>
<td>Pier 1 Imports, Inc</td>
<td>Warwick, RI</td>
<td>.................</td>
</tr>
<tr>
<td>96,111</td>
<td>Associated Spring</td>
<td>Corry, PA</td>
<td>.................</td>
</tr>
</tbody>
</table>

The following determinations terminating investigations were issued in cases where the petition regarding the investigation has been deemed invalid.
The following determinations terminating investigations were issued because the worker group on whose behalf the petition was filed is covered under an existing certification.

<table>
<thead>
<tr>
<th>TA–W No.</th>
<th>Subject firm</th>
<th>Location</th>
<th>Impact date</th>
</tr>
</thead>
<tbody>
<tr>
<td>96,146</td>
<td>James Counts</td>
<td>Surprise, AZ</td>
<td></td>
</tr>
<tr>
<td>96,147A</td>
<td>Pittsburgh Glass Works, LLC, Division of Vitro SAB DE C.V., Belcan Technical Services, Robert Half Mgmt.</td>
<td>Rochester Hills, Mi.</td>
<td></td>
</tr>
<tr>
<td>96,146</td>
<td>James Counts</td>
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<td></td>
</tr>
<tr>
<td>96,147A</td>
<td>Pittsburgh Glass Works, LLC, Division of Vitro SAB DE C.V., Belcan Technical Services, Robert Half Mgmt.</td>
<td>Rochester Hills, Mi.</td>
<td></td>
</tr>
</tbody>
</table>

The following determinations terminating investigations were issued because the petitioning group of workers is covered by an earlier petition investigation for which a determination has not yet been issued.

<table>
<thead>
<tr>
<th>TA–W No.</th>
<th>Subject firm</th>
<th>Location</th>
<th>Impact date</th>
</tr>
</thead>
<tbody>
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<td>Visron Design, Inc., Delphi Technologies Services, Technical Center Rochester, etc.</td>
<td>West Henrietta, NY.</td>
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<td>95,746</td>
<td>Mondelēz Global LLC</td>
<td>Hanover Township, PA.</td>
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<td>95,756</td>
<td>Lufkin Industries, Oilfield â€“ Buck Creek Division, Quinn Pumps, Inc</td>
<td>Lufkin, TX.</td>
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<td>95,814</td>
<td>Dun &amp; Bradstreet</td>
<td>Tucson, AZ.</td>
<td></td>
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<tr>
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<td>Waltham, MA.</td>
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<td>95,953</td>
<td>SAC Wireless, Nokia of America, Nokia, Nokia Solutions &amp; Networks, Alcatel-Lucent USA</td>
<td>Naperville, IL.</td>
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<td>96,029</td>
<td>The Boeing Company, Boeing Commercial Aircraft (BCA)</td>
<td>Seal Beach, CA.</td>
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<td>96,030</td>
<td>FTE Automotive, USA, Inc., Valeo USA, Inc</td>
<td>Auburn Hills, Mi.</td>
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<tr>
<td>96,069</td>
<td>NTT Security</td>
<td>Omaha, NE.</td>
<td></td>
</tr>
<tr>
<td>96,147</td>
<td>Pittsburgh Glass Works, LLC, Division of Vitro SAB DE C.V., Belcan Technical Services, Robert Half Mgmt.</td>
<td>Pittsburgh, PA.</td>
<td></td>
</tr>
<tr>
<td>96,147A</td>
<td>Pittsburgh Glass Works, LLC, Division of Vitro SAB DE C.V</td>
<td>Rochester Hills, Mi.</td>
<td></td>
</tr>
</tbody>
</table>

I hereby certify that the aforementioned determinations were issued during the period of August 1, 2020 through August 31, 2020. These determinations are available on the Department’s website https://www.doleta.gov/tradeact/petitioners/taa_search_form.cfm under the searchable listing determinations or by calling the Office of Trade Adjustment Assistance toll free at 888-365-6822.

Signed at Washington DC this 16th day of September 2020.

Hope D. Kinglock,
Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2020–21711 Filed 9–30–20; 8:45 am]
BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR
Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Consumer Expenditure Surveys: Quarterly Interview and Diary

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Bureau of Labor Statistics (BLS)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before November 2, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Anthony May by telephone at 202-693-4129 (this is not a toll-free number) or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency’s estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

The Consumer Expenditure (CE) Surveys collect data on consumer expenditures, demographic information, and related data needed by the Consumer Price Index (CPI) and other public and private data users. The continuing surveys provide a constant measurement of changes in consumer expenditure patterns for economic analysis and to obtain data for future CPI revisions. The CE Surveys have been ongoing since 1979. The data from the CE Surveys are used (1) for CPI revisions, (2) to provide a continuous flow of data on income and expenditure patterns for use in economic analysis and policy formulation, and (3) to provide a flexible consumer survey vehicle that is available for use by other Federal Government agencies. Public
and private users of price statistics, including Congress and the economic policymaking agencies of the Executive branch, rely on data collected in the CPI in their day-to-day activities. Hence, data users and policymakers widely accept the need to improve the process used for revising the CPI. If the CE Surveys were not conducted on a continuing basis, current information necessary for more timely and more accurate, updating of the CPI would not be available. In addition, data would not be available to respond to the continuing demand from the public and private sectors for current information on consumer spending. In the Quarterly Interview Survey, each consumer unit (CU) in the sample is interviewed every three months over four calendar quarters. The sample for each quarter is divided into three panels, with CUs being interviewed every three months in the same panel of every quarter. The Quarterly Interview Survey is designed to collect data on the types of expenditures that respondents can be expected to recall for a period of three months or longer. In general, the expenses reported in the Interview Survey are either relatively large, such as property, automobiles, or major appliances, or expenses which occur on a fairly regular basis, such as rent, utility bills, or insurance premiums. The Diary (or recordkeeping) Survey is completed at home by the respondent family for two consecutive one-week periods. The primary objective of the Diary Survey is to obtain expenditure data on small, frequently purchased items which normally are difficult to recall over longer periods of time. For additional substantive information about this ICR, see the related notice published in the Federal Register on June 11, 2020 (85 FR 35665).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL—BLS.

Title of Collection: Consumer Expenditure Surveys: Quarterly Interview and Diary.

OMB Control Number: 1220–0050.

Affected Public: Individuals and households.

Total Estimated Number of Respondents: 7,535.

Total Estimated Number of Responses: 60,856.

Total Estimated Annual Time Burden: 50,669 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))


Anthony May,
Management and Program Analyst.

[FR Doc. 2020–21663 Filed 9–30–20; 8:45 am]

BILLING CODE 4510–24–P

MILLENIUM CHALLENGE CORPORATION

[MCC FR 20–08]

Notice of Open Meeting

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: In accordance with the requirements of the Federal Advisory Committee Act, the Millennium Challenge Corporation (MCC) Advisory Council was established as a discretionary advisory committee on July 14, 2018. Its charter was renewed for a second term on July 11, 2018 and a third term on July 8, 2020. The MCC Advisory Council serves MCC in an advisory capacity only and provides insight regarding innovations in infrastructure, technology, and sustainability; perceived risks and opportunities in MCC partner countries; and new financing mechanisms for developing country contexts. The MCC Advisory Council provides a platform for systematic engagement with the private sector and other external stakeholders and contributes to MCC’s mission—to reduce poverty through sustainable, economic growth.

DATES: Monday, October 19, 2020, from 10:00 a.m.—12:30 p.m. ET.

ADDRESSES: The meeting will be held via conference call and/or WebEx.

FOR FURTHER INFORMATION CONTACT: Jennifer Rimbach 202.521.3932. MCCAdvisoryCouncil@mcc.gov or visit https://www.mcc.gov/about/org-unit/advisory-council.

SUPPLEMENTARY INFORMATION:

Agenda. During the Fall 2020 meeting of the MCC Advisory Council, members will receive an update from MCC leadership. MCC will also present on issues related to the ongoing development of MCC’s potential compact with Indonesia, during which members will have the opportunity to provide advice on the compact development process and MCC’s potential investment strategy.

Public Participation. The meeting will be open to the public. Members of the public may file written statement(s) before or after the meeting. If you plan to attend, please submit your name and affiliation no later than Monday, October 12, 2020 to MCCAdvisoryCouncil@mcc.gov to receive connection instructions and be placed on an attendee list.


Brian Finkelstein,
Acting VP/General Counsel and Corporate Secretary.

[FR Doc. 2020–21758 Filed 9–30–20; 8:45 am]

BILLING CODE 9211–03–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Education and Human Resources Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Education and Human Resources (#1119) (Virtual Meeting).

Date and Time: October 28–29, 2020; 1:00 p.m.–5:30 p.m. daily.

Place: National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

To attend the virtual meeting, all visitors must connect with the Directorate for Education and Human Resources at least 48 hours prior to the meeting. The final meeting agenda with instructions to register for the meeting will be posted to: https://www.nsf.gov/ehr/advisory.jsp.

Type of Meeting: Open.

Contact Person: Keaven M. Stevenson, National Science Foundation, 2415 Eisenhower Avenue, Room C11001, Alexandria, VA 22314; (703) 292–8600/ksstein@nsf.gov.

Summarized Minutes: Minutes and meeting materials will be available on the EHR Advisory Committee website at http://www.nsf.gov/ehr/advisory.jsp or can be obtained from Dr. Nafesa.
Owens, National Science Foundation, 2415 Eisenhower Avenue, Room C11000, Alexandria, VA 22314; (703) 292–8600; ehr_ac@nsf.gov.

Purpose of Meeting: To provide advice with respect to the Foundation’s science, technology, engineering, and mathematics (STEM) education and human resources programming.

Agenda
October 28, 2020; 1:00 p.m.–5:30 p.m.
• Welcoming Remarks from the EHR AC Chair & the EHR Assistant Director
• Session 1: Improve Stem Learning & Learning Environments
• Session 2: Broadening Participation Panel
• Session 3: Enhance Broadening Participation

October 29, 2020; 1:00 p.m.–5:30 p.m.
• Session 4: Prepare the Future Stem Workforce
• Session 5: The Future of EHR
• Discussions with NSF Leadership and Closing Remarks

Crystal Robinson,
Committee Management Officer.

Table of Contents
I. Introduction
II. Docketed Proceeding(s)

I. Introduction
The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request’s acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service’s request(s) can be accessed via the Commission’s website (http://www.prc.gov). Non-public portions of the Postal Service’s request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.1

The Commission invites comments on whether the Postal Service’s request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

This Notice will be published in the Federal Register.

Mallory Smith,
Federal Register Liaison.

[FR Doc. 2020–21726 Filed 9–30–20; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34029]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940


The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of September 2020. A copy of each application may be obtained via the Commission’s website by searching for the file number, or for an applicant using the Company name box, at http://www.sec.gov/search/search.htm or by calling (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by emailing the SEC’s Secretary at Secretarys-Office@sec.gov and serving the relevant applicant with a copy of the request by email, if an email address is listed for the relevant applicant below, or personally or by mail, if a physical address is listed for the relevant applicant below. Hearing requests should be received by the SEC by 5:30 p.m. on October 20, 2020, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested.

Persons who wish to be notified of a hearing may request notification by writing to the Commission’s Secretary at Secretarys-Office@sec.gov.

ADDRESSES: The Commission: Secretarys-Office@sec.gov.

FOR FURTHER INFORMATION CONTACT:
Shawn Davis, Assistant Director, at (202) 551–6413 or Chief Counsel’s Office at (202) 551–6821; SEC, Division
of Investment Management, Chief Counsel’s Office, 100 F Street NE, Washington, DC 20549–8010.

BMT Investment Funds [File No. 811–23234]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On April 24, 2020, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $6,295 incurred in connection with the liquidation were paid by the applicant, and the applicant’s investment adviser.

Filing Dates: The application was filed on July 1, 2020, and amended on September 18, 2020.

Applicant’s Address: lcm@csopasset.com.

Entoro Gray Swan Fund [File No. 811–23571]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Dates: The application was filed on May 21, 2020.

Applicant’s Address: rreneau@entoro.com.

First Investors Equity Funds [File No. 811–06618]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Delaware Group Equity Funds IV, and on October 4, 2019 made a final distribution to its shareholders based on net asset value. Expenses of $1,935,468 incurred in connection with the reorganization were paid by the applicant’s investment adviser and acquiring fund’s investment advisor.

Filing Dates: The application was filed on December 6, 2019, and amended on July 28, 2020, and September 10, 2020.

Applicant’s Address: frank.genna@foresters.com.

First Investors Income Funds [File No. 811–03967]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Delaware Group Equity Funds IV, and on October 4, 2019 made a final distribution to its shareholders based on net asset value. Expenses of $612,992 incurred in connection with the reorganization were paid by the applicant’s investment adviser and acquiring fund’s investment advisor.

Filing Dates: The application was filed on December 6, 2019, and amended on July 28, 2020, and September 10, 2020.

Applicant’s Address: frank.genna@foresters.com.

Harvest Volatility Edge Trust [File No. 811–23286]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company.

Filing Dates: The application was filed on October 31, 2019, and amended on March 10, 2020 and July 31, 2020.

Applicant’s Address: GPaolello@hvm.com.

Miller/Howard Funds Trust [File No. 811–23111]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On June 15, 2020, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of approximately $30,600 incurred in connection with the reorganization were paid by the applicant’s investment adviser.

Filing Dates: The application was filed on August 31, 2020.
Applicant’s Address: Tom.Majewski@Shearman.com.

Nuveen Mortgage Opportunity Term Fund 2 [File No. 811–22374]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On December 20, 2019, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $6,748 incurred in connection with the liquidation were paid by the applicant.

Filing Dates: The application was filed on March 11, 2020, and amended on September 17, 2020.

Applicant’s Address: dglatz@stradley.com.

Oppenheimer Integrity Funds [File No. 811–03420]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to AIM Investment Funds (Invesco Investment Funds) and, on May 24, 2019, made a final distribution to its shareholders based on net asset value. Expenses of $3,030,306.94 incurred in connection with the reorganization were paid by the applicant’s investment adviser (or its affiliates) and the acquiring fund.

Filing Date: The application was filed on April 30, 2020.

Applicant’s Address: Taylor.Edwards@invesco.com.

Resource Real Estate Diversified Income Fund [File No. 811–22749]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Goldman Sachs Real Estate Diversified Income Fund and, on May 18, 2020, made a final distribution to its shareholders based on net asset value. Expenses of $653,634 incurred in connection with the reorganization were paid by the applicant’s investment adviser and the acquiring fund.

Filing Date: The application was filed on July 2, 2020, and amended on September 18, 2020.

Applicant’s Address: Latasha.Love@ThompsonHine.com.

USAA ETF Trust [File No. 811–23271]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. The applicant has transferred its assets to Victory Portfolios II and on July 1, 2019, made a final distribution to its shareholders based on net asset value. Expenses of $511,491.16 incurred in connection with the reorganization were paid by the applicant’s investment adviser and Victory Capital Management Inc.

Filing Dates: The application was filed on December 26, 2019, and amended on August 10, 2020.

Applicant’s Address: ewagner@vc.com.

UST Global Private Markets Fund, LLC [File No. 811–22069]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On August 4, 2020, applicant made liquidating distributions to its shareholders based on net asset value. Expenses of $32,450 incurred in connection with the liquidation were paid by the applicant. Applicant has also retained $195,136 for the purpose of paying outstanding liabilities and unclaimed distributions.

Filing Date: The application was filed on August 26, 2020.

Applicant’s Address: corey.issing@nb.com.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2020–21676 Filed 9–30–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Temporary Period for Specified Commentaries to Rules 7.35, 7.35A, 7.35B, and 7.35C and Temporary Rule Relief in Rule 36.30


Pursuant to Section 19(b)(1) 1 of the Securities Exchange Act of 1934 (the “Act”) 2 and Rule 19b–4 thereunder, 3 notice is hereby given that on September 23, 2020, New York Stock Exchange LLC (“NYSE” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the temporary period for specified Commentaries to Rules 7.35, 7.35A, 7.35B, and 7.35C and temporary rule relief in Rule 36.30, to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on December 31, 2020. The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the temporary period for specified Commentaries to Rules 7.35, 7.35A, 7.35B, and 7.35C and temporary rule relief to Rule 36.30, to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on December 31, 2020. The current temporary period that these Rules are in effect ends on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on September 30, 2020.

Background

To slow the spread of COVID–19 through social-distancing measures, on March 18, 2020, the CEO of the Exchange made a determination under Rule 7.1(c)(3) that, beginning March 23, 2020, the Trading Floor facilities located at 11 Wall Street in New York City would close and the Exchange would move, on a temporary basis, to fully
On May 14, 2020, the CEO of the Exchange made a determination under Rule 7.1(c)(3) to reopen the Trading Floor on a limited basis on May 26, 2020 to a subset of Floor brokers, subject to safety measures designed to prevent the spread of COVID–19.5 On June 15, 2020, the CEO of the Exchange made a determination under Rule 7.1(c)(3) to begin the second phase of the Trading Floor reopening by allowing DMMs to return on June 17, 2020, subject to safety measures designed to prevent the spread of COVID–19.6 Consistent with these safety measures, both DMMs and Floor broker firms continue to operate with reduced staff on the Trading Floor.

Proposed Rule Change

The Exchange has modified its rules to add Commentaries to Rules 7.35, 7.35A, 7.35B, and 7.35C and rule relief in Rule 36.307 that are in effect until the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on September 30, 2020.8 The first and second phases of the reopening of the Trading Floor are subject to safety measures designed to prevent the spread of COVID–19.9 To meet these safety measures, Floor brokers and DMM units that have chosen to return to the Trading Floor are operating with reduced staff. The Exchange is therefore proposing to extend the following temporary rules until such time that there is a full reopening of the Trading Floor facilities to DMMs:

- Commentaries .01 and .02 to Rule 7.35;
- Commentaries .01, .02, .03, .04, .05, and .06 to Rule 7.35A;
- Commentaries .01 and .03 to Rule 7.35B;
- Commentaries .01, .02, and .03, and .04 to Rule 7.35C; and
- Amendments to Rule 36.30.

The Exchange is not proposing any substantive changes to these Rules.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,10 in general, and furthers the objectives of Section 6(b)(5) of the Act,11 in particular, that it is 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 facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

To reduce the spread of COVID–19, the CEO of the Exchange made a determination under Rule 7.1(c)(3) that beginning March 23, 2020, the Trading Floor facilities located at 11 Wall Street in New York City would close and the Exchange would move, on a temporary basis, to fully electronic trading. On May 14, 2020, the CEO made a determination under Rule 7.1(c)(3) that, beginning May 26, 2020, the Trading Floor would be partially reopened to allow a subset of Floor brokers to return to the Trading Floor. On June 15, 2020, the CEO made a determination under Rule 7.1(c)(3) that, beginning June 17, 2020, DMM units may choose to return a subset of staff to the Trading Floor.

The Exchange believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system because the Trading Floor has not yet reopened in full to DMMs or Floor brokers. Accordingly, the Exchange believes that the temporary rule changes in effect pursuant to the Commentaries to Rules 7.35, 7.35A, 7.35B, and 7.35C and amendments to Rule 36.30, which are intended to be in effect during the temporary period while the Trading Floor has not yet opened in full to DMMs, should be extended until such time that there is a full reopening of the Trading Floor facilities to DMMs. The Exchange is not proposing any substantive changes to these Rules.

The Exchange believes that, by clearly stating that this relief will be in effect through the earlier of a full reopening of the Trading Floor facilities to DMMs or the close of the Exchange on December 31, 2020, market participants will have advance notice of the temporary period during which the Commentaries to Rules 7.35, 7.35A, 7.35B, and 7.35C and amendments to Rule 36.30 will be in effect.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues but rather would extend the temporary period during which Commentaries .01 and .02 to Rule 7.35; Commentaries .01, .02, .03, .04, .05,
and .06 to Rule 7.35A; Commentaries .01 and .03 to Rule 7.35B; Commentaries .01, .02, .03, and .04 to Rule 7.35C; and amendments to Rule 36.30 will be in effect. These Commentaries are intended to be in effect during the temporary period while the Trading Floor has not yet been opened in full to DMMs and Floor brokers and currently expire on September 30, 2020. Because the Trading Floor has not been opened in full to DMMs, the Exchange proposes to extend the temporary period for these temporary rules to end on the earlier of a full reopening of the Trading Floor facilities to DMMs or after the Exchange closes on December 31, 2020.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act 12 and Rule 19b–4(f)(6) thereunder. 13 Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; or (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act 14 and Rule 19b–4(f)(6) thereunder. 15 A proposed rule change filed under Rule 19b–4(f)(6) 16 normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii), 17 the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may take effect immediately. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will allow the rules discussed above to remain in effect during the temporary period during which the Trading Floor has not yet been reopened in full to DMMs because of health precautions related to the COVID–19 pandemic. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing. 18 At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(3)(A)(ii) 19 of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

• 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–NYSE–2020–78 on the subject line.

Electronic Comments

• Submit paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

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–NYSE–2020–78 and should be submitted on or before October 22, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 20

J. Matthew DeLesDernier, Assistant Secretary.

[FR Doc. 2020–21661 Filed 9–30–20; 8:45 am]

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89998; File No. SR–MSRB–2020–05]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Consisting of Amendments to MSRB Rules A–3 and A–4 Relating to Board Quorum, Meeting, and Voting Requirements


Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") or "Exchange Act") 1 and Rule 19b–4 thereunder, 2 notice is hereby given that on September 15, 2020 the Municipal Securities Rulemaking Board ("MSRB") 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 MSRB. 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 MSRB filed with the Commission a proposed rule change consisting of amendments to MSRB Rules A–3 and A–4 (the “proposed rule change”) relating to Board quorum, meeting, and voting requirements. The MSRB has designated the proposed rule change as “concerned solely with the administration of the self regulatory organization” under Section 19(b)(3)(A)(iii) of the Act and Rule 19b–4(f)(3) thereunder, which renders the proposal effective upon filing with the Commission. As described below, the draft amendments would:

- Revise the Board’s quorum requirement by replacing the specific Board category representation requirements with a more general requirement that a majority of the Board’s public representatives and a majority of the Board’s regulated members be present;
- Modify the voting requirement for the Board to remove a member for cause by replacing the requirement for the vote to include the affirmative vote of members from specified Board categories with a requirement that the vote include the affirmative vote of a majority of the Board’s public representatives and a majority of the Board’s regulated members;
- Add an express statement that the Board may meet through the use of any means of communication by which all persons participating may simultaneously hear each other (including through the use of captioning or other similar transcription means) during the meeting;
- Update the requirement for taking Board action without a meeting; and
- Move the provision on Board resolutions into its own subsection and rephrase the provision on special meetings of the Board to clarify its meaning.

The text of the proposed rule change is available on the MSRB’s website at www.msrb.org/Rules-and-Interpretations/SEC-Filings/2020-Filings.aspx, at the MSRB’s principal office, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the MSRB 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 MSRB 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

MSRB Quorum and Cause Removal Voting Requirements

MSRB Rule A–4(c) currently provides that a quorum consists of “two-thirds of the members of the whole Board (at least one of whom shall be a public representative, one a broker-dealer representative, one a bank representative and one a municipal advisor representative) . . . ” MSRB Rule A–3(c) uses the same formulation when describing the vote required to remove a Board member for cause. The proposed rule change includes parallel amendments to both of these provisions. Specifically, the amendments would replace the specific category representation requirements in both rules with a requirement that there be a majority of the public representatives and a majority of the regulated representatives.

The purpose of these amendments is twofold. First, requiring a majority of the public representatives and a majority of the regulated representatives would provide additional assurance of the Board’s commitment to balanced representation on the Board, including the substantial participation of both public and regulated representatives in Board decisions. Second, eliminating the more specific category requirements would mitigate the risk, increased by the Board’s impending reduction in size, that the absence of a single Board member (or a small group of Board members) could prevent the Board from meeting the quorum requirement or the voting requirement for removal for cause even if the other requirements are met.

In addition, the proposed rule change would move two sentences in MSRB Rule A–4(c) that relate to Board resolutions into a new subsection, A–4(e). Locating the provision on resolutions in its own subsection, rather than in the subsection on the Board’s quorum requirement, will improve the overall organization of the rule.

Board Meetings and Board Action Without a Meeting

MSRB Rule A–4(a) requires the Board to meet at least quarterly and governs the conduct of regular and special meetings. In practice, the Board generally meets in person each quarter and by conference call more frequently. While the Board’s power to conduct meetings telephonically or otherwise remotely has never been in doubt, the proposed rule change includes an amendment to MSRB Rule A–4(a) expressly providing that meetings may be held through the use of any communications method by means of which all persons participating in the meeting can hear each other (including through the use of captioning or other similar transcription means). This amendment is intended to provide additional assurance to the public that the Board is able to conduct business even when circumstances prevent it from meeting in person. The proposed rule change also includes an amendment to rephrase the sentence in MSRB Rule A–4(a) on special meetings of the Board to clarify its meaning.

MSRB Rule A–4 also sets forth the requirements for the Board to take action without a meeting. The Board takes action without a meeting infrequently, generally when a matter requires prompt attention in between scheduled meetings and circumstances preclude convening a special meeting. MSRB Rule A–4(d) provides that such action may be taken by written consent or by telephone or email poll of all members.

3 MSRB Rule A–3(c) provides, “In the event the Board shall find that any member has willfully violated any provision of the Act, any rule or regulation of the Commission thereunder, or any rule of the Board or has abused his or her authority or has otherwise acted, or failed to act, so as to affect adversely the public interest or the best interests of the Board, the Board may, upon the affirmative vote of two-thirds of the whole Board (which shall include the affirmative vote of at least one public representative, one broker-dealer representative, one bank representative and one municipal advisor representative), remove such member from office.” The Commission recently approved amendments to Rule A–3 that are effective on October 1, 2020. See Exchange Act Release No. 89484 (Aug. 5, 2020), 85 FR 48579 (Aug. 11, 2020) (File No. SR–MSRB–2020–04). The approved amendments include minor wording changes to the language quoted above but do not modify the substance.

members of the Board. The proposed amendments to MSRB Rule A–4(d) are intended to simplify the rule and more clearly describe the process for taking action without a meeting under the Virginia Nonstock Corporation Act, which provides that the MSRB’s rules shall:

which provides that the MSRB’s rules shall:

provide for the operation and administration of the Board, including the selection of a Chairman from among the members of the Board, the compensation of the members of the Board, and the appointment and compensation of such employees, attorneys, and consultants as may be necessary or appropriate to carry out the Board’s functions under this section.

The amendment to MSRB Rule A–3 would modify the existing voting requirement to remove a Board member for cause by requiring the vote to include the affirmative vote of a majority of the public representatives and a majority of the regulated representatives. Similarly, the proposed rule change would modify the existing quorum requirement in MSRB Rule A–4(c) to require that a majority of the public representatives and a majority of the regulated representatives be present. As such, these amendments provide for the operation and administration of the Board and are therefore consistent with Section 15B(b)(2)(I) of the Exchange Act.

The amendments to MSRB Rule A–4 also would include an express statement that the Board may meet remotely, update the Board’s requirements for taking Board action without a meeting, relocate the existing provision governing Board resolutions, and clarify an existing sentence regarding special meetings of the Board. Accordingly, these amendments also provide for the operation and administration of the Board and are therefore consistent with Section 15B(b)(2)(I) of the Exchange Act.

2. Statutory Basis

The MSRB has adopted the proposed rule change pursuant to Section 15B(b)(2)(I) of the Exchange Act, which provides that the MSRB’s rules shall:

which provides that the MSRB’s rules shall:

provide for the operation and administration of the Board, including the selection of a Chairman from among the members of the Board, the compensation of the members of the Board, and the appointment and compensation of such employees, attorneys, and consultants as may be necessary or appropriate to carry out the Board’s functions under this section.

The amendment to MSRB Rule A–3 would modify the existing voting requirement to remove a Board member for cause by requiring the vote to include the affirmative vote of a majority of the public representatives and a majority of the regulated representatives. Similarly, the proposed rule change would modify the existing quorum requirement in MSRB Rule A–4(c) to require that a majority of the public representatives and a majority of the regulated representatives be present. As such, these amendments provide for the operation and administration of the Board and are therefore consistent with Section 15B(b)(2)(I) of the Exchange Act.

The amendments to MSRB Rule A–4 also would include an express statement that the Board may meet remotely, update the Board’s requirements for taking Board action without a meeting, relocate the existing provision governing Board resolutions, and clarify an existing sentence regarding special meetings of the Board. Accordingly, these amendments also provide for the operation and administration of the Board and are therefore consistent with Section 15B(b)(2)(I) of the Exchange Act.

B. Self-Regulatory Organization’s Statement on Burden on Competition

Section 15B(b)(2)(C) of the Exchange Act requires that MSRB rules not be designed to impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act. The proposed rule change relates only to the administration of the Board and would not impose requirements on dealers, municipal advisors or others. Accordingly, the MSRB does not believe that the proposed rule change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and paragraph (f) of Rule 19b–4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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:

- 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–MSRB–2020–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–MSRB–2020–05. 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 MSRB. 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–MSRB–2020–05 and should be submitted on or before October 22, 2020.

For the Commission, pursuant to delegated authority.

J. Matthew DeLiesDernier,
Assistant Secretary.

[FR Doc. 2020–21659 Filed 9–30–20; 8:45 am]
For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.

J. Matthew DeLesDernier,
Assistant Secretary.

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Notice on Public Content; WOSB NAICS Study

AGENCY: U.S. Small Business Administration.

ACTION: 30-Day notice and request for comments.

SUMMARY: The National Defense Authorization Act for Fiscal Year 2015 requires the Small Business Administration (SBA) to produce a study every five years regarding the participation of small business concerns owned and controlled by women. Public Law 113–291, 128 Stat. 3202 (Dec. 19, 2014). In accordance with this requirement, SBA is preparing to conduct the study. SBA is currently developing the process and methodology that will be used to conduct this study and is requesting public input and feedback.

DATES: Submit comments on or before November 2, 2020.


SUPPLEMENTARY INFORMATION:

A. Program Background

The Small Business Act, 15 U.S.C. 637(m), authorizes contracting officers to restrict competition for Federal awards to eligible Women-Owned Small Businesses (WOSBs) and/or Economically-Disadvantaged Women-Owned Small Businesses (EDWOSBs) in certain circumstances. Specifically, a contracting officer may restrict competition, or “set aside’’ a contract to the Kauffman-RAND Institute for Entrepreneurship Public Policy (RAND) to complete a study of the underrepresentation of WOSBs in Federal prime contracts by industry code. The resulting study (the RAND Report) was published in April 2007 and is available to the public at https://www.rand.org/pubs/technical_reports/TR442.html.

As the RAND Report explains more fully, RAND measured WOSB representation in each industry code through a “disparity ratio,” which is a measure comparing the utilization of WOSBs in Federal contracting. The disparity ratio itself is calculated utilizing availability and availability and is available for Federal contracts in specific industries are actually being utilized to perform such contracts.

A contracting officer may restrict competition, or “set aside” a competition for WOSBs, if:

• There is a reasonable expectation that two or more WOSBs will submit offers in response to the solicitation;

• The contracting officer believes that award can be made at a fair and reasonable price; and

• The procurement is for goods or services with respect to an industry identified by the SBA’s Administrator as underrepresented.

A contracting officer may restrict competition, or “set aside” a competition for EDWOSBs if:

• There is a reasonable expectation that two or more EDWOSBs will submit offers in response to the solicitation;

• The contracting officer believes that award can be made at a fair and reasonable price; and

• The procurement is for goods or services with respect to an industry identified by the SBA’s Administrator as underrepresented.

Federal contract dollars awarded to WOSBs in a given industry code to total Federal contract dollars awarded in that industry code. It calculated availability as the ratio of the gross receipts (revenues) of WOSBs in a particular industry code to the gross receipts (revenues) of all firms in that code. When using numbers as the measure, RAND calculated utilization as the ratio of the number of Federal contracts awarded to WOSBs in a particular industry code to the number of Federal contracts awarded overall in that code, and availability as the ratio of the number of WOSBs in a particular industry code to the total number of firms in that code.

According to the RAND Report, if the disparity ratio in an industry code is equal to 1.0 when measuring in terms of dollars, that indicates that WOSBs have been awarded contract dollars in the same proportion as their economic representation in the industry; that is, they are awarded contracting dollars in proportion to their share of total business in that industry and are therefore neither over- nor underrepresented. Similarly, if the disparity ratio in an industry code is equal to 1.0 when measuring in terms of numbers, this indicates that WOSBs are awarded contracts (of whatever dollar value) in the same proportion as their numerical representation in the industry. A ratio of less than 1.0 (lower utilization than availability) suggests some degree of underrepresentation with respect to that particular means of measuring disparity (dollars or numbers); a ratio of greater than 1.0 (greater utilization than availability) suggests some measure of overrepresentation with respect to a given metric. RAND classified an industry as “underrepresented” if its disparity ratio was between 0.5 and 0.8 (using either the numbers or dollars approach, and “substantially underrepresented” if its ratio was less than 0.5. It is important to note that RAND states disparity ratios are not in and of themselves measures of discrimination, although they have been used in numerous court cases to infer discrimination. Nonetheless they are a starting point, a way to identify whether there are any differences in outcomes between different types of firms.

RAND calculated these ratios using a variety of different data sets. For the utilization component of the disparity ratio, RAND used the data from the FY 2005 Federal Procurement Data System/Next Generation (FPDS/NG) procurement database. This was the only data source identified by RAND with respect to the utilization component of the disparity ratio. However, RAND did adjust the FPDS to account for possible miscoding of business size. Specifically, RAND linked the FPDS data to 2004 Dun and Bradstreet (D&B) data using the Data Universal Numbering System (DUNS) to identify the parent companies of local establishments, and then used the DUNS to assess whether a firm was small. However, because the data file was also prone to error, RAND presented results both with and without the DUNS cross-reference.

For the availability component of the disparity ratio, RAND used two different databases: The 2002 Survey of Business Owners (SBO) from the five-year Economic Census, and the FY 2006 Central Contractor Registration (CCR) registration database. Using the SBO database, RAND presented results only at the two-digit industry code level, a comparatively generalized level of industry disaggregation. Using the CCR, in contrast, RAND presented results at the two-, three-, and four-digit industry code levels. RAND also presented full sample results and trimmed sample results (eliminating the top and bottom 0.5 percent of the data) for each disparity ratio. RAND did this in order to examine the sensitivity of the disparity ratio to extreme values, such as very large contracts or negative dollar amounts resulting from contract actions based on multi-year contracts or modifications to such contracts to earlier contracts. Using these different data sources and various adjustments, the RAND Report identified twenty-eight different possible approaches to determining the degree of underrepresentation of WOSBs in Federal procurement contracting.

C. Overview of the Office Chief Economist Study of the U.S. Department of Commerce Assisting SBA To Conduct WOSB NAICS Study

In 2014, Congress amended the Small Business Act to require SBA to submit a report to Congress reflecting the results of a new study by January 2, 2016, and then continue to conduct a new study every five years. Public Law 113-291 § 825(c) (Dec. 19, 2014). In response to this statutory mandate, SBA asked the Office of the Chief Economist (OCE) of the U.S. Department of Commerce for assistance in conducting a new study on the WOSB Program, which would analyze data to help SBA determine those NAICS codes in which WOSBs are underrepresented and substantially underrepresented. OCE of the U.S. Department of Commerce for assistance in conducting a new study on the WOSB Program, which would analyze data to help SBA determine those NAICS codes in which WOSBs are underrepresented and substantially underrepresented. OCE looked at whether, holding constant various factors that might influence the award of a contract, the odds of winning Federal prime contracts by firms that were owned by women were greater or less than the odds of winning contracts by otherwise similar businesses.

In its analysis, OCE controlled for the size and age of the firm; its membership in various categories of firms for which the Federal government has government-wide prime contracting goals; its legal form of organization; its level of government security clearance; and its Federal prime contracting past performance ratings. OCE also looked at whether women-owned businesses typically have significantly different experiences in winning contracts depending on their industry. OCE performed this analysis at the four-digit NAICS industry group level. OCE included each firm in its sample in an industry analysis if the firm had registered as being able to perform work in that industry or if the firm had won a contract assigned to that industry. OCE found that women-owned businesses were less likely to win Federal contracts in 254 of the 304 industries included in the study. In 109 out of the 304 industries, OCE found that women-owned businesses have statistically significant lower odds of winning Federal contracts than otherwise similar non-women-owned businesses at the 95% confidence level. SBA has determined that the finding by OCE of a statistically significant lower likelihood of winning contracts demonstrates that WOSBs are substantially underrepresented in these 109 NAICS codes. However, of these industries, 17 are in sectors 42 and 44–45, which are not applicable to Federal contracts under SBA’s regulations. 13 CFR 121.201.

Since some industry groups cannot be used to classify Federal contracts, SBA has excluded them from the list of industries designated as substantially underrepresented. In addition, OCE found that in 145 out of the 304 industries, the odds of women-owned businesses winning contracts were lower than those of otherwise similar non-women-owned businesses, but there was not a statistically significant difference between the odds of winning for the two groups. Although there was not a finding of statistical significance for these industries, 21 of them were previously found by the RAND study to be industries in which WOSBs are underrepresented or substantially underrepresented. Thus, SBA was provided with information showing historical underrepresentation of women-owned businesses in these 21 industries, which was consistent with
the OCE finding that women-owned businesses are less likely to win contracts. As a result, SBA found that it possessed sufficient data to determine that WOSBs are underrepresented in these 21 industries. SBA also believed that this decision fulfills the intent of the Small Business Act, which demonstrates the intent that the designations of eligible industries be based on at least five years of data. The full OCE study is available on SBA’s website at www.sba.gov/wosb.

D. Solicitation of Public Comments

As both the RAND and OCE studies indicate, there is no single solution to determine underrepresentation, with each study methodology choice having its own benefits and shortcomings. As discussed above, the previous studies made choices regarding certain measures. Through this request, SBA seeks input from stakeholders on the areas below.

1. For the past two studies SBA has looked at the value of contracts as part of determining the utilization ratio. One issue raised by this approach is that this may be reflecting very few contracts awards (meaning awards to a few companies) which may not be representative of the actual competitive balance in the industry. SBA is seeking input on whether a hybrid approach should be used accounting for both value of contracts and number of contracts in a given industry. SBA is also considering using higher level NAICS (meaning fewer digits) for low volume industries.

2. SBA is also seeking input on how best to determine women-owned businesses that are ready, willing, and able. Past studies have used SAM registration as a measure for ready, willing, and able. However, it may be that there are women-owned firms that are ready, willing, and able to perform government contracts that are not registered in SAM. Another option would be to look at women-owned small businesses in the US generally rather than limiting it to sam.gov registered businesses. SBA would like public comment input if it should continue to use the ready, willing, and able that was used in the previous studies, use general women-owned businesses in the US, or is there another method that SBA should consider.

Another issue with the ready, willing, and able determination is the possible overestimate of the number of WOSBs in a given NAICS because of the ability of firms to self-select NAICS in sam.gov without regard for capability. It may be possible to perform a sensitivity analysis to try to identify if there is a problem with overestimates and to correct the analysis accordingly. SBA would like public input on whether this possible overestimate is a problem, and, if so, is SBA’s proposed solution useful.

3. SBA is seeking comments on the appropriate thresholds for underrepresented versus substantially underrepresented. Currently, the threshold for underrepresented is <1 and the threshold for substantially underrepresented is <.5. Another factor SBA would like the public to consider is what should the thresholds be if they are changed? In addition, SBA is also considering utilizing different thresholds for low-volume NAICS. Should it be the same for all industries?

4. The past two studies have each had issues with low-volume industries. This occurs when there are either low-dollar value or low volume of contracts in a given industry. The result is that minor changes in in either category can have extreme effects on the outcome. SBA is considering the use of power analysis calculations to determine which industries have a sufficient number of firms to detect a small effect size for the difference between the use of WOSBs and that of other businesses. SBA is also considering determining the level of industry concentration using a Normalized Herfindahl Index. In addition, SBA may also consider measuring disparity metrics independently by fiscal year and using pooled data over multiple years. This could reduce the number of low-volume NAICS, but could be considered less reliable if there is significant variance in disparity metrics over time. SBA would like public input on whether it should make changes to the treatment of low-volume NAICS and whether or not the proposed methods are a good way to taking into account low-volume NAICS.

Barbara Carson, Deputy Associate Administrator, Office of Government Contracting and Business Development.

[FR Doc. 2020–21678 Filed 9–30–20; 8:45 am]
BILLING CODE 8025–03–P

TENNESSEE VALLEY AUTHORITY

Meeting of the Regional Energy Resource Council

AGENCY: Tennessee Valley Authority (TVA).

ACTION: Notice of meeting.

SUMMARY: The TVA Regional Energy Resource Council (RERC) will hold a virtual meeting on Wednesday, October 14, 2020, regarding regional energy related issues in the Tennessee Valley.

DATES: The meeting will be held on Wednesday, October 14, 2020, from 9:30 a.m. to 12:00 p.m. EDT, followed by a 1 hour lunch break and reconvene at 12:55 p.m. EDT. The afternoon session will end no later than 3:30 p.m. EDT.

ADDRESSES: The meeting is virtual and open to the public. Public members must preregister at the following link: https://bit.ly/RercOct14. Anyone needing special accommodations should let the contact below know at least a week in advance.

FOR FURTHER INFORMATION CONTACT: Cathy Coffey, ccoffey@tva.gov or 865/632–4494.

SUPPLEMENTARY INFORMATION: The RERC was established to advise TVA on its energy resource activities and the priorities among competing objectives and values. Notice of this meeting is given under the Federal Advisory Committee Act (FACA), 5 U.S.C. App.2.

The meeting agenda includes the following:

1. Welcome and Introductions
2. TVA Updates
3. Presentations Regarding TVA Electric Vehicle Strategy
4. Public Comments
5. Council Discussion

The RERC will hear views of citizens by providing a public comment session running from 1:00 p.m.–1:30 p.m. EDT, that day. Persons wishing to speak must register at ccoffey@tva.gov by 5:00 p.m. EDT, on Tuesday, October 13, 2020, and will be called on during the public comment period for up to two minutes to share their views. Written comments are also invited and may be mailed to the Regional Energy Resource Council, Tennessee Valley Authority, 400 West Summit Hill Drive, WT 9D, Knoxville, Tennessee 37902.


Joseph J. Hoagland, Vice President, Innovation and Research, Tennessee Valley Authority.

[FR Doc. 2020–21747 Filed 9–30–20; 8:45 am]
BILLING CODE 8120–08–P
requests comments that identify online and physical markets to be considered for inclusion in the 2020 Review of Notorious Markets for Counterfeiting and Piracy (Notorious Markets List). The Notorious Markets List identifies examples of online and physical markets that reportedly engage in and facilitate substantial copyright piracy or trademark counterfeiting. The issue focus for the 2020 Notorious Markets List will examine the use of e-commerce platforms and other third-party intermediaries to facilitate the importation of counterfeit and pirated goods into the United States.

DATES: November 8, 2020 at 11:59 p.m. ET: Deadline for submission of written comments. November 22, 2020 at 11:59 p.m. ET: Deadline for submission of rebuttal comments and other information USTR should consider during the review.

ADDRESSES: You should submit written comments through the Federal eRulemaking Portal: http://www.regulations.gov (Regulations.gov). Follow the instructions for submitting comments in section III below. For alternatives to online submissions, please contact Jacob Ewerdt at Notorious Markets@ustr.eop.gov or (202) 395–4510 before transmitting a comment and in advance of the relevant deadline.

FOR FURTHER INFORMATION CONTACT: Jacob Ewerdt, Director for Innovation and Intellectual Property, at Notorious Markets@ustr.eop.gov or (202) 395–4510. You can find information about the Special 301 Review, including the Notorious Markets List, at www.ustr.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The United States is concerned with trademark counterfeiting and copyright piracy on a commercial scale because these illicit activities cause significant financial losses for right holders, legitimate businesses, and governments. In addition, they undermine critical U.S. comparative advantages in innovation and creativity to the detriment of American workers, and can pose significant risks to consumer health and safety and privacy and security. Conducted under the auspices of the Special 301 program and the authority of the U.S. Trade Representative to address practices that have significant adverse impact on the value of U.S. innovation, the Notorious Markets List identifies examples of online and physical markets that reportedly engage in and facilitate substantial copyright piracy or trademark counterfeiting that infringe on U.S. intellectual property (IP).

Beginning in 2006, USTR identified notorious markets in the annual Special 301 Report. In 2010, USTR announced that it would publish the Notorious Markets List as an Out-of-Cycle Review, separate from the annual Special 301 Report. USTR published the first Notorious Markets List in February 2011. USTR develops the annual Notorious Markets List based upon public comments solicited through the Federal Register and in consultation with Federal agencies that serve on the Special 301 Subcommittee of the Trade Policy Staff Committee.

The United States encourages owners and operators of markets reportedly involved in piracy or counterfeiting to adopt business models that rely on the licensed distribution of legitimate content and products and to work with right holders and enforcement officials to address infringement. USTR also encourages foreign governments and authorities to intensify their efforts to investigate reports of piracy and counterfeiting in such markets, and to pursue appropriate enforcement actions. The Notorious Markets List does not purport to reflect findings of legal violations, nor does it reflect the U.S. Government’s analysis of the general IP protection and enforcement climate in the country or countries concerned. For an analysis of the IP climate in particular countries, please refer to the annual Special 301 Report, published each spring no later than 30 days after USTR submits the National Trade Estimate to Congress.

II. Public Comments

USTR invites written comments concerning examples of online and physical markets that reportedly engage in and facilitate substantial copyright piracy or trademark counterfeiting that infringe on U.S. intellectual property (IP). To facilitate the review, written comments should be as detailed as possible. Comments must clearly identify the market and the reasons why the commenter believes that the market should be included in the Notorious Markets List. Commenters should include the following information, as applicable:

For physical markets:

• The market’s name and location, e.g., common name, street address, neighborhood, shopping district, city, etc., and the identity of the principal owners/operators.

For online markets:

• The domain name(s) past and present, available registration information, and name(s) and location(s) of the hosting provider(s) and operator(s).

• Information on the volume of internet traffic associated with the website, including number of visitors and page views, average time spent on the site, estimate of the number of infringing goods offered, sold, or traded and number of infringing files streamed, shared, seeded, leechied, downloaded, uploaded, or otherwise distributed or reproduced, and global or country popularity rating (e.g., Alexa rank).

• Revenue sources such as sales, subscriptions, donations, upload incentives, or advertising and the methods by which that revenue is collected.

For physical and online markets:

• Whether the market is owned, operated, or otherwise affiliated with a government entity.

• Types of counterfeit or pirated products or services sold, traded, distributed, or otherwise made available at that market.

• Volume of counterfeit or pirated goods or services or other indicia of a market’s scale, reach, or relative significance in a given geographic area or with respect to a category of goods or services.

• Estimates of economic harm to right holders resulting from the piracy or counterfeiting and a description of the methodology used to calculate the harm.

• Whether the volume of counterfeit or pirated goods or estimates of harm has increased or decreased from previous years, and an approximate calculation of that increase or decrease for each year.

• Whether the infringing goods or services sold, traded, distributed, or made available pose a risk to public health or safety.

• Any known contractual, civil, administrative, or criminal enforcement activity against the market and the outcome of that enforcement activity.
• Additional actions taken by right holders against the market such as takedown notices, requests to sites to remove URLs or infringing content, cease and desist letters, warning letters to landlords and requests to enforce the terms of their leases, requests to providers to enforce their terms of service or terms of use, and the outcome of these actions.
• Additional actions taken by the market owners or operators to remove, limit, or discourage the availability of counterfeit or pirated goods or services, including policies to prevent or remove access to such goods or services, or to disable seller or user accounts, the effectiveness of market policies and guidelines in addressing counterfeiting and piracy, and the level of cooperation with right holders and law enforcement.
• Any other additional information relevant to the review.

III. Submission Instructions

All submissions must be in English and sent electronically via Regulations.gov. To submit comments, locate the docket (folder) by entering the docket number USTR–2020–0035 in the ‘Enter Keyword or IP’ window at the Regulations.gov homepage and click ‘search.’ The site will provide a search-results page listing all documents associated with this docket. Locate the reference to this notice by selecting ‘notice under ‘document type’ on the left side of the search-results page, and click on the link entitled ‘comment now!’ You should provide comments in an attached document, and name the file according to the following protocol, as appropriate: Commenter Name or Organization_2020 Notorious Markets. Please include the following information in the ‘type comment’ field: 2020 Review of Notorious Markets for Counterfeiting and Piracy. USTR prefers submissions in Microsoft Word (.docx) or Adobe Acrobat (.pdf) format. If the submission is in another file format, please indicate the name of the software application in the ‘type comment’ field. For further information on using Regulations.gov, please select ‘how to use Regulations.gov’ on the bottom of any page.

Please do not attach separate cover letters to electronic submissions. Instead, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the comment itself, rather than submitting them as separate files.

For any comment submitted electronically that contains business confidential information (BCI), the file name of the business confidential version should begin with the characters ‘BCI’. Any page containing BCI must be clearly marked “BUSINESS CONFIDENTIAL” on the top of that page and the submission should clearly indicate, via brackets, highlighting, or other means, the specific information that is business confidential. A filer requesting business confidential treatment must certify that the information is business confidential and that they would not customarily release it to the public. Additionally, the submitter should type ‘Business Confidential 2020 Review of Notorious Markets for Counterfeiting and Piracy’ in the ‘comment’ field.

Filiers of comments containing BCI also must submit a public version of their comments. The file name of the public version should begin with the character ‘P’. The non-business confidential version will be placed in the docket at Regulations.gov and be available for public inspection.

As noted, USTR strongly urges submitters to file comments through Regulations.gov. You must make any alternative arrangements in advance of the relevant deadline and before transmitting a comment by contacting Jacob Ewerdt at Notorious Markets@ustr.eop.gov or (202) 395–4510 before transmitting a comment and in advance of the relevant deadline.

USTR will post comments in the docket for public inspection, except properly designated BCI. You can view comments on Regulations.gov by entering docket number USTR–2020–0035 in the search field on the home page.

Daniel Lee,
Assistant U.S. Trade Representative for Innovation and Intellectual Property (Acting), Office of the United States Trade Representative.

SUPPLEMENTARY INFORMATION:

This notice announces that the FAA has given its overall approval to the Burlington International Airport noise compatibility program, effective August 27, 2020. Under Section 104 (a) of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter the Act), an airport operator who has previously submitted a noise exposure map may submit to the FAA a noise compatibility program which sets forth the measures taken or proposed by the airport operator for the reduction of existing non-compatible land uses and prevention of additional non-compatible land uses within the area covered by the noise exposure maps.

The Act requires such programs to be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and FAA personnel.

Each airport noise compatibility program developed in accordance with 14 CFR part 150 is a local program, not a federal program. The FAA does not substitute its judgment for that of the airport proprietor with respect to which measures should be recommended for action. The FAA’s approval or disapproval of the Part 150 program recommendations is measured according to the standards expressed in Part 150 and the Act, and is limited to the following determinations:

Burlington, Vermont under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 and FAA regulations. These findings are made in recognition of the description of federal and non-federal responsibilities in Senate Report No. 96–52 (1980). On August 27, 2020, the Airports Division Manager approved the Burlington International Airport noise compatibility program. All of the proposed program elements were approved.

DATES: The date of the FAA’s approval of the Burlington International Airport noise compatibility program is August 27, 2020.

FOR FURTHER INFORMATION CONTACT:
Richard Doucette, Federal Aviation Administration, New England Region, Airports Division, 1200 District Avenue, Burlington, Massachusetts 01803, Telephone (781) 238–7613, Email: richard.doucette@faa.gov.

Documents reflecting this FAA action may be obtained from the same individual. The Noise Compatibility Plan and supporting information can also be found at www.bvsound.com.
(a) The noise compatibility program was developed in accordance with the provisions and procedures of FAR Part 150;

(b) Program measures are reasonably consistent with achieving the goals of reducing existing non-compatible land uses around the airport and preventing the introduction of additional non-compatible land uses;

(c) Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the federal government; and

(d) Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator as prescribed by law.

Specific limitations with respect to FAA’s approval of an airport noise compatibility program are delineated in Part 150, Section 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, state, or local law. Approval does not by itself constitute a FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action.

Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA under the Airport and Airway Improvement Act of 1982. Where Federal funding is sought, requests for project grants must be submitted to the FAA Regional Office in Burlington, Massachusetts.

The Burlington International Airport study contains a proposed noise compatibility program comprised of actions designed for implementation by airport management and adjacent jurisdictions from the date of study completion to beyond the year 2011. The Burlington International Airport, South Burlington, Vermont requested that the FAA evaluate and approve this material as a noise compatibility program as described in Section 104 (b) of the Act. The FAA began its review of the program on April 15, 2020, and was required by a provision of the Act to approve or disapprove the program within 180 days (other than the use of new flight procedures for noise control). Failure to approve or disapprove such a program within the 180-day period shall be deemed to be an approval of such a program.

The submitted program contained 9 noise mitigation measures, including 2 to be removed. The FAA completed its review and determined that the procedural and substantive requirements of the Act and Part 150 have been satisfied. The Airports Division Manager therefore approved the program effective August 27, 2020.

All 7 recommended measures were approved, and 2 recommended for removal were approved for removal. The new program will de-emphasize land acquisition in lieu of sound insulation, as the primary noise mitigation measure.

FAA’s determinations are set forth in detail in a Record of Approval endorsed by the Airports Division Director on August 27, 2020. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above and at the administrative offices of Burlington International Airport, South Burlington, Vermont.

Issued in Burlington, Massachusetts on August 27, 2020.

Julie Selltsam-Wilps,
Airports Division Deputy Director, FAA New England Region.

[F8 Doc. 2020–19227 Filed 9–30–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration


Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 14 individuals from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these hard of hearing and deaf individuals to continue to operate CMVs in interstate commerce.

DATES: The exemptions are applicable on October 13, 2020. The exemptions expire on October 13, 2022. Comments must be received on or before November 2, 2020.


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

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

• Hand Delivery: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

• Fax: (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the “Public Participation” portion of the SUPPLEMENTARY INFORMATION section for instructions on submitting comments.

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 Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to http://www.regulations.gov, put the docket number, FMCSA–2013–0121, FMCSA–2014–0103, FMCSA–2014–0385, FMCSA–2015–0329, FMCSA–2016–0002, FMCSA–2017–0059, or FMCSA–2018–0135, in the keyword box, and click “Search.” When the new screen appears, click on the “Comment Now!” button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 81⁄2 by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

B. 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–2013–0121, FMCSA–2014–0103, FMCSA–2014–0385, FMCSA–2015–0329, FMCSA–2016–0002, FMCSA–2017–0059, or FMCSA–2018–0135, 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 by visiting Docket Operations 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. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

C. 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 (DOTH/ALL–14 FDMS), which can be reviewed at www.transportation.gov/privacy.

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver’s medical certification.

The physical qualification standard for drivers regarding hearing found in 49 CFR 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5–1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, 35 FR 6458, 6463 (April 22, 1970) and 36 FR 12857 (July 3, 1971). The 14 individuals listed in this notice have satisfied the renewal conditions for their exemptions from the hearing standard in § 391.41(b)(11), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 14 applicants has satisfied the renewal conditions for obtaining an exemption from the hearing requirement. The 14 drivers in this notice remain in good standing with the Agency. In addition, for Commercial Driver’s License (CDL) holders, the Commercial Driver’s License Information System and the Motor Carrier Management Information System are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver’s Licensing Agency. These factors provide an adequate basis for predicting each driver’s ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each of these drivers for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

As of October 13, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following 14 individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Cory Adkins (FL)
David Alagna (TN)
Matthew Albrecht (PA)
Keith Bryd (TN)
David Chappelear (TX)
Ralph Domet (TX)
Jacquelyn Hetherington (OK)
Paul Mansfield (KS)
Evin Mitchell (TX)
Jose Ramirez (IL)
Fernando Ramirez-Savon (FL)
Thomas Sneer (MN)
Daniel Stroud (UT)
Jason Wynne (TX)


V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must report any crashes or accidents as defined in §390.5; (2) report all citations and convictions for disqualifying offenses under 49 CFR 383 and 49 CFR 391 to FMCSA; and (3) each driver is prohibited from operating a motorcoach or bus with passengers in
interstate commerce. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. In addition, the exemption does not exempt the individual from meeting the applicable CDL testing requirements. Each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be rescinded if: (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 before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

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 14 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the hearing requirement in §391.41(b)(11). In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for two years unless revoked earlier by FMCSA.

Larry W. Minor, Associate Administrator for Policy.

[FR Doc. 2020–21683 Filed 9–30–20; 8:45 am]
BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2020–0087]

Qualification of Drivers: Exemption Applications; Implantable Cardioverter Defibrillator

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of denial.

SUMMARY: FMCSA announces its decision to deny applications from five individuals treated with Implantable Cardioverter Defibrillators (ICDs) who requested an exemption from the Federal Motor Carrier Safety Regulations (FMCSRs) prohibiting operation of a commercial motor vehicle (CMV) in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope (transient loss of consciousness), dyspnea (shortness of breath), collapse, or congestive heart failure.

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 materials in the docket, contact Docket Operations, (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/docket?D=FMCSA-2020-0087 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 Operations 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. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

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 April 15, 2020, FMCSA published a Federal Register notice (85 FR 21061) announcing receipt of applications from five individuals treated with ICDs and requested comments from the public. These five individuals requested an exemption from §391.41(b)(4) which prohibits operation of a CMV in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive heart failure. The public comment period closed on May 15, 2020 and four comments were received. On May 19, 2020 FMCSA published a correction notice in the Federal Register (85 FR 30007) to fix an error in the April 15, 2020 notice. This correction notice extended the comment period for an additional 30 days until June 15, 2020 and there were no additional comments received.

FMCSA has evaluated the eligibility of these applicants and concluded that granting these five exemption requests would not provide a level of safety that would be equivalent to, or greater than, the level of safety that would be obtained by complying with §391.41(b)(4). A summary of each applicant’s medical history related to their ICD exemption request was discussed in the April 15, 2020 and May 19, 2020, Federal Register notices and will not be repeated here.

The Agency’s decision regarding these exemption applications is based on information from the Cardiomedical Medical Advisory Criteria, an April 2007 evidence report titled “Cardiovascular Disease and Commercial Motor Vehicle Driver Safety,” and a December 2014 focused research report titled “Implantable Cardioverter Defibrillators and the Impact of a Shock in a Patient When Deployed.” Copies of these reports are included in the docket for this notice.

FMCSA has published Medical Advisory Criteria to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. The Medical Advisory Criteria for §391.41(b)(4) indicates that coronary artery bypass surgery and pacemaker implantation are remedial procedures and thus, not medically disqualifying. Implantable cardioverter defibrillators are disqualifying due to risk of syncope.

III. Discussion of Comments

FMCSA received four comments in this proceeding. Two of the four commenters were favorable towards the applicants continuing to drive CMVs with ICDs. Another commenter indicated that the cost and overall safety impact of granting an exemption to an individual who has an ICD would result
in financial loss for the company if the individual has a crash and causes a casualty. The Minnesota Department of Public Safety commented that there was no record of a CDL driver in Minnesota by the name of Theodore J. Engelke.

In response to the comments, FMCSA believes that a driver with an ICD is at risk for incapacitation if the device discharges. This risk is combined with the risks associated with the underlying cardiovascular condition for which the ICD was implanted either as a primary or secondary preventive measure. In the correction notice discussed above, the State of Domicile for Mr. Theodore J. Engelke was changed from Minnesota to Wisconsin.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver’s medical certification.

The Agency’s decision regarding these exemption applications is based on an individualized assessment of each applicant’s medical information, available medical and scientific data concerning ICDs, and any relevant public comments received.

In the case of persons with ICDs, the underlying condition for which the ICD was implanted places the individual at high risk for syncope or other unpredictable events known to result in gradual or sudden incapacitation. ICDs may discharge, which could result in loss of ability to safely control a CMV. The December 2014 focused research report discussed earlier upholds the findings of the April 2007 report and indicates that the available scientific data on persons with ICDs and CMV driving does not support that persons with ICDs who operate CMVs are able to meet an equal or greater level of safety.

V. Conclusion

The Agency has determined that the available medical and scientific literature and research provides insufficient data to enable the Agency to conclude that granting these exemptions would achieve a level of safety equivalent to, or greater than, the level of safety maintained without the exemption. Therefore, the following five applicants have been denied exemptions from the physical qualification standards in § 391.41(b)(4):

- Cory Brister (MS)
- Christopher K. Chrestman (MS)
- Theodore J. Engelke (WI)
- Charles Michaux (CA)
- John Warner (CO)

Each applicant has, prior to this notice, received a letter of final disposition regarding his/her exemption request. Those decision letters fully outlined the basis for the denial and constitute final action by the Agency. The list published today summarizes the Agency’s recent denials as required under 49 U.S.C. 31315(b)(4).

Larry W. Minor, Associate Administrator for Policy.

[FR Doc. 2020–21682 Filed 9–30–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0125]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel OSPREY (Safe Boat); 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 2, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0125 by any one of the following methods:

- 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–2020–0125, 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:


SUPPLEMENTARY INFORMATION: As described by the applicant, the intended service of the vessel OSPREY is:

— Intended Commercial Use of Vessel: “Water safety and rescue, marine environment monitoring”


—Vessel Length and Type: 27’ safe boat.

The complete application is available for review identified in the DOT docket as MARAD–2020–0125 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–2020–0125 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. 552(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.


* * *

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,
Secretary, Maritime Administration.

[FR Doc. 2020–21704 Filed 9–30–20; 8:45 am]
BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0126]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel OUR HERITAGE (Motor Vessel); 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 2, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0126 by any one of the following methods:

• 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, Maritime Administration, 1200 New Jersey Avenue SE, 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.


SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel OUR HERITAGE is:

—Intended Commercial Use of Vessel: “Bareboat Charters”
—Geographic Region Including Base of Operations: “California” (Base of Operations: Marina Del Rey, CA)
—Vessel Length and Type: 62.6’ Motor Vessel

The complete application is available for review identified in the DOT docket as MARAD–2020–0126 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–2020–0126 or visit the Docket Management Facility (see ADDRESSES for hours of operation). We recommend that
DEPARTMENT OF THE TREASURY
Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request on Burden Related to the Continuation Sheet for Item # 16 (Additional Information) for OF–306, Declaration for Federal Employment

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning the burden associated with the continuation sheet for Item # 16 (Additional Information) for Form OF–306, Declaration for Federal Employment.

DATES: Written comments should be received on or before November 30, 2020 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224. Requests for additional information or copies of the regulations should be directed to Ronald J. Durbala, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at RJoseph.Durbala@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Continuation Sheet for Item # 16 (Additional Information)—OF–306, Declaration for Federal Employment.

OMB Number: 1545–1921.

Regulation Project Number: Form 12114.

Abstract: This form is used by recruitment personnel of the Covington Host Site. This form is provided to applicants when completing OF 306, Declaration for Federal Employment. It is used as a continuation sheet to clearly define additional information that is requested in item 15 of the OF 306. Due to lack of space on the OF 306 this form can be used in lieu of an additional sheet of paper.

Current Actions: There are no changes to the burden previously approved by OMB. This submission is for renewal purposes.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 24,813.

Estimated Time per Respondent: 15 min.

Estimated Total Annual Burden Hours: 6,203.

The following paragraph applies to all the collections of information covered by this notice:

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

Books or records relating to a collection of information must be retained in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.


Ronald J. Durbala,
IRS Tax Analyst.

[FR Doc. 2020–21720 Filed 9–30–20; 8:45 am]

BILLING CODE 4830–01–P
FEDERAL REGISTER

Vol. 85
No. 191

Thursday,

October 1, 2020

Part II

Department of the Interior

Office of Natural Resources Revenue

30 CFR Parts 1202 and 1206
Consolidated Federal Oil and Gas and Federal and Indian Coal Valuation Reform; Final Rule
I. Executive Summary

The requirements of section: Are derived from section:

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DERIVATION TABLE FOR PART 1206

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II. Procedural Matters

Because it is undisputed that the 2016 Valuation Rule was reinstated by operation of law, ONRR finds good cause to issue this final rule without notice and opportunity for public comment under 5 U.S.C. 553(b)(3)(B). Additionally, a 30-day period is not required between publication of a final rule and its effective date under 5 U.S.C. 553(d). As mentioned above, the Court’s Order reinstated the 2016 Valuation Rule, effective January 1, 2017.

1. Derivation Table

The following derivation table lists the sections of the respective subparts to be changed:
## DERIVATION TABLE FOR PART 1206—Continued

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### Subpart D—Federal Gas

| 1206.140                     | 1206.150.                |
| 1206.141(a)(1)–(3)           | 1206.152(a)(1).          |
| 1206.141(b)(1)–(3)           | 1206.152(a)(2).          |
| 1206.141(b)(4)               | 1206.152(b)(1)(iv).     |
| 1206.142(a)(4)               | 1206.153(a)(1).         |
| 1206.142(b)                  | 1206.153(a)(2).         |
| 1206.142(c)                  | 1206.153(b)(1)(i).     |
| 1206.143(a)(1)(a) and (b)   | 1206.152(b)(1)(ii).    |
| 1206.143(a)(2)               | 1206.152(f); 1206.153(f).|
| 1206.143(c)                  | 1206.152(b)(1)(iii); 1206.153(b)(1)(iii).|
| 1206.144                     | 1206.152(c)(1)–(3); 1206.153(c)(1)–(3).|
| 1206.145                     | 1206.152(e)(1) and (2); 1206.157(c)(1)(i) and (iii); 1206.159(c)(1)(ii) and (c)(2)(iii).|
| 1206.146                     | 1206.152(f); 1206.153(i).|
| 1206.147                     | 1206.152(k); 1206.153(k).|
| 1206.148                     | 1206.152(g); 1206.153(g).|
| 1206.149                     | 1206.152(l); 1206.153(l).|
| 1206.150                     | 1206.154.                |
| 1206.151                     | 1206.155.                |
| 1206.152(a)                  | 1206.156(a).             |
| 1206.152(b)                  | 1206.156(b); 1206.157(a)(2) and (b)(3).|
| 1206.152(c)(1)               | 1206.157(a)(2) and (b)(4).|
| 1206.152(f)                  | 1206.157(a)(4).         |
| 1206.153(b)                  | 1206.157(f).             |
| 1206.153(c)                  | 1206.157(g).             |
| 1206.154(a)                  | 1206.157(b).             |
| 1206.154(e)–(h)              | 1206.157(b)(2)(i)–(iii).|
| 1206.154(i)                  | 1206.157(b)(2)(iv).     |
| 1206.154(i)(3)               | 1206.157(b)(2)(v).      |
| 1206.155                     | 1206.157(c)(1)(i)–(ii). |
| 1206.156                     | 1206.157(c)(2)(i)–(iv). |
| 1206.157(a)(1) and (c)       | 1206.156(d).             |
| 1206.157(a)(2) and 1206.158  | 1206.157(e).             |
| 1206.159(a)(1)               | 1206.158(a).             |
| 1206.159(b)                  | 1206.158(b).             |
| 1206.159(c)(1) and (2)       | 1206.158(c)(1) and (2).|
| 1206.159(d)                  | 1206.158(d)(1).          |
| 1206.160                     | 1206.159(a).             |
| 1206.161                     | 1206.159(b).             |
| 1206.162                     | 1206.159(c)(1).          |
| 1206.163                     | 1206.159(c)(2).          |
| 1206.164                     | 1206.159(d).             |
| 1206.165                     | 1206.159(e).             |

### Subpart F—Federal Coal

| 1206.250                     | 1206.250.                |
| 1206.251                     | 1206.250; 1206.255; 1206.260.|
| 1206.252(d)                  | 1206.258(a); 1206.261(b).|
| 1206.260(a)(1) and (b)       | 1206.261(a).             |
| 1206.260(c)(2)               | 1206.261(a)(2).          |
| 1206.260(d)                  | 1206.261(c)(3).          |
| 1206.260(e)                  | 1206.261(c)(1), (c)(2), and (e).|
| 1206.260(f)                  | 1206.262(a)(4).          |
| 1206.260(g)                  | 1206.262(a)(2) and (a)(3).|
| 1206.261                     | 1206.262(a)(1).          |
| 1206.262                     | 1206.262(b).             |
| 1206.263                     | 1206.262(c)(1).          |
| 1206.264                     | 1206.262(c)(2).          |
| 1206.265                     | 1206.262(d).             |
| 1206.266                     | 1206.262(e).             |
| 1206.267(a)                  | 1206.258(a).             |
| 1206.267(b)(2)               | 1206.258(c); 1206.260. |
The requirements of section: | Are derived from section:
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1206.267(c) | 1206.259(a)(4).  
1206.267(d) | 1206.259(a)(2) and (a)(3).  
1206.267(e) | 1206.258(e).  
1206.268 | 1206.259(a)(1).  
1206.269 | 1206.259(b).  
1206.270 | 1206.259(c)(1).  
1206.271 | 1206.259(c)(2).  
1206.272 | 1206.259(d).  
1206.273 | 1206.259(e).  

**Subpart J—Indian Coal**

1206.450 | 1206.450.  
1206.451 | 1206.453; 1206.454; 1206.459.  
1206.460 | 1206.461(a)(1).  
1206.463 | 1206.461(c).  

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2. **Regulatory Planning and Review**  
(Executive Orders 12866 and 13563)

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) will review all significant rulemakings. While the 2016 Valuation Rule was considered significant when originally published, its republication here is not significant. The republication restates existing law, and does not change the law in any way.

Executive Order 13563 reaffirms the principles of E.O. 12866, while calling for improvements in the nation’s regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. This rule is consistent with the requirements of E.O. 13563 because it restates the law without change, as required by court order.

3. **Regulatory Flexibility Act**

The Department certified that the 2016 Valuation Rule did not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). Thus, a Regulatory Flexibility Analysis was not required, and, accordingly, a Small Entity Compliance Guide was not required. Similarly, the Regulatory Flexibility Analysis and Small Entity Compliance Guide are not required to republish the 2016 Valuation Rule.

Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and ten Regional Fairness Boards receive comments from small businesses about Federal agency enforcement actions. The Ombudsman annually evaluates the enforcement activities and rates each agency’s responsiveness to small business. If you wish to comment on ONRR’s actions, call 1 (888) 734–3247. You may comment to the Small Business Administration without fear of retaliation. Allegations of discrimination/retaliation filed with the Small Business Administration will be investigated for appropriate action.

4. **Small Business Regulatory Enforcement Fairness Act**

The 2016 Valuation Rule was not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule:

a. Did not have an annual effect on the economy of $100 million or more.  
b. Did not cause a major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions.  
c. Did not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. ONRR is the only agency that promulgates rules for royalty valuation on Federal oil and gas leases and Federal and Indian coal leases. This republication of the 2016 Valuation Rule is not a major rule because it simply republishes the law, as determined by court order.

5. **Unfunded Mandates Reform Act**

The 2016 Valuation Rule did not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. The 2016 Valuation Rule did not have a significant or unique effect on State, local, or Tribal governments or the private sector. ONRR was not required to provide a statement containing the information that the Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.) requires because the 2016 Valuation Rule was not an unfunded mandate. Similarly, this republication of the 2016 Valuation Rule is not an unfunded mandate.

6. **Takings** (E.O. 12630)

Under the criteria in section 2 of E.O. 12630, the 2016 Valuation Rule did not have any significant takings implications. The rule did not impose conditions or limitations on the use of any private property. The rule applied to Federal oil, Federal gas, Federal coal, and Indian coal leases only. Therefore, the rule did not require a Takings Implication Assessment, and this republication of the 2016 Valuation Rule does not either.

7. **Federalism** (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, the 2016 Valuation Rule did not have sufficient Federalism implications to warrant the preparation of a Federalism summary impact statement. The management of Federal oil leases, Federal gas leases, and Federal and Indian coal leases is the responsibility of the Secretary of the Interior, and ONRR distributes all of the royalties that it collects from the leases to States, Tribes, and individual Indian mineral owners. The rule did not impose administrative costs on States or local governments. The rule also did not substantially and directly affect the relationship between the Federal and State governments. Similarly, the republication of the 2016 Valuation Rule does not require a Federalism summary impact statement either.

8. **Civil Justice Reform** (E.O. 12988)

The 2016 Valuation Rule, as well as the republication, comply with the
requirements of E.O. 12988. Specifically, the republished rule:

a. Meets the criteria of section 3(a), which requires that ONRR review all regulations to eliminate errors and ambiguity and write them to minimize litigation.

b. Meets the criteria of section 3(b)(2), which requires that ONRR write all regulations in clear language using clear legal standards.

9. Consultation With Indian Tribal Governments (E.O. 13175)

Under the criteria in E.O. 13175, ONRR evaluated the 2016 Valuation Rule, and determined that it potentially affected Federally-recognized Indian Tribes. Specifically, the rule changed the valuation method for coal produced from Indian leases. Accordingly:

a. ONRR held a public workshop on October 20, 2011, in Albuquerque, New Mexico, to consider Tribal comments on the Indian coal valuation regulations.

b. ONRR solicited comments from all Tribes and received comments from a Tribe through an Advance Notice of Proposed Rulemaking published on May 27, 2011 (76 FR 30881).

c. ONRR requested further comments from its Tribal partners through our biannual State and Tribal Royalty Audit Committee meetings held in May and November 2015.

d. ONRR considered Tribal views in the 2016 Valuation Rule. See 82 FR 36952.

Because this rule republishes the 2016 Valuation Rule without change, ONRR did not solicit Tribal comments on the republication.

10. Paperwork Reduction Act

The 2016 Valuation Rule:

a. Did not contain any new information collection requirements.

b. Did not require a submission to OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

The rule also referred to, but did not change, the information collection requirements that OMB already approved under OMB Control Numbers 1012–0004, 1012–0005, and 1012–0010. Similarly, this republication of the 2016 Valuation Rule does not contain any new information collection requirements or submissions to OMB. Since the rule reorganized ONRR’s regulations, please refer to the Derivations Table in Section II for specifics. The corresponding information collection burden tables will be updated during the normal renewal cycle. See 5 CFR 1320.4(a)(2).

11. National Environmental Policy Act

The 2016 Valuation Rule did not constitute a major Federal action significantly affecting the quality of the human environment. ONRR was not required to provide a detailed statement under the National Environmental Policy Act of 1969 (NEPA) because the rule qualified for a categorical exclusion under 43 CFR 46.210(c) and (i) and the DOI Departmental Manual, part 516, section 15.4:D: “(c) Routine financial transactions including such things as . . . audits, fees, bonds, and royalties . . . (i) Policies, directives, regulations, and guidelines: That are of an administrative, financial, legal, technical, or procedural nature.” ONRR also determined that the rule was not involved in any of the extraordinary circumstances listed in 43 CFR 46.215 that require further analysis under NEPA. The procedural changes resulting from the amendments had no consequence on the physical environment. The rule did not alter, in any material way, natural resources exploration, production, or transportation. Likewise, this republication of the 2016 Valuation Rule does not alter, in any material way, natural resources exploration, production, or transportation because it republisher the law, as determined by court order.

12. Effects on the Nation’s Energy Supply (E.O. 13211)

The 2016 Valuation Rule was not a significant energy action under the definition in E.O. 13211. Nor is this republication of the 2016 Valuation Rule a significant energy action under the definition in E.O. 13211. Thus, a Statement of Energy Effects is not required.

List of Subjects in 30 CFR Parts 1202 and 1206

Coal, Continental shelf, Government contracts, Indian lands, Mineral royalties, Natural gas, Oil, Oil and gas exploration, Public lands—mineral resources, Reporting and recordkeeping requirements.

Kimbra G. Davis, Director for Office of Natural Resources Revenue.

Authority and Issuance

For the reasons discussed in the preamble, ONRR amends 30 CFR parts 1202 and 1206 as set forth below:

PART 1202—ROYALTIES

1. The authority citation for part 1202 continues to read as follows:


Subpart B—Oil, Gas, and OCS Sulfur, General

2. In § 1202.51, revise paragraph (b) to read as follows:

§ 1202.51 Scope and definitions.

(b) The definitions in § 1206.20 of this chapter are applicable to subparts B, C, D, and J of this part.

Subpart F—Coal

3. Add § 1202.251 to subpart F to read as follows:

§ 1202.251 What coal is subject to royalties?

(a) All coal (except coal unavoidably lost as BLM determines under 43 CFR part 3400) from a Federal or Indian lease is subject to royalty. This includes coal used, sold, or otherwise disposed of by you on or off of the lease.

(b) If you receive compensation for unavoidably lost coal through insurance coverage or other arrangements, you must pay royalties at the rate specified in the lease on the amount of compensation that you receive for the coal. No royalty is due on insurance compensation that you received for other losses.

(c) If you rework waste piles or slurry ponds to recover coal, you must pay royalty at the rate specified in the lease at the time when you use, sell, or otherwise finally dispose of the recovered coal.

(1) The applicable royalty rate depends on the production method that you used to initially mine the coal contained in the waste pile or slurry pond (such as an underground mining method or a surface mining method).

(2) You must allocate coal in waste pits or slurry ponds that you initially mined from Federal or Indian leases to those Federal or Indian leases regardless of whether it is stored on Federal or Indian lands.

(3) You must maintain accurate records demonstrating how to allocate the coal in the waste pit or slurry pond to each individual Federal or Indian coal lease.

PART 1206—PRODUCT VALUATION

4. The authority citation for part 1206 continues to read as follows:

Subpart A—General Provisions and Definitions

Sec. 1206.10 Has the Office of Management and Budget (OMB) approved the information collection requirements in this part?

1206.20 What definitions apply to this part?

Subpart A—General Provisions and Definitions

§ 1206.10 Has the Office of Management and Budget (OMB) approved the information collection requirements in this part?

OMB has approved the information collection requirement contained in this part under 44 U.S.C. 3501 et seq. See 30 CFR part 1210 for details concerning the estimated reporting burden and how to comment on the accuracy of the burden estimate.

§ 1206.20 What definitions apply to this part?

Ad valorem lease means a lease where the royalty due to the lessor is based upon a percentage of the amount or value of the coal.

Affiliate means a person who controls, is controlled by, or is under common control with another person. For the purposes of this subpart:

(1) Ownership or common ownership of more than 50 percent of the voting securities, or instruments of ownership or other forms of ownership, of another person constitutes control. Ownership of less than 10 percent constitutes a presumption of non-control that ONRR may rebut.

(2) If there is ownership or common ownership of 10 through 50 percent of the voting securities or instruments of ownership, or other forms of ownership, of another person, ONRR will consider each of the following factors to determine if there is control under the circumstances of a particular case:

(i) The extent to which there are common officers or directors.

(ii) With respect to the voting securities, or instruments of ownership or other forms of ownership: The percentage of ownership or common ownership, the relative percentage of ownership or common ownership compared to the percentage(s) of ownership by other persons, if a person is the greatest single owner, or if there is an opposing voting bloc of greater ownership.

(iii) Operation of a lease, plant, pipeline, or other facility.

(iv) The extent of others’ participation in operations and day-to-day management of a lease, plant, or other facility.

(v) The exercise of power to make decisions over or common control with another person.

(3) Regardless of any percentage of ownership or common ownership, relatives, either by blood or marriage, are affiliates.

ANS means Alaska North Slope.

Area means a geographic region at least as large as the limits of an oil and/or gas field, in which oil and/or gas lease products have similar quality and economic characteristics. Area boundaries are not officially designated and the areas are not necessarily named.

Arm’s-length-contract means a contract or agreement between independent persons who are not affiliates and who have opposing economic interests regarding that contract. To be considered arm’s-length for any production month, a contract must satisfy this definition for that month, as well as when the contract was executed.

Audit means an examination, conducted under the generally accepted Governmental Auditing Standards, of royalty reporting and payment compliance activities of lessees, designees or other persons who pay royalties, rents, or bonuses on Federal leases or Indian leases.

BIA means the Bureau of Indian Affairs of the Department of the Interior.

BLM means the Bureau of Land Management of the Department of the Interior.


BSEE means the Bureau of Safety and Environmental Enforcement of the Department of the Interior.

Coal means coal of all ranks from lignite through anthracite.

Coal cooperative means an entity organized to provide coal or coal-related services to the entity’s members (who may or may not also be owners of the entity), partners, and others. The entity may operate as a coal lessee, operator, payor, logistics provider, or electricity generator, or any of their affiliates, and may be organized to be non-profit or for-profit.

Coal washing means any treatment to remove impurities from coal. Coal washing may include, but is not limited to, operations, such as flotation, air, water, or heavy media separation; drying; and related handling (or combination thereof).

Compression means the process of raising the pressure of gas.

Condensate means liquid hydrocarbons (normally exceeding 40 degrees of API gravity) recovered at the surface without processing. Condensate is the mixture of liquid hydrocarbons resulting from condensation of petroleum hydrocarbons existing initially in a gaseous phase in an underground reservoir.

Constraint means a reduction in, or elimination of, gas flow, deliveries, or sales required by the delivery system.

Contract means any oral or written agreement, including amendments or revisions, between two or more persons, that is enforceable by law and that, with due consideration, creates an obligation.

Designee means the person whom the lessee designates to report and pay the lessee’s royalties for lease.

Exchange agreement means an agreement where one person agrees to deliver oil to another person at a specified location in exchange for oil deliveries at another location. Exchange agreements may or may not specify prices for the oil involved. They frequently specify dollar amounts reflecting location, quality, or other differentials. Exchange agreements include buy/sell agreements, which specify prices to be paid at each exchange point and may appear to be two separate sales within the same agreement. Examples of other types of exchange agreements include, but are not limited to, exchanges of produced oil for other crude oil at specific pipelines (such as West Texas Intermediate); exchanges of produced oil for other crude oil at other locations (Location Trades); exchanges of produced oil for other grades of oil (Grade Trades); and multi-party exchanges.


Field means a geographic region situated over one or more subsurface oil and gas reservoirs and encompassing at least the outermost boundaries of all oil and gas accumulations known within those reservoirs, vertically projected to the land surface. State oil and gas regulatory agencies usually name onshore fields and designate their official boundaries. BOEM names and designates boundaries of OCS fields.

Gas means any fluid, either combustible or non-combustible, hydrocarbon or non-hydrocarbon, which is extracted from a reservoir and which has neither independent shape nor volume, but tends to expand indefinitely. It is a substance that exists in a gaseous or rarefied state under standard temperature and pressure conditions.

Gas plant products means separate marketable elements, compounds, or mixtures, whether in liquid, gaseous, or solid form, resulting from processing gas, excluding residue gas.

Gathering means the movement of lease production to a central accumulation or treatment point on the lease, unit, or communitized area, or to
a central accumulation or treatment point off of the lease, unit, or communited area that BLM or BSEE approves for onshore and offshore leases, respectively, including any movement of bulk production from the wellhead to a platform offshore. Geographic region means, for Federal gas, an area at least as large as the defined limits of an oil and or gas field in which oil and/or gas lease products have similar quality and economic characteristics.

Gross proceeds means the total monies and other consideration accruing for the disposition of any of the following:

(1) Oil. Gross proceeds also include, but are not limited to, the following examples:

(i) Payments for services such as dehydration, marketing, measurement, or gathering which the lessee must perform at no cost to the Federal Government
(ii) The value of services, such as salt water disposal, that the producer normally performs but that the buyer performs on the producer’s behalf
(iii) Reimbursements for harboring or terminating fees, royalties, and any other reimbursements
(iv) Tax reimbursements, even though the Federal royalty interest may be exempt from taxation
(v) Payments made to reduce or buy down the purchase price of oil produced in later periods by allocating such payments over the production whose price that the payment reduces and including the allocated amounts as proceeds for the production as it occurs
(vi) Monies and all other consideration to which a seller is contractually or legally entitled, but does not seek to collect through reasonable efforts

Index means:

(1) For gas, the calculated composite price ($/MMBtu) of spot market sales that a publication that meets ONRR-established criteria for acceptability at the index pricing point publishes
(2) For oil, the calculated composite price ($/barrel) of spot market sales that a publication that meets ONRR-established criteria for acceptability at the index pricing point publishes

Index pricing point means any point on a pipeline for which there is an index, which ONRR-approved publications may refer to as a trading location.

Index zone means a field or an area with an active spot market and published indices applicable to that field or an area that is acceptable to ONRR under §1206.141(d)(1).

Indian Tribe means any Indian Tribe, band, nation, pueblo, community, rancheria, colony, or other group of Indians for which any minerals or interest in minerals is held in trust by the United States or is subject to Federal restriction against alienation.

Individual Indian mineral owner means any Indian for whom minerals or an interest in minerals is held in trust by the United States or who holds title subject to Federal restriction against alienation.

Keepwhole contract means a processing agreement under which the processor delivers to the lessee a quantity of gas after processing equivalent to the quantity of gas that the processor received from the lessee prior to processing, normally based on heat content, less gas used as plant fuel and gas unaccounted for and/or lost. This includes, but is not limited to, agreements under which the processor retains all NGLs that it recovered from the lessee’s gas.

Lease means any contract, profit-sharing arrangement, joint venture, or other agreement issued or approved by the United States under any mineral leasing law, including the Indian Mineral Development Act, 25 U.S.C. 2101–2108, that authorizes exploration for, extraction of, or removal of lease products. Depending on the context, lease may also refer to the land area that the authorization covers.

Lease products mean any leased minerals, attributable to, originating from, or allocated to a lease or produced in association with a lease.

Lessee means any person to whom the United States, an Indian Tribe, and/or individual Indian mineral owner issues a lease, and any person who has been assigned all or a part of record title, operating rights, or an obligation to make royalty or other payments required by the lease. Lessee includes:

(1) Any person who has an interest in a lease.
(2) In the case of leases for Indian coal or Federal coal, an operator, payor, or other person with no lease interest who makes royalty payments on the lessee’s behalf.

Like quality means similar chemical and physical characteristics.

Location differential means an amount paid or received (whether in money or in barrels of oil) under an exchange agreement that results from differences in location between oil delivered in exchange and oil received in the exchange. A location differential may represent all or part of the difference between the price received for oil delivered and the price paid for oil received under a buy/sell exchange agreement.

Market center means a major point that ONRR recognizes for oil sales, refining, or transshipment. Market centers generally are locations where ONRR-approved publications publish oil spot prices.

 Marketable condition means lease products which are sufficiently free from impurities and otherwise in a condition that they will be accepted by a purchaser under a sales contract typical for the field or area for Federal oil and gas, and region for Federal and Indian coal.

Mine means an underground or surface excavation or series of excavations and the surface or underground support facilities that contribute directly or indirectly to mining, production, preparation, and handling of lease products.

Misconduct means any failure to perform a duty owed to the United States under a statute, regulation, or lease, or unlawful or improper behavior, regardless of the mental state of the lessee or any individual employed by or associated with the lessee.

Net output means the quantity of:
For gas, residue gas and each gas plant product that a processing plant produces.

For coal, the quantity of washed coal that a coal wash plant produces.

Netting means reducing the reported sales value to account for an allowance instead of reporting the allowance as a separate entry on the Report of Sales and Royalty Remittance (Form ONRR–2014) or the Solid Minerals Production and Royalty Report (Form ONRR–4430).

NGLs means Natural Gas Liquids.

NYMEX price means the average of the New York Mercantile Exchange (NYMEX) settlement prices for light sweet crude oil delivered at Cushing, Oklahoma, calculated as follows:

(1) First, sum the prices published for each day during the calendar month of production (excluding weekends and holidays) for oil to be delivered in the prompt month corresponding to each such day.

(2) Second, divide the sum by the number of days on which those prices are published (excluding weekends and holidays).

Oil means a mixture of hydrocarbons that existed in the liquid phase in natural underground reservoirs, remains liquid at atmospheric pressure after passing through surface separating facilities, and is marketed or used as a liquid. Condensate recovered in lease facilities, and is marketed or used as a liquid. holidays).

field processes which normally take place on or near the lease, such as natural pressure reduction, mechanical separation, heating, cooling, dehydration, and compression, are not considered processing. The changing of pressures and/or temperatures in a reservoir is not considered processing.

The use of a Joule-Thomson (JT) unit to remove NGLs from gas is considered processing regardless of where the JT unit is located, provided that you market the NGLs as NGLs.

Processing allowance means a deduction in determining royalty value for the reasonable, actual costs the lessee incurs for processing gas.

Prompt month means the nearest month of delivery for which NYMEX futures prices are published during the trading month.

Quality differential means an amount paid or received under an exchange agreement (whether in money or in barrels of oil) that results from differences in API gravity, sulfur content, viscosity, metals content, and other quality factors between oil delivered and oil received in the exchange. A quality differential may represent all or part of the difference between the price received for oil delivered and the price paid for oil received under a buy/sell agreement.

Region for coal means the eight Federal coal production regions, which the Bureau of Land Management designates as follows: Denver-Raton Mesa Region, Fort Union Region, Green River-Hams Fork Region, Powder River Region, San Juan River Region, Southern Appalachian Region, Uinta-Southwestern Utah Region, and Western Interior Region. See 44 FR 65197 (1979).

Residue gas means that hydrocarbon gas consisting principally of methane resulting from processing gas.

Rocky Mountain Region means the States of Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming, except for those portions of the San Juan Basin and other oil-producing fields in the “Four Corners” area that lie within Colorado and Utah.

Roll means an adjustment to the NYMEX price that is calculated as follows: 

\[ \text{Roll} = \frac{1}{2} \left( \text{P}_1 - \text{P}_2 \right) + 0.3333 \times \left( \text{P}_0 - \text{P}_2 \right), \]

where \( \text{P}_0 \) is the average of the daily NYMEX settlement prices for deliveries during the prompt month that is the same as the month of production, as published for each day during the trading month for which the month of production is the prompt month; \( \text{P}_1 \) is the average of the daily NYMEX settlement prices for deliveries during the month following the month of production; and \( \text{P}_2 \) is the average of the daily NYMEX settlement prices for deliveries during the second month following the month of production, as published for each day during the trading month for which the month of production is the prompt month. Calculate the average of the daily NYMEX settlement prices using only the days on which such prices are published (excluding weekends and holidays).

(1) Example 1. Prices in Out Months are Lower Going Forward: The month of production for which you must determine royalty value is December.

December was the prompt month (for year 2011) from October 21 through November 18. January was the first month following the month of production, and February was the second month following the month of production.

\( \text{P}_1 \) is the average of the daily NYMEX settlement prices for deliveries during December published for each business day between October 21 and November 18.

\( \text{P}_2 \) is the average of the daily NYMEX settlement prices for deliveries during January published for each business day between October 21 and November 18.

\( \text{P}_0 \) is the average of the daily NYMEX settlement prices for deliveries during February published for each business day between October 21 and November 18. In this example, assume that \( \text{P}_0 \) is $95.08 per bbl, \( \text{P}_1 \) is $95.03 per bbl, and \( \text{P}_2 \) is $94.93 per bbl. In this example (a declining market), Roll = .6667 × ($95.08 − $95.03) + .3333 × ($95.08 − $94.93) = $0.03 + $0.05 = $0.08. You add this number to the NYMEX price.

(2) Example 2. Prices in Out Months are Higher Going Forward: The month of production for which you must determine royalty value is November.

November was the prompt month (for year 2012) from September 21 through October 22. December was the first month following the month of production, and January was the second month following the month of production.

\( \text{P}_0 \) is the average of the daily NYMEX settlement prices for deliveries during November published for each business day between September 21 and October 22.

\( \text{P}_1 \) is the average of the daily NYMEX settlement prices for deliveries during December published for each business day between September 21 and October 22.

\( \text{P}_2 \) is the average of the daily NYMEX settlement prices for deliveries during January published for each business day between September 21 and October 22. In this example, assume that...
Price \( P_0 \) = $91.28 per bbl, \( P_1 \) = $91.65 per bbl, and \( P_2 \) = $92.10 per bbl. In this example (a rising market), Roll = .6667 \times \\
\left( \frac{\text{\$91.28} - \text{\$91.65}}{\text{\$91.28}} \times 3.333 \times \right) \\
\left( \frac{\text{\$91.28} - \text{\$92.10}}{-0.025} \times \right) \\
\left( -0.052 \right). You add this negative number to the NYMEX price \\
( effectively, a subtraction from the NYMEX price).

Sale means a contract between two persons where:

1. The seller unconditionally transfers title to the oil, gas, gas plant product, or coal to the buyer and does not retain any related rights, such as the right to buy back similar quantities of oil, gas, gas plant product, or coal from the buyer elsewhere; and
2. The buyer pays money or other consideration for the oil, gas, gas plant product, or coal; and
3. The parties’ intent is for a sale of the oil, gas, gas plant product, or coal to occur.

**Section 6 lease** means an OCS lease subject to section 6 of the Outer Continental Shelf Lands Act, as amended, 43 U.S.C. 1335.

**Short ton** means 2,000 pounds.

**Spot price** means the price under a spot sales contract where:

1. A seller agrees to sell to a buyer a specified amount of oil at a specified price over a specified period of short duration.
2. No cancellation notice is required to terminate the sales agreement.
3. There is no obligation or implied intent to continue to sell in subsequent periods.

**Tonnage** means tons of coal measured in short tons.

**Trading month** means the period extending from the second business day before the 25th day of the calendar month preceding the delivery month (or, if the 25th day of that month is a non-business day, the second business day before the last business day preceding the 25th day of that month) through the third business day before the 25th day of the calendar month preceding the delivery month (or, if the 25th day of that month is a non-business day, the third business day before the last business day preceding the 25th day of that month), unless the NYMEX publishes a different definition or different dates on its official website, www.cmegroup.com, in which case, the NYMEX definition will apply.

**Transportation allowance** means a deduction in determining royalty value for the reasonable, actual costs that the lessee incurs for moving:

1. Oil to a point of sale or delivery off of the lease, unit area, or communitized area. The transportation allowance does not include gathering costs.
2. Unprocessed gas, residue gas, or gas plant products to a point of sale or delivery off of the lease, unit area, or communitized area, or away from a processing plant. The transportation allowance does not include gathering costs.
3. Coal to a point of sale remote from both the lease and mine or wash plant. **Washing allowance** means a deduction in determining royalty value for the reasonable, actual costs the lessee incurs for coal washing.

**WTI differential** means the average of the daily mean differentials for location and quality between a grade of crude oil at a market center and West Texas Intermediate (WTI) crude oil at Cushing published for each day for which price publications perform surveys for deliveries during the production month, calculated over the number of days on which those differentials are published (excluding weekends and holidays). Calculate the daily mean differentials by averaging the daily high and low differentials for the month in the selected publication. Use only the days and corresponding differentials for which such differentials are published.

6. Revise subpart C to read as follows:

**Subpart C—Federal Oil**

1206.100 **What is the purpose of this subpart?**

1206.101 **How do I calculate royalty value for oil I or my affiliate sell(s) under an arm’s-length contract?**

1206.102 **How do I value oil not sold under an arm’s-length contract?**

1206.103 **What publications does ONRR approve?**

1206.104 **How will ONRR determine if my royalty payments are correct?**

1206.105 **How will ONRR determine the value of my oil for royalty purposes?**

1206.106 **What records must I keep to support my calculations of value under this subpart?**

1206.107 **What are my responsibilities to place production into marketable condition and to market production?**

1206.108 **How do I request a valuation determination?**

1206.109 **Does ONRR protect information I provide?**

1206.110 **What general transportation allowance requirements apply to me?**

1206.111 **How do I determine a transportation allowance if I have an arm’s-length transportation contract?**

1206.112 **How do I determine a transportation allowance if I do not have an arm’s-length transportation contract?**

1206.113 **What adjustments and transportation allowances apply when I value oil production from my lease using NYMEX prices or ANS spot prices?**

1206.114 **How will ONRR identify market centers?**

1206.115 **What are my reporting requirements under an arm’s-length transportation contract?**

1206.116 **What are my reporting requirements under a non-arm’s-length transportation contract?**

1206.117 **What interest and penalties apply if I improperly report a transportation allowance?**

1206.118 **What reporting adjustments must I make for transportation allowances?**

1206.119 **How do I determine royalty quantity and quality?**
affiliates under the arm’s-length contract less applicable allowances determined under §1206.111 or §1206.112. This value does not apply if you exercise an option to use a different value provided in paragraph (c)(1) or (c)(2)(i) of this section or if ONRR decides to value your oil under §1206.105. You must use this paragraph (a) to value oil when:

1. You sell under an arm’s-length sales contract; or
2. You sell or transfer to your affiliate or another person under a non-arm’s-length contract and that affiliate or person, or another affiliate of either of them, then sells the oil under an arm’s-length contract, unless you exercise the option provided in paragraph (c)(2)(i) of this section.

(b) If you have multiple arm’s-length contracts to sell oil produced from a lease that is valued under paragraph (a) of this section, the value of the oil is the volume-weighted average of the values established under this section for each contract for the sale of oil produced from that lease.

(c)(1) If you enter into an arm’s-length exchange agreement, or multiple sequential arm’s-length exchange agreements, and following the exchange(s) that you or your affiliate sell(s) the oil received in the exchange(s) under an arm’s-length contract, then you may use either paragraph (a) of this section or §1206.102 to value your production for royalty purposes. If you fail to make the election required under this paragraph, you may not make a retroactive election, and ONRR may decide your value under §1206.105.

(i) If you use paragraph (a) of this section, your gross proceeds are the gross proceeds under your or your affiliate’s arm’s-length sales contract after the exchange(s) occur(s). You must adjust your gross proceeds for any location or quality differentials, or other adjustments, that you received or paid under the arm’s-length exchange agreement(s). If ONRR determines that any arm’s-length exchange agreement does not reflect reasonable location or quality differentials, ONRR may decide your value under §1206.105. You may not otherwise use the price or differential specified in an arm’s-length exchange agreement to value your production.

(ii) When you elect under paragraph (c)(1) of this section to use paragraph (a) of this section or §1206.102, you must make the same election for all of your production from the same unit, communitization agreement, or lease (if the lease is not part of a unit or communitization agreement) sold under arm’s-length contracts following arm’s-length exchange agreements. You may not change your election more often than once every two years.

(2)(i) If you sell or transfer your oil production to your affiliate, and that affiliate or another affiliate then sells the oil under an arm’s-length contract, you may use either paragraph (a) of this section or §1206.102 to value your production for royalty purposes.

(ii) When you elect under paragraph (c)(2)(i) of this section to use paragraph (a) of this section or §1206.102, you must make the same election for all of your production from the same unit, communitization agreement, or lease (if the lease is not part of a unit or communitization agreement) that your affiliates resell at arm’s-length. You may not change your election more often than once every two years.

§1206.102 How do I value oil not sold under an arm’s-length contract?

This section explains how to value oil that you may not value under §1206.101 or that you elect under §1206.101(c)(1) to value under this section, unless ONRR decides to value your oil under §1206.105. First, determine if paragraph (a), (b), or (c) of this section applies to production from your lease, or if you may apply paragraph (d) or (e) of this section with ONRR’s approval.

(a) Production from leases in California or Alaska. Value is the average of the daily mean ANS spot prices published in any ONRR-approved publication during the trading month most concurrent with the production month. For example, if the production month is June, calculate the average of the daily mean prices using the daily ANS spot prices published in the ONRR-approved publication for all of the business days in June.

1. To calculate the daily mean spot price, you must average the daily high and low prices for the month in the selected publication.

2. You must use only the days and corresponding spot prices for which such prices are published.

3. You must adjust the value for applicable location and quality differentials, and you may adjust it for transportation costs, under §1206.111.

4. After you select an ONRR-approved publication, you may not select a different publication more often than once every two years, unless the publication you use is no longer published or ONRR revokes its approval of the publication. If you must change publications, you must begin a new two-year period.

(b) Production from leases not located in California, Alaska, or the Rocky Mountain Region.

1. Value is the NYMEX price (without the roll), adjusted for applicable location and quality differentials and transportation costs under §1206.113.

2. If you demonstrate to ONRR’s satisfaction that paragraphs (b)(2) through (3) of this section result in an unreasonable value for your production as a result of circumstances regarding that production, ONRR’s Director may establish an alternative valuation method.

(c) Production from leases not located in California, Alaska, or the Rocky Mountain Region.

1. Value is the NYMEX price, plus the roll, adjusted for applicable location and quality differentials and transportation costs under §1206.113.

2. If ONRR’s Director determines that the use of the roll no longer reflects prevailing industry practice in crude oil sales contracts or that the most common formula that industry uses to calculate the roll changes, ONRR may terminate
or modify the use of the roll under paragraph (c)(1) of this section at the end of each two-year period as of January 1, 2017, through a notice published in the Federal Register not later than 60 days before the end of the two-year period. ONRR will explain the rationale for terminating or modifying the use of the roll in this notice.

(d) Unreasonable value. If ONRR determines that the NYMEX price or ANS spot price does not represent a reasonable royalty value in any particular case, ONRR may decide to value your oil under § 1206.105.

(e) Production delivered to your refinery and the NYMEX price or ANS spot price is an unreasonable value. If ONRR determines that the NYMEX price or ANS spot price does not represent a reasonable royalty value in any particular case, ONRR may decide to value your oil under § 1206.105.

§ 1206.103 What publications does ONRR approve?

(a) ONRR will periodically publish on www.onrr.gov a list of ONRR-approved publications for the NYMEX price and ANS spot price based on certain criteria including, but not limited to:

(1) Publications buyers and sellers frequently use.

(2) Publications frequently mentioned in purchase or sales contracts.

(3) Publications that use adequate survey techniques, including development of estimates based on daily surveys of buyers and sellers of crude oil, and, for ANS spot prices, buyers and sellers of ANS crude oil.

(4) Publications independent from ONRR, other lessors, and lessees.

(b) Any publication may petition ONRR to be added to the list of acceptable publications.

(c) ONRR will specify the tables that you must use in the acceptable publications.

(d) ONRR may revoke its approval of a particular publication if we determine that the prices or differentials published in the publication do not accurately represent NYMEX prices or differentials or ANS spot market prices or differentials.

§ 1206.104 How will ONRR determine if my royalty payments are correct?

(a) ONRR may monitor, review, and audit the royalties that you report, and, if ONRR determines that your reported value is inconsistent with the requirements of this subpart, ONRR may direct you to use a different measure of royalty value or decide your value under § 1206.105.

(b) When the provisions in this subpart refer to gross proceeds, in conducting reviews and audits, ONRR will examine if your or your affiliate’s contract reflects the total consideration actually transferred, either directly or indirectly, from the buyer to you or to your affiliate for the oil. If ONRR determines that a contract does not reflect the total consideration, ONRR may decide your value under § 1206.105.

§ 1206.105 How will ONRR determine the value of my oil for royalty purposes?

§ 1206.105 How will ONRR determine the value of my oil for royalty purposes?

If ONRR decides that we will value your oil for royalty purposes under § 1206.104, or any other provision in this subpart, then we will determine value, for royalty purposes, by considering any information that we deem relevant, which may include, but is not limited to, the following:

(a) The value of like-quality oil in the same field or nearby fields or areas.

(b) The value of like-quality oil from the refinery or area.

(c) Public sources of price or market information that ONRR deems reliable.

(d) Information available and reported to ONRR, including but not limited to the data on form ONRR–2014 and the Oil and Gas Operations Report (Form ONRR–4054).

(e) Costs of transportation or processing if ONRR determines that they are applicable.

(f) Any information that ONRR deems relevant regarding the particular lease operation or the salability of the oil.

§ 1206.106 What records must I keep to support my calculations of value under this subpart?

If you determine the value of your oil under this subpart, you must retain all data relevant to the determination of royalty value.

(a) You must show both of the following:

(1) How you calculated the value that you reported, including all adjustments for location, quality, and transportation.

(2) How you complied with these rules.

(b) You can find recordkeeping requirements in parts 1207 and 1212 of this chapter.

(c) ONRR may review and audit your data, and ONRR will direct you to use a different value if we determine that the reported value is inconsistent with the requirements of this subpart.
§ 1206.107 What are my responsibilities to place production into marketable condition and to market the oil?

(a) You must place oil in marketable condition and market the oil for the mutual benefit of the lessee and the lessor at no cost to the Federal government.

(b) If you use gross proceeds under an arm’s-length contract in determining value, you must increase those gross proceeds to the extent that the purchaser, or any other person, provides certain services that the seller normally would be responsible to perform to place the oil in marketable condition or to market the oil.

§ 1206.108 How do I request a valuation determination?

(a) You may request a valuation determination from ONRR regarding any oil produced. Your request must:

(1) Be in writing;

(2) Identify, specifically, all leases involved, all interest owners of those leases, the designee(s), and the operator(s) for those leases;

(3) Completely explain all relevant facts; you must inform ONRR of any changes to relevant facts that occur before we respond to your request;

(4) Include copies of all relevant documents;

(5) Provide your analysis of the issue(s), including citations to all relevant precedents (including adverse precedents); and

(6) Suggest your proposed valuation method.

(b) In response to your request, ONRR may:

(1) Request that the Assistant Secretary for Policy, Management and Budget issue a valuation determination;

(2) Decide that ONRR will issue guidance; or

(3) Inform you in writing that ONRR will not provide a determination or guidance. Situations in which ONRR typically will not provide any determination or guidance include, but are not limited to, the following:

(i) Requests for guidance on hypothetical situations

(ii) Matters that are the subject of pending litigation or administrative appeals

(c)(1) A valuation determination that the Assistant Secretary for Policy, Management and Budget signs is binding on both you and ONRR until the Assistant Secretary modifies or rescinds it.

(2) After the Assistant Secretary issues a valuation determination, you must make any adjustments to royalty payments that follow from the determination and, if you owe additional royalties, you must pay the additional royalties due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter.

(3) A valuation determination that the Assistant Secretary signs is the final action of the Department and is subject to judicial review under 5 U.S.C. 701–706.

(d) Guidance that ONRR issues is not binding on ONRR, delegated States, or you with respect to the specific situation addressed in the guidance.

(1) Guidance and ONRR’s decision whether or not to issue guidance or request an Assistant Secretary determination, or neither, under paragraph (b) of this section, are not appealable decisions or orders under 30 CFR part 1290.

(2) If you receive an order requiring you to pay royalty on the same basis as the guidance, you may appeal that order under 30 CFR part 1290.

(e) ONRR or the Assistant Secretary may use any of the applicable valuation criteria in this subpart to provide guidance or to make a determination.

(i) A change in an applicable statute or regulation on which ONRR or the Assistant Secretary based any determination or guidance takes precedence over the determination or guidance, regardless of whether ONRR or the Assistant Secretary modifies or rescinds the determination or guidance.

(2) ONRR or the Assistant Secretary generally will not retroactively modify or rescind a valuation determination issued under paragraph (d) of this section, unless:

(1) There was a misstatement or omission of material facts; or

(2) The facts subsequently developed are materially different from the facts on which the guidance was based.

(h) ONRR may make requests and replies under this section available to the public, subject to the confidentiality requirements under § 1206.109.

§ 1206.109 Does ONRR protect information that I provide?

(a) Certain information that you or your affiliate submit(s) to ONRR regarding valuation of oil, including transportation allowances, may be exempt from disclosure.

(b) To the extent that applicable laws and regulations permit, ONRR will keep confidential any data that you or your affiliate submit(s) that is privileged, confidential, or otherwise exempt from disclosure.

(c)(1) Where you or your affiliate transport(s) both gaseous and liquid products through the same transportation system, you must propose a cost allocation procedure to ONRR.

§ 1206.110 What general transportation allowance requirements apply to me?

(a) ONRR will allow a deduction for the reasonable, actual costs to transport oil from the lease to the point off of the lease under § 1206.110, § 1206.111, or § 1206.112, as applicable. You may not deduct transportation costs that you incur to move a particular volume of production to reduce royalties that you owe on production for which you did not incur those costs. This paragraph applies when:

(1)(i) The movement to the sales point is not gathering;

(ii) For oil produced on the OCS, the movement of oil from the wellhead to the first platform is not transportation; and

(2) You value oil under § 1206.101 based on a sale at a point off of the lease, unit, or communized area where the oil is produced; or

(3) You do not value your oil under § 1206.102(a)(3) or (b)(3).

(b) You must calculate the deduction for transportation costs based on your or your affiliate’s cost of transporting each product through each individual transportation system. If your or your affiliate’s transportation contract includes more than one liquid product, you must allocate costs consistently and equitably to each of the liquid products that are transported. Your allocation must use the same proportion as the ratio of the volume of each liquid product (excluding waste products with no value) to the volume of all liquid products (excluding waste products with no value).

(1) You may not take an allowance for transporting lease production that is not royalty-bearing.

(2) You may propose to ONRR a prospective cost allocation method based on the values of the liquid products transported. ONRR will approve the method if it is consistent with the purposes of the regulations in this subpart.

(3) You may use your proposed procedure to calculate a transportation allowance beginning with the production month following the month when ONRR received your proposed procedure until ONRR accepts or rejects your cost allocation. If ONRR rejects your cost allocation, you must amend your form ONRR–2014 for the months that you used the rejected method and pay any additional royalty due, plus late payment interest.

(c)(1) Where you or your affiliate transport(s) both gaseous and liquid products through the same transportation system, you must propose a cost allocation procedure to ONRR.
You may use your proposed procedure to calculate a transportation allowance until ONRR accepts or rejects your cost allocation. If ONRR rejects your cost allocation, you must amend your form ONRR–2014 for the months when you used the rejected method and pay any additional royalty and interest due.

You must submit your initial proposal, including all available data, within three months after you first claim the allocated deductions on form ONRR–2014.

Your transportation allowance may not exceed 50 percent of the value of the oil, as determined under §1206.101 of this subpart.

If ONRR approved your request to take a transportation allowance in excess of the 50-percent limitation under former §1206.109(c), that approval is terminated as of January 1, 2017.

You must express transportation allowances for oil as a dollar-value equivalent. If your or your affiliate’s payments for transportation under a contract are not on a dollar-per-unit basis, you must convert whatever consideration you or your affiliate are paid to a dollar-value equivalent.

ONRR may determine your transportation allowance under §1206.105 because:

(1) There is misconduct by or between the contracting parties;

(2) ONRR determines that the consideration that you or your affiliate paid under an arm’s-length transportation contract does not reflect the reasonable cost of the transportation because you breached your duty to market the oil for the mutual benefit of yourself and the lessor by transporting your oil at a cost that is unreasonably high. We may consider a transportation allowance to be unreasonably high if it is 10 percent higher than the highest reasonable measures of transportation costs including, but not limited to, transportation allowances reported to ONRR and tariffs for gas, residue gas, or gas plant product transported through the same system; or

(3) ONRR cannot determine if you properly calculated a transportation allowance under §1206.111 or §1206.112 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents that ONRR requests under 30 CFR part 1212, subpart B.

You do not need ONRR’s approval before reporting a transportation allowance.

How do I determine a transportation allowance if I have an arm’s-length transportation contract?

If you or your affiliate incur transportation costs under an arm’s-length transportation contract, you may claim a transportation allowance for the reasonable, actual costs incurred, as more fully explained in paragraph (b) of this section, except as provided in §1206.110(f) and subject to the limitation in §1206.110(d).

You must be able to demonstrate that your or your affiliate’s contract is at arm’s-length.

You do not need ONRR’s approval before reporting a transportation allowance for costs incurred under an arm’s-length transportation contract.

Subject to the requirements of paragraph (c) of this section, you may include, but are not limited to, the following costs to determine your transportation allowance under paragraph (a) of this section: you may not use any cost as a deduction that duplicates all or part of any other cost that you use under this section including, but not limited to:

(1) The amount that you pay under your arm’s-length transportation contract or tariff.

(2) Fees paid (either in volume or in value) for actual or theoretical line losses.

(3) Fees paid for administration of a quality bank.

(4) Fees paid to a terminal operator for loading and unloading of crude oil into or from a vessel, vehicle, pipeline, or other conveyance.

(5) Fees paid for short-term storage (30 days or less) incidental to transportation as a transporter requires.

(6) Fees paid to pump oil to another carrier’s system or vehicles as required under a tariff.

(7) Transfer fees paid to a hub operator associated with physical movement of crude oil through the hub when you do not sell the oil at the hub. These fees do not include title transfer fees.

(8) Payments for a volumetric deduction to cover shrinkage when high-gravity petroleum (generally in excess of 51 degrees API) is mixed with lower gravity crude oil for transportation.

(9) Costs of securing a letter of credit, or other surety, that the pipeline requires you, as a shipper, to maintain.

(10) Hurricane surcharges that you or your affiliate actually pay(s).

(11) The cost of carrying on your books as inventory a volume of oil that the pipeline operator requires you, as a shipper, to maintain and that you do maintain in the line as line fill. You must calculate this cost as follows:

First, multiply the volume that the pipeline requires you to maintain—and that you do maintain—in the pipeline by the value of that volume for the current month calculated under §1206.101 or §1206.102, as applicable.

Second, multiply the value calculated under paragraph (b)(11)(i) of this section by the monthly rate of return, calculated by dividing the rate of return specified in §1206.112(i)(3) by 12.

You may not include the following costs to determine your transportation allowance under paragraph (a) of this section:

(1) Fees paid for long-term storage (more than 30 days)

(2) Administrative, handling, and accounting fees associated with terminalling

(3) Title and terminal transfer fees

(4) Fees paid to track and match receipts and deliveries at a market center or to avoid paying title transfer fees

(5) Fees paid to brokers

(6) Fees paid to a scheduling service provider

(7) Internal costs, including salaries and related costs, rent/space costs, office equipment costs, legal fees, and other costs to schedule, nominate, and account for sale or movement of production

(8) Gauging fees

If you have no written contract for the arm’s-length transportation of oil, then ONRR will determine your transportation allowance under §1206.105. You may not use this paragraph (d) if you or your affiliate perform(s) your own transportation.

You must propose to ONRR a method to determine the allowance using the procedures in §1206.108(a).

You may use that method to determine your allowance until ONRR issues its determination.

How do I determine a transportation allowance if I do not have an arm’s-length transportation contract?

This section applies if you or your affiliate do(es) not have an arm’s-length transportation contract, including situations where you or your affiliate provide your own transportation services. You must calculate your transportation allowance based on your or your affiliate’s reasonable, actual costs for transportation during the reporting period using the procedures prescribed in this section.

Your or your affiliate’s actual costs may include the following:

(1) Capital costs and operating and maintenance expenses under paragraphs (e), (f), and (g) of this section.

(2) Overhead under paragraph (h) of this section.
(3)(i) Depreciation and a return on undepreciated capital investment under paragraph (i)(1) of this section, or you may elect to use a cost equal to a return on the initial depreciable capital investment in the transportation system under paragraph (i)(2) of this section. After you have elected to use either method for a transportation system, you may not later elect to change to the other alternative without ONRR's approval. If ONRR accepts your request to change methods, you may use your changed method beginning with the production month following the month when ONRR received your change request.

(ii) A return on the reasonable salvage value under paragraph (i)(1)(iii) of this section after you have depreciated the transportation system to its reasonable salvage value.

(c) To the extent not included in costs identified in paragraphs (e) through (h) of this section.

(1) If you or your affiliate incur(s) the following actual costs under your or your affiliate's non-arm's-length contract, you may include these costs in your calculations under this section:

(i) Fees paid to a non-affiliated terminal operator for loading and unloading of crude oil into or from a vessel, vehicle, pipeline, or other conveyance

(ii) Transfer fees paid to a hub operator associated with physical movement of crude oil through the hub when you do not sell the oil at the hub; these fees do not include title transfer fees

(iii) A volumetric deduction to cover shrinkage when high-gravity petroleum (generally in excess of 51 degrees API) is mixed with lower gravity crude oil for transportation

(iv) Fees paid to a non-affiliated quality bank administrator for administration of a quality bank

(v) The cost of carrying on your books as inventory a volume of oil that the pipeline operator requires you, as a shipper, to maintain—and that you do maintain—in the line as line fill; you must calculate this cost as follows:

(A) First, multiply the volume that the pipeline requires you to maintain—and that you do maintain—in the pipeline by the value of that volume for the current month calculated under §1206.101 or §1206.102, as applicable.

(B) Second, multiply the value calculated under paragraph (c)(1)(v)(A) of this section by the monthly rate of return, calculated by dividing the rate of return specified in paragraph (i)(3) of this section by 12.

(2) You may not include in your transportation allowance:

(i) Any of the costs identified under §1206.111(c); and/or

(ii) Fees paid (either in volume or in value) for actual or theoretical line losses.

(d) You may not use any cost as a deduction that duplicates all or part of any other cost that you use under this section.

(e) Allowable capital investment costs are generally those for depreciable fixed assets (including the costs of delivery and installation of capital equipment) that are an integral part of the transportation system.

(f) Allowable operating expenses include the following:

(1) Operations supervision and engineering

(2) Operations labor

(3) Fuel

(4) Utilities

(5) Materials

(6) Ad valorem property taxes

(7) Rent

(8) Supplies

(9) Any other directly allocable and attributable operating expense that you can document

(g) Allowable maintenance expenses include the following:

(1) Maintenance of the transportation system

(2) Maintenance of equipment

(3) Maintenance labor

(4) Other directly allocable and attributable maintenance expenses that you can document

(h) Overhead, directly allocable and allocable to the operation and maintenance of the transportation system, is an allowable expense. State and Federal income taxes and severance taxes and other fees, including royalties, are not allowable expenses.

(i) You must use the monthly average BBB rate that Standard & Poor's publishes for the first month for which the allowance is applicable.

(ii) You must re-determine the rate at the beginning of each subsequent calendar year.

§1206.113 What adjustments and transportation allowances apply when I value oil production from my lease using NYMEX prices or ANS spot prices?

This section applies when you use NYMEX prices or ANS spot prices to calculate the value of production under §1206.102. As specified in this section, you must adjust the NYMEX price to reflect the difference in value between your lease and Cushing, Oklahoma, or adjust the ANS spot price to reflect the difference in value between your lease and the appropriate ONRR-recognized market center at which the ANS spot price is published (for example, Long Beach, California, or San Francisco, California). Paragraph (a) of this section explains how you adjust the value between the lease and the market center, and paragraph (b) of this section explains how you adjust the value between the market center and Cushing when you use NYMEX prices. Paragraph (c) of this section explains how adjustments may be made for quality differentials that are not accounted for through exchange agreements.

Paragraph (d) of this section gives some examples. References in this section to "you" include your affiliates, as applicable.

(a) To adjust the value between the lease and the market center:
(1)(i) For oil that you exchange at arm’s-length between your lease and the market center (or between any intermediate points between those locations), you must calculate a lease-to-market center differential by the applicable location and quality differentials derived from your arm’s-length exchange agreement applicable to production during the production month.

(ii) For oil that you exchange between your lease and the market center (or between any intermediate points between those locations), you must obtain approval from ONRR for a location and quality differential. Until you obtain such approval, you may use the location and quality differential derived from that exchange agreement applicable to production during the production month. If ONRR prescribes a different differential, you must apply ONRR’s differential to all periods for which you used your proposed differential. You must pay any additional royalties due resulting from using ONRR’s differential, plus late payment interest from the original royalty due date, or you may report a credit for any overpaid royalties plus interest under 30 U.S.C. 1721(h).

(2) For oil that you transport between your lease and the market center (or between any intermediate points between those locations), you may take an allowance for the cost of transporting that oil between the relevant points, as determined under §1206.111 or 1206.112, as applicable.

(3) If you transport or exchange at arm’s-length (or both transport and exchange) at least 20 percent—but not all—of your oil produced from the lease to a market center, you must determine the adjustment between the lease and the market center for the oil that is not transported or exchanged (or both transported and exchanged) to or through a market center as follows:

(i) Determine the volume-weighted average of the lease-to-market center adjustment calculated under paragraphs (a)(1) and (2) of this section for the oil that you do transport or exchange (or both transport and exchange) from your lease to a market center.

(ii) Use that volume-weighted average lease-to-market center adjustment as the adjustment for the oil that you do not transport or exchange (or both transport and exchange) from your lease to a market center.

(iii) If you transport or exchange (or both transport and exchange) less than 20 percent of the crude oil produced from your lease between the lease and a market center, you must propose to ONRR an adjustment between the lease and the market center for the portion of the oil that you do not transport or exchange (or both transport and exchange) to a market center. Until you obtain such approval, you may use your proposed adjustment. If ONRR prescribes a different adjustment, you must apply ONRR’s adjustment to all periods for which you used your proposed adjustment. You must pay any additional royalties due resulting from using ONRR’s adjustment, plus late payment interest from the original royalty due date, or you may report a credit for any overpaid royalties plus interest under 30 U.S.C. 1721(h).

(4) You must pay any additional royalties due resulting from using ONRR’s differential, plus late payment interest from the original royalty due date, or you may report a credit for any overpaid royalties plus interest under 30 U.S.C. 1721(h).

(b) For oil that you value using NYMEX prices, you must adjust the value between the market center and Cushing, Oklahoma, as follows:

(1) If you have arm’s-length exchange agreements between the market center and Cushing under which you exchange to Cushing at least 20 percent of all of the oil that you own at the market center during the production month, you must use the volume-weighted average of the location and quality differentials from those agreements as the adjustment between the market center and Cushing for all of the oil that you produce from the leases during that production month for which that market center is used.

(2) If paragraph (b)(1) of this section does not apply, you must use the WTI differential published in an ONRR-approved publication for the market center nearest to your lease, for crude oil most similar in quality to your production, as the adjustment between the market center and Cushing. For example, for light sweet crude oil produced offshore of Louisiana, you must use the WTI differential for Light Louisiana Sweet crude oil at St. James, Louisiana. After you select an ONRR-approved publication, you may not select a different publication more often than once every two years, unless the publication you use is no longer published or ONRR revokes its approval of the publication. If you must change publications, you must begin a new two-year period.

(c)(1) You may request prior ONRR approval to use a different adjustment.

(ii) If ONRR approves your request to use a different quality adjustment, you may begin using that adjustment for the production month following the month when ONRR received your request.

(d) The examples in this paragraph illustrate how to apply the requirement of this section.

(1) Example 1. Assume that a Federal lessee produces crude oil from a lease near Artesia, New Mexico. Further, assume that the lessee transports the oil to Roswell, New Mexico, and then exchanges the oil to Midland, Texas. Assume that the NYMEX price of $86.21/bbl, adjusted for the roll; that the WTI differential (Cushing to Midland) is $8.22/bbl; and that the lessee’s actual cost of transporting the oil from Artesia to Roswell is $0.40/bbl. In this example, the royalty value of the oil is $86.21 − $2.27 − $0.08 − $0.40 = $83.46/bbl.

(2) Example 2. Assume the same facts as in the example in paragraph (d)(1) of this
§ 1206.114 How will ONRR identify market centers?

ONRR will monitor market activity and, if necessary, add to or modify the list of market centers that we publish to www.onrr.gov. ONRR will consider the following factors and conditions in specifying market centers:

(a) Points where ONRR-approved publications publish prices useful for index purposes

(b) Markets served

(c) Input from industry and others knowledgeable in crude oil marketing and transportation

(d) Simplification

(e) Other relevant matters

§ 1206.115 What are my reporting requirements under an arm’s-length transportation contract?

(a) You must use a separate entry on form ONRR–2014 to notify ONRR of an allowance based on transportation costs that you or your affiliate incur(s).

(b) ONRR may require you or your affiliate to submit arm’s-length transportation contracts, production agreements, operating agreements, and related documents.

(c) You can find recordkeeping requirements in parts 1207 and 1212 of this chapter.

§ 1206.116 What are my reporting requirements under a non-arm’s-length transportation contract?

(a) You must use a separate entry on form ONRR–2014 to notify ONRR of an allowance based on transportation costs that you or your affiliate incur(s).

(b) For new non-arm’s-length transportation facilities or arrangements, you must base your initial deduction on estimates of allowable transportation costs for the applicable period.

(c) ONRR may require you or your affiliate to submit all data used to calculate the allowance deduction. You may find recordkeeping requirements in parts 1207 and 1212 of this chapter.

(d) If you are authorized under § 1206.112(j) to use an exception to the requirement to calculate your actual transportation costs, you must follow the reporting requirements of § 1206.115.

§ 1206.117 What interest and penalties apply if I improperly report a transportation allowance?

(a) If you deduct a transportation allowance on form ONRR–2014 that exceeds 50 percent of the value of the oil transported, you must pay additional royalties due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter. In this example, the other lessee transports and exchanges to Midland 40 percent of the volume measured at the approved point of royalty settlement that BLM or BSEE approves, you must adjust that value for the differences in quantity and/or quality.

(b) If you improperly report a transportation allowance, you must pay royalties on 100 percent of the volume measured at the approved point of royalty settlement. You may not claim a reduction in that measured volume for actual losses beyond the approved point of royalty settlement or for theoretical losses that you claim to have taken place either before or after the approved point of royalty settlement.

§ 1206.118 What are my reporting requirements under a non-arm’s-length transportation contract?

(a) You must use a separate entry on form ONRR–2014 to notify ONRR of an allowance based on transportation costs that you or your affiliate incur(s).

(b) If you improperly report a transportation allowance against the oil instead of reporting the allowance as a separate entry on form ONRR–2014, ONRR may assess a civil penalty under 30 CFR part 1241.

§ 1206.119 How do I determine royalty quantity and quality?

(a) You must calculate royalties based on the quantity and quality of oil as measured at the point of royalty settlement that BLM or BSEE approves for onshore leases and OCS leases, respectively.

(b) If you base the value of oil determined under this subpart on a quantity and/or quality that is different from the quantity and/or quality at the point of royalty settlement that BLM or BSEE approves, you must adjust that value for the differences in quantity and/or quality.

(c) You may not make any deductions from the royalty volume or royalty value for actual or theoretical losses. Any actual loss that you sustain before the royalty settlement metering or measurement point is not subject to royalty if BLM or BSEE, whichever is appropriate, determines that such loss was unavoidable.

(d) You must pay royalties on 100 percent of the volume measured at the approved point of royalty settlement. You may not claim a reduction in that measured volume for actual losses beyond the approved point of royalty settlement or for theoretical losses that you claim to have taken place either before or after the approved point of royalty settlement.
§ 1206.141 How do I calculate royalty value for unprocessed gas that I or my affiliate sell(s) under an arm's-length or non-arm's-length contract?

(a) This section applies to unprocessed gas. Unprocessed gas is:

(1) Gas that is not processed;

(2) Any gas that you are not required to value under § 1206.142 or that ONRR does not value under § 1206.144; or

(3) Any gas that you sell prior to processing based on a price per MMBtu or Mcf when the price is not based on the residue gas and gas plant products.

(b) The value of gas under this section for royalty purposes is the gross proceeds accruing to you or your affiliate under the first arm’s-length contract less a transportation allowance determined under § 1206.152. This value does not apply if you exercise the option provided in paragraph (c) of this section or if ONRR decides to value your gas under § 1206.144. You must use this paragraph (b) to value gas when:

(1) You sell under an arm’s-length contract;

(2) You sell or transfer unprocessed gas to your affiliate or another person under a non-arm’s-length contract and that affiliate or person, or an affiliate of either of them, then sells the gas under an arm’s-length contract, unless you exercise the option provided in paragraph (c) of this section;

(3) You, your affiliate, or another person sell(s) unprocessed gas produced from a lease under multiple arm’s-length contracts, and that gas is valued under this paragraph. Unless you exercise the option provided in paragraph (c) of this section, the value of the gas is the volume-weighted average of the values, established under this paragraph, for each contract for the sale of gas produced from that lease; or

(4) You or your affiliate sell(s) under a pipeline cash-out program. In that case, for over-delivered volumes within the tolerance under a pipeline cash-out program, the value is the price that the pipeline must pay you or your affiliate under the transportation contract. You must use the same value for volumes that exceed the over-delivery tolerances, even if those volumes are subject to a lower price under the transportation contract.

(c) If you do not sell under an arm’s-length contract, you may elect to value your gas under this paragraph (c). You may not change your election more often than once every two years.

(d) If you can only transport gas to one index pricing point published in an ONRR-approved publication available at www.onrr.gov, your value, for royalty purposes, is the highest reported monthly bidweek price for that index pricing point for the production month.

(ii) If you can transport gas to more than one index pricing point published in an ONRR-approved publication available at www.onrr.gov, your value, for royalty purposes, is the highest reported monthly bidweek price for the index pricing points to which your gas could be transported for the production month, whether or not there are constraints for that production month.

(iii) If there are sequential index pricing points on a pipeline, you must use the first index pricing point at or after your gas enters the pipeline.

(iv) You must reduce the number calculated under paragraphs (c)(1)(i) and (c)(1)(ii) of this section by 5 percent for sales from the OCS Gulf of Mexico and by 10 percent for sales from all other areas, but not by less than 10 cents per MMBtu or more than 30 cents per MMBtu.

(v) After you select an ONRR-approved publication available at www.onrr.gov, you may not select a different publication more often than once every two years.

(vi) ONRR may exclude an individual index pricing point found in an ONRR-approved publication if ONRR determines that the index pricing point does not accurately reflect the values of production. ONRR will publish a list of excluded index pricing points available at www.onrr.gov.

(2) You may not take any other deductions from the value calculated under this paragraph (c).

(d) If some of your gas is used, lost, unaccounted for, or retained as a fee under the terms of a sales or service agreement, that gas will be valued for royalty purposes using the same royalty valuation method for valuing the rest of the gas that you do sell.

(e) If you have no written contract for the sale of gas or no sale of gas subject to this section and:

(1) There is an index pricing point for the gas, then you must value your gas under paragraph (c) of this section; or

(2) There is not an index pricing point for the gas, then ONRR will decide the value under § 1206.144.

(i) You must propose to ONRR a method to determine the value using the procedures in § 1206.148(a).

(ii) You may use that method to determine value, for royalty purposes, until ONRR issues our decision.

(iii) After ONRR issues our determination, you must make the adjustments under § 1206.143(a)(2).
§ 1206.142 How do I calculate royalty value for processed gas that I or my affiliate sell(s) under an arm’s-length or non-arm’s-length contract?

(a) This section applies to the valuation of processed gas, including but not limited to:

(1) Gas that you or your affiliate do not sell, or otherwise dispose of, under an arm’s-length contract prior to processing.

(2) Gas where your or your affiliate’s arm’s-length contract for the sale of gas prior to processing provides for payment to be determined on the basis of the value of any products resulting from processing, including residue gas or natural gas liquids.

(3) Gas that you or your affiliate process under an arm’s-length keepwhole contract.

(4) Gas where your or your affiliate’s arm’s-length contract includes a reservation of the right to process the gas, and you or your affiliate exercise(s) that right.

(b) The value of gas subject to this section, for royalty purposes, is the combined value of the residue gas and all gas plant products that you determine under this section plus the value of any condensate recovered downstream of the point of royalty settlement without resorting to processing that you determine under subpart C of this part less applicable transportation and processing allowances that you determine under this subpart, unless you exercise the option provided in paragraph (d) of this section.

c) The value of residue gas or any gas plant product under this section for royalty purposes is the gross proceeds accruing to you or your affiliate under the first arm’s-length contract. This value does not apply if you exercise the option provided in paragraph (d) of this section, or if ONRR decides to value your residue gas or any gas plant product under §1206.144. You must use this paragraph (c) to value residue gas or any gas plant product when:

(1) You sell under an arm’s-length contract;

(2) You sell or transfer to your affiliate or another person under a non-arm’s-length contract, and that affiliate or person, or another affiliate of either of them, then sells the residue gas or any gas plant product under an arm’s-length contract, unless you exercise the option provided in paragraph (d) of this section;

(3) You, your affiliate, or another person sell(s), under multiple arm’s-length contracts, residue gas or any gas plant products recovered from gas produced from a lease that you value under this paragraph. In that case, unless you exercise the option provided in paragraph (d) of this section, because you sold non-arm’s-length to your affiliate or another person, the value of the residue gas or any gas plant product is the volume-weighted average of the gross proceeds established under this paragraph for each arm’s-length contract for the sale of residue gas or any gas plant products recovered from gas produced from that lease; or

(4) You or your affiliate sell(s) under a pipeline cash-out program. In that case, for over-delivered volumes within the tolerance under a pipeline cash-out program, the value is the price that the pipeline must pay to you or your affiliate under the transportation contract. You must use the same value for volumes that exceed the over-delivery tolerances, even if those volumes are subject to a lower price under the transportation contract.

(d) If you do not sell under an arm’s-length contract, you may elect to value your residue gas and NGLs under this paragraph (d). You may not change your election more often than once every two years.

(i) If you can only transport residue gas to one index pricing point published in an ONRR-approved publication available at www.onrr.gov, your value, for royalty purposes, is the highest reported monthly bidweek price for that index pricing point for the production month.

(ii) If you can transport residue gas to more than one index pricing point published in an ONRR-approved publication available at www.onrr.gov, your value, for royalty purposes, is the highest reported monthly bidweek price for the index pricing points to which your gas could be transported for the production month, whether or not there are constraints, for the production month.

(iii) If there are sequential index pricing points on a pipeline, you must use the first index pricing point at or after your residue gas enters the pipeline.

(iv) You must reduce the number calculated under paragraphs (d)(1)(i) and (ii) of this section by 5 percent for sales from the OCS Gulf of Mexico and by 10 percent for sales from all other areas, but not by less than 10 cents per MMBtu or more than 30 cents per MMBtu.

(v) After you select an ONRR-approved publication available at www.onrr.gov, you may not select a different publication more often than once every two years.

(vi) ONRR may exclude an individual index pricing point found in an ONRR-approved publication if ONRR determines that the index pricing point does not accurately reflect the values of production. ONRR will publish a list of excluded index pricing points on www.onrr.gov.

(ii) If you sell NGLs in an area with one or more ONRR-approved commercial price bulletins available at www.onrr.gov, you must choose one bulletin, and your value, for royalty purposes, is the monthly average price for that bulletin for the production month.

(iv) After you select an ONRR-approved commercial price bulletin available at www.onrr.gov, you may not select a different commercial price bulletin more often than once every two years.

(iii) If some of your gas or gas plant products are used, lost, unaccounted for, or retained as a fee under the terms of a sales or service agreement, that gas will be valued for royalty purposes using the same royalty valuation method for valuing the rest of the gas or gas plant products that you do sell.

(f) If you have no written contract for the sale of gas or no sale of gas subject to this section and:

(1) There is an index pricing point or commercial price bulletin for the gas, then ONRR will determine the value under §1206.144.

(i) You must propose to ONRR a method to determine the value using the procedures in §1206.148(a).

(ii) You may use that method to determine value, for royalty purposes, until ONRR issues our decision.

(iii) After ONRR issues our determination, you must make the adjustments under §1206.143(a)(2).

§ 1206.143 How will ONRR determine if my royalty payments are correct?

(a)(1) ONRR may monitor, review, and audit the royalties that you report. If
ONRR determines that your reported value is inconsistent with the requirements of this subpart, ONRR will direct you to use a different measure of royalty value or decide your value under §1206.144.

(2) If ONRR directs you to use a different royalty value, you must either pay any additional royalties due, plus late payment interest calculated under §§1218.54 and 1218.102 of this chapter, or report a credit for, or request a refund of, any overpaid royalties.

(b) When the provisions in this subpart refer to gross proceeds, in conducting reviews and audits, ONRR will examine if your or your affiliate’s contract reflects the total consideration actually transferred, either directly or indirectly, from the buyer to you or your affiliate for the gas, residue gas, or gas plant products. If ONRR determines that a contract does not reflect the total consideration actually transferred, either directly or indirectly, from the buyer to you or your affiliate for the gas, residue gas, or gas plant products. If ONRR determines that a contract does not reflect the total consideration, ONRR may decide your value under §1206.144.

(c) ONRR may decide your value under §1206.144 if ONRR determines that the gross proceeds accruing to you or your affiliate under a contract do not reflect reasonable consideration because:

(1) There is misconduct by or between the contracting parties;

(2) You have breached your duty to market the gas, residue gas, or gas plant products for the mutual benefit of yourself and the lessor by selling your gas, residue gas, or gas plant products at a value that is unreasonably low. ONRR may consider a sales price unreasonably low if it is 10 percent less than the lowest reasonable measures of market price, including, but not limited to, index prices and prices reported to ONRR for like-quality residue gas, residue gas, or gas plant products; or

(3) ONRR cannot determine if you properly valued your gas, residue gas, or gas plant products under §1206.141 or §1206.142 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents that ONRR requests under 30 CFR part 1212, subpart B.

You have the burden of demonstrating that your or your affiliate’s contract is arm’s-length.

(e) ONRR may require you to certify that the provisions in your or your affiliate’s contract include(s) all of the consideration that the buyer paid to you or your affiliate, either directly or indirectly, for the gas, residue gas, or gas plant products.

(f)(1) Absent contract revision or amendment, if you or your affiliate fail(s) to take proper or timely action to receive prices or benefits to which you or your affiliate are entitled, you must pay royalty based upon that obtainable price or benefit.

(2) If you or your affiliate make timely application for a price increase or benefit allowed under your or your affiliate’s contract, but the purchaser refuses, and you or your affiliate take reasonable, documented measures to force purchaser compliance, you will not owe additional royalties unless or until you or your affiliate receive additional monies or consideration resulting from the price increase. You may not construe this paragraph to permit you to avoid your royalty payment obligation in situations where a purchaser fails to pay, in whole or in part, or in a timely manner, for a quantity of gas, residue gas, or gas plant products.

(1) You or your affiliate must make all contracts, contract revisions, or amendments in writing, and all parties to the contract must sign the contract, contract revisions, or amendments.

(2) If you or your affiliate fail(s) to comply with paragraph (g)(1) of this section, ONRR may decide your value under §1206.144.

(3) This provision applies notwithstanding any other provisions in this title 30 to the contrary.

§1206.144 How will ONRR determine the value of my gas for royalty purposes?

If ONRR decides to value your gas, residue gas, or gas plant products for royalty purposes under §1206.143, or any other provision in this subpart, then ONRR will determine the value for royalty purposes, by considering any information that we deem relevant, which may include, but is not limited to:

(a) The value of like-quality gas in the same field or nearby fields or areas.

(b) The value of like-quality residue gas or gas plant products from the same plant or area.

(c) Public sources of price or market information that ONRR deems to be reliable.

(d) Information available or reported to ONRR, including, but not limited to, on form ONRR–2014 and form ONRR–4054.

(e) Costs of transportation or processing if ONRR determines that they are applicable.

(f) Any information that ONRR deems relevant regarding the particular lease operation or the salability of the gas.

§1206.145 What records must I keep in order to support my calculations of royalty under this subpart?

If you value your gas under this subpart, you must retain all data relevant to the determination of the royalty that you paid. You can find recordkeeping requirements in parts 1207 and 1212 of this chapter.

(a) You must show:

(1) How you calculated the royalty value, including all allowable deductions; and

(2) How you complied with this subpart.

(b) Upon request, you must submit all data to ONRR. You must comply with any such requirement within the time that ONRR specifies.

§1206.146 What are my responsibilities to place production into marketable condition and to market production?

(a) You must place gas, residue gas, and gas plant products in marketable condition and market the gas, residue gas, and gas plant products for the mutual benefit of the lessee and the lessor at no cost to the Federal government.

(b) If you use gross proceeds under an arm’s-length contract to determine royalty, you must increase those gross proceeds to the extent that the purchaser, or any other person, provides certain services that you normally are responsible to perform in order to place the gas, residue gas, and gas plant products in marketable condition or to market the gas.

§1206.147 When is an ONRR audit, review, reconciliation, monitoring, or other like process considered final?

Notwithstanding any provision in these regulations to the contrary, ONRR does not consider any audit, review, reconciliation, monitoring, or other like process that results in ONRR re-determining royalty due, under this subpart, final or binding as against the Federal government or its beneficiaries unless ONRR chooses to, in writing, formally close the audit period.

§1206.148 How do I request a valuation determination?

(a) You may request a valuation determination from ONRR regarding any gas produced. Your request must:

(1) Be in writing;

(2) Identify specifically all leases involved, all interest owners of those leases, the designee(s), and the operator(s) for those leases;

(3) Complete all relevant facts. You must inform ONRR of any changes to relevant facts that occur before we respond to your request;

(4) Include copies of all relevant documents;

(5) Provide your analysis of the issue(s), including citations to all relevant precedents (including adverse precedents); and
(6) Suggest your proposed valuation method;
(b) In response to your request, ONRR may:
(1) Request that the Assistant Secretary for Policy, Management and Budget issue a determination;
(2) Decide that ONRR will issue guidance; or
(3) Inform you in writing that ONRR will not provide a determination or guidance. Situations in which ONRR typically will not provide any determination or guidance include, but are not limited to:
(i) Requests for guidance on hypothetical situations; or
(ii) Matters that are the subject of pending litigation or administrative appeals.
(c)(1) A determination that the Assistant Secretary for Policy, Management and Budget signs is binding on both you and ONRR until the Assistant Secretary modifies or rescinds it.
(2) After the Assistant Secretary issues a determination, you must make any adjustments to royalty payments that follow from the determination, and, if you owe additional royalties, you must pay the additional royalties due, plus late payment interest calculated under §§1218.54 and 1218.102 of this chapter.
(3) A determination that the Assistant Secretary signs is the final action of the Department and is subject to judicial review under 5 U.S.C. 701–706.
(d) Guidance that ONRR issues is not binding on ONRR, delegated States, or you with respect to the specific situation addressed in the guidance.
(1) Guidance and ONRR’s decision whether or not to issue guidance or to request an Assistant Secretary determination, or neither, under paragraph (b) of this section, are not appealable decisions or orders under part 1290 of this title.
(2) If you receive an order requiring you to pay royalty on the same basis as the guidance, you may appeal that order under part 1290 of this title.
(e) ONRR or the Assistant Secretary may use any of the applicable criteria in this subpart to provide guidance or to make a determination.
(f) A change in an applicable statute or regulation on which ONRR based any guidance, or the Assistant Secretary based any determination, takes precedence over the determination or guidance after the effective date of the statute or regulation, regardless of whether ONRR or the Assistant Secretary modifies or rescinds the guidance or determination.
(g) ONRR may make requests and replies under this section available to the public, subject to the confidentiality requirements under §1206.149.
§1206.149 Does ONRR protect information that I provide?
(a) Certain information that you or your affiliate submit(s) to ONRR regarding royalties on gas, including deductions and allowances, may be exempt from disclosure.
(b) To the extent that applicable laws and regulations permit, ONRR will keep confidential any data that you or your affiliate submit(s) that is privileged, confidential, or otherwise exempt from disclosure.
(c) You and others must submit all requests for information under the Freedom of Information Act regulations of the Department of the Interior at 43 CFR part 2.
§1206.150 How do I determine royalty quantity and quality?
(a)(1) You must calculate royalties based on the quantity and quality of unprocessed gas as measured at the point of royalty settlement that BLM or BSEE approves for onshore leases and OCS leases, respectively.
(2) If you base the value of gas determined under this subpart on a quantity and/or quality that is different from the quantity and/or quality at the point of royalty settlement that BLM or BSEE approves, you must adjust that value for the differences in quantity and/or quality.
(b)(1) For residue gas and gas plant products, the quantity basis for computing royalties due is the monthly net output of the plant, even though residue gas and/or gas plant products may be in temporary storage.
(2) If you value residue gas and/or gas plant products determined under this subpart on a quantity and/or quality of residue gas and/or gas plant products that is different from that which is attributable to a lease determined under paragraph (c) of this section, you must adjust that value for the differences in quantity and/or quality.
(c) You must determine the quantity of the residue gas and gas plant products attributable to a lease based on the following procedure:
(1) When you derive the net output of the processing plant from gas obtained from only one lease, you must base the quantity of the residue gas and gas plant products for royalty computation on the net output of the plant.
(2) When you derive the net output of a processing plant from gas obtained from more than one lease producing gas of the same kind, you must base the quantity of the residue gas and gas plant products allocable to each lease on the same proportions as the ratios obtained by dividing the amount of gas delivered to the plant from each lease by the total amount of gas delivered from all leases.
(3) When the net output of a processing plant is derived from gas obtained from more than one lease producing gas of non-uniform content:
(i) You must determine the quantity of the residue gas allocable to each lease by multiplying the amount of gas delivered to the plant from the lease by the residue gas content of the gas, and dividing that arithmetic product by the sum of the similar arithmetical products separately obtained for all leases from which gas is delivered to the plant, and then multiplying the net output of the residue gas by the arithmetic quotient obtained.
(ii) You must determine the net output of gas plant products allocable to each lease by multiplying the amount of gas delivered to the plant from the lease by the gas plant product content of the gas, dividing that arithmetic product by the sum of the similar arithmetical products separately obtained for all leases from which gas is delivered to the plant, and then multiplying the net output of each gas plant product by the arithmetic quotient obtained.
(4) You may request prior ONRR approval of other methods for determining the quantity of residue gas and gas plant products allocable to each lease. If approved, you must apply that method to all gas production from Federal leases that is processed in the same plant. You must do so beginning with the production month following the month when ONRR received your request to use another method.
(d)(1) You may not make any deductions from the royalty volume or royalty value for actual or theoretical losses. Any actual loss of unprocessed gas that you sustain before the royalty settlement meter or measurement point is not subject to royalty if BLM or BSEE, whichever is appropriate, determines that such loss was unavoidable.
(2) Except as provided in paragraph (d)(1) of this section and §1202.151(c), you must pay royalties due on 100 percent of the volume determined under paragraphs (a) through (c) of this section. You may not reduce that determined volume for actual losses after you have determined the quantity basis, or for theoretical losses that you claim to have taken place. Royalties are due on 100 percent of the value of the unprocessed gas, residue gas, and/or gas plant products, as provided in this subpart, less applicable allowances. You may not take any deductions from the value of the unprocessed gas, residue gas, and/or gas plant products to
compensate for actual losses after you have determined the quantity basis or for theoretical losses that you claim to have taken place.

§ 1206.151 [Reserved]

§ 1206.152 What general transportation allowance requirements apply to me?

(a) ONRR will allow a deduction for the reasonable, actual costs to transport residue gas, gas plant products, or unprocessed gas from the lease to the point off of the lease under § 1206.153 or § 1206.154, as applicable. You may not deduct transportation costs that you incur when moving a particular volume of production to reduce royalties that you owe on production for which you did not incur those costs. This paragraph applies when:

1. You value unprocessed gas under § 1206.141(b) or residue gas and gas plant products under § 1206.142(b) based on a sale at a point off of the lease, unit, or communitized area where the residue gas, gas plant products, or unprocessed gas is produced; and

2. You must be able to demonstrate your transportation costs based on your or your affiliate’s cost of transporting each product through each individual transportation system. If your or your affiliate’s transportation contract includes more than one product in a gaseous phase, you must allocate costs consistently and equitably to each of the products transported. Your allocation must use the same proportion as the ratio of the volume of each product (excluding waste products with no value) to the volume of all products in the gaseous phase (excluding waste products with no value).

1. You may not take an allowance for transporting lease production that is not royalty-bearing.

2. You may propose to ONRR a prospective cost allocation method based on the values of the products transported. ONRR will approve the method if it is consistent with the purposes of the regulations in this subpart.

3. You may use your proposed procedure to calculate a transportation allowance beginning with the production month following the month when ONRR received your proposed procedure until ONRR accepts or rejects your cost allocation. If ONRR rejects your cost allocation, you must amend your form ONRR–2014 for the months when you used the rejected method and pay any additional royalty due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter.

(c)(1) Where you or your affiliate transport(s) both gaseous and liquid products through the same transportation system, you must propose a cost allocation procedure to ONRR.

2. You may use your proposed procedure to calculate a transportation allowance until ONRR accepts or rejects your cost allocation. If ONRR rejects your cost allocation, you must amend your form ONRR–2014 for the months when you used the rejected method and pay any additional royalty due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter.

3. You must submit your initial proposal, including all available data, within three months after you first claim the allocated deductions on form ONRR–2014.

(d) If you value unprocessed gas under § 1206.141(c) or residue gas and gas plant products under § 1206.142(d), you may not take a transportation allowance.

(e)(1) Your transportation allowance may not exceed 50 percent of the value of the residue gas, gas plant products, or unprocessed gas as determined under § 1206.141 or § 1206.142 of this subpart.

2. If ONRR approved your request to take a transportation allowance in excess of the 50-percent limitation under former § 1206.156(c)(3), that approval is terminated as of January 1, 2017.

2. You must express transportation allowances for residue gas, gas plant products, or unprocessed gas as a dollar-value equivalent. If your or your affiliate’s payments for transportation under a contract are not on a dollar-per-unit basis, you must convert whatever consideration that you or your affiliate are/is paid to a dollar-value equivalent.

(g) ONRR may determine your transportation allowance under § 1206.144 because:

1. There is misconduct by or between the contracting parties;

2. ONRR determines that the consideration that you or your affiliate paid under an arm’s-length transportation contract does not reflect the reasonable cost of the transportation because you breached your duty to market the gas, residue gas, or gas plant products for the mutual benefit of yourself and the lessor by transporting your gas, residue gas, or gas plant products at a cost that is unreasonably high. We may consider a transportation allowance unreasonably high if it is 10 percent higher than the highest reasonable measures of transportation costs, including, but not limited to, transportation allowances reported to ONRR and tariffs for gas, residue gas, or gas plant products transported through the same system; or

3. ONRR cannot determine if you properly calculated a transportation allowance under § 1206.153 or § 1206.154 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents that ONRR requests under 30 CFR part 1212, subpart B.

(h) You do not need ONRR’s approval before reporting a transportation allowance.

§ 1206.153 How do I determine a transportation allowance if I have an arm’s-length transportation contract?

(a)(1) If you or your affiliate incur transportation costs under an arm’s-length transportation contract, you may claim a transportation allowance for the reasonable, actual costs incurred, as more fully explained in paragraph (b) of this section, except as provided in § 1206.152(g) and subject to the limitation in § 1206.152(e).

2. You must be able to demonstrate that your or your affiliate’s contract is arm’s-length.

(b) Subject to the requirements of paragraph (c) of this section, you may include, but are not limited to, the following costs to determine your transportation allowance under paragraph (a) of this section; you may not use any cost as a deduction that duplicates all or part of any other cost that you use under this section:

1. Firm demand charges paid to pipelines. You may deduct firm demand charges or capacity reservation fees that you or your affiliate paid to a pipeline, including charges or fees for unused firm capacity that you or your affiliate have not sold before you report your allowance. If you or your affiliate receive(s) a payment from any party for release or sale of firm capacity after reporting a transportation allowance that included the cost of that unused firm capacity, or if you or your affiliate receive(s) a payment or credit from the pipeline for penalty refunds, rate case refunds, or other reasons, you must reduce the firm demand charge claimed on form ONRR–2014 by the amount of that payment. You must modify form ONRR–2014 by the amount received or credited for the affected reporting period and pay any resulting royalty due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter.

2. Gas Supply Restructuring (GSR) costs. The GSR costs result from a pipeline reforming or terminating
supply contracts with producers in order to implement the restructuring requirements of FERC Orders in 18 CFR part 284.

(3) Commodity charges. The commodity charge allows the pipeline to recover the costs of providing service.

(4) Wheeling costs. Hub operators charge a wheeling cost for transporting gas from one pipeline to either the same or another pipeline through a market center or hub. A hub is a connected manifold of pipelines through which a series of incoming pipelines are interconnected to a series of outgoing pipelines.

(5) Gas Research Institute (GRI) fees. The GRI conducts research, development, and commercialization programs on natural gas-related topics for the benefit of the U.S. gas industry and gas customers. GRI fees are allowable, provided that such fees are mandatory in FERC-approved tariffs.

(6) Annual Charge Adjustment (ACA) fees. FERC charges these fees to pipelines to pay for its operating expenses.

(7) Payments (either volumetric or in value) for actual or theoretical losses. Theoretical losses are not deductible in transportation arrangements unless the transportation allowance is based on arm’s-length transportation rates charged under a FERC or State regulatory-approved tariff. If you or your affiliate receive(s) volumes or credit for line gain, you must reduce your transportation allowance accordingly and pay any resulting royalties plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter.

(8) Temporary storage services. This includes short-duration storage services that market centers or hubs (commonly referred to as “parking” or “banking”) offer or other temporary storage services that pipeline transporters provide, whether actual or provided as a matter of accounting. Temporary storage is limited to 30 days or fewer.

(9) Supplemental costs for compression, dehydration, and treatment of gas. ONRR allows these costs only if such services are required for transportation and exceed the services necessary to place production into marketable condition required under §1206.146 of this part.

(10) Costs of surety. You may deduct the costs of securing a letter of credit, or other surety, that the pipeline requires you or your affiliate, as a shipper, to maintain under a transportation contract.

(11) Hurricane surcharges. You may deduct hurricane surcharges that you or your affiliate actually pay(s).

(c) You may not include the following costs to determine your transportation allowance under paragraph (a) of this section:

(1) Fees or costs incurred for storage. This includes storing production in a storage facility, whether on or off of the lease, for more than 30 days.

(2) Aggregator/marketer fees. This includes fees that you or your affiliate pay(s) to another person (including your affiliates) to market your gas, including purchasing and reselling the gas or finding or maintaining a market for the gas production.

(3) Penalties that you or your affiliate incur(s) as a shipper. These penalties include, but are not limited to:

(i) Over-delivery cash-out penalties. This includes the difference between the price that the pipeline pays to you or your affiliate for over-delivered volumes outside of the tolerances and the price that you or your affiliate receive(s) for over-delivered volumes within the tolerances.

(ii) Scheduling penalties. This includes penalties that you or your affiliate incur(s) for differences between daily volumes delivered into the pipeline and volumes scheduled or nominated at a receipt or delivery point.

(iii) Imbalance penalties. This includes penalties that you or your affiliate incur(s) (generally on a monthly basis) for differences between volumes delivered into the pipeline and volumes scheduled or nominated at a receipt or delivery point.

(iv) Operational penalties. This includes fees that you or your affiliate incur(s) for violation of the pipeline’s curtailment or operational orders issued to protect the operational integrity of the pipeline.

(4) Intra-hub transfer fees. These are fees that you or your affiliate pay(s) to hub operators for administrative services (such as title transfer tracking) necessary to account for the sale of gas within a hub.

(5) Fees paid to brokers. This includes fees that you or your affiliate pay(s) to parties who arrange marketing or transportation, if such fees are separately identified from aggregator/marketer fees.

(6) Fees paid to scheduling service providers. This includes fees that you or your affiliate pay(s) to parties who provide scheduling services, if such fees are separately identified from aggregator/marketer fees.

(7) Internal costs. This includes salaries and related costs, rent/space costs, office equipment costs, legal fees, and other costs to schedule, nominate, and account for the sale or movement of production.

(8) Other non-allowable costs. Any cost you or your affiliate incur(s) for services that you are required to provide at no cost to the lessor, including, but not limited to, costs to place your gas, residue gas, or gas plant products into marketable condition disallowed under §1206.146 and costs of boosting residue gas disallowed under §1202.151(b).

(d) If you have no written contract for the transportation of gas, then ONRR will determine your transportation allowance under §1206.144. You may not use this paragraph (d) if you or your affiliate perform(s) your own transportation.

(1) You must propose to ONRR a method to determine the allowance using the procedures in §1206.148(a).

(2) You may use that method to determine your allowance until ONRR issues its determination.

§1206.154 How do I determine a transportation allowance if I have a non-arm’s-length transportation contract?

(a) This section applies if you or your affiliate do(es) not have an arm’s-length transportation contract, including situations where you or your affiliate provide your own transportation services. You must calculate your transportation allowance based on your or your affiliate’s reasonable, actual costs for transportation during the reporting period using the procedures prescribed in this section.

(b) Your or your affiliate’s actual costs may include:

(1) Capital costs and operating and maintenance expenses under paragraphs (e), (f), and (g) of this section.

(2) Overhead under paragraph (h) of this section.

(3) Depreciation and a return on undepreciated capital investment under paragraph (i)(1) of this section, or you may elect to use a cost equal to a return on the initial depreciable capital investment in the transportation system under paragraph (i)(2) of this section.

After you have elected to use either method for a transportation system, you may not later elect to change to the other alternative without ONRR’s approval. If ONRR accepts your request to change methods, you may use your changed method beginning with the production month following the month when ONRR received your change request.

(4) A return on the reasonable salvage value under paragraph (i)(1)(iii) of this section, after you have depreciated the transportation system to its reasonable salvage value.

(c)(1) To the extent not included in costs identified in paragraphs (e) through (g) of this section, if you or your
(i) A change in ownership of a transportation system will not alter the depreciation schedule that the original transporter/lessee established for the purposes of the allowance calculation.  
(ii) You may depreciate a transportation system only once with or without a change in ownership.  
(iii) To calculate the return on undepreciated capital investment, you may use an amount equal to the undepreciated capital investment in the transportation system multiplied by the rate of return that you determine under paragraph (j)(3) of this section.  
(B) After you have depreciated a transportation system to the reasonable salvage value, you may continue to include in the allowance calculation a cost equal to the reasonable salvage value multiplied by a rate of return under paragraph (j)(3) of this section.  
§ 1206.157 What interest and penalties apply if I improperly report a transportation allowance?  
(a) [1] If ONRR determines that you took an unauthorized transportation allowance, then you must pay any additional royalties due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter.  
(b) If you understated your transportation allowance, you may be entitled to a credit, with interest.  
(c) If you deduct a transportation allowance on form ONRR–2014 that exceeds 50 percent of the value of the gas, residue gas, or gas plant products transported, you must pay late payment interest on the excess allowance amount taken from the date when that amount is taken until the date when you pay the additional royalties due.  
§ 1206.158 What reporting adjustments must I make for transportation allowances?  
(a) If your actual transportation allowance is less than the amount that you claimed on form ONRR–2014 for any month during the allowance reporting period, you must pay additional royalties due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter.
(b) If the actual transportation allowance is greater than the amount that you claimed on form ONRR–2014 for any month during the period reported on the allowance form, you are entitled to a credit, plus interest.
§ 1206.159 What general processing allowances requirements apply to me?

(a)(1) When you value any gas plant product under §1206.142(c) of this subpart, you may deduct from the value the reasonable, actual costs of processing.

(2) You do not need ONRR's approval before reporting a processing allowance.

(b) You must allocate processing costs among the gas plant products. You must determine a separate processing allowance for each gas plant product and processing plant relationship. ONRR considers NGLs to be one product.

(c)(1) You may not apply the processing allowance against the value of the residue gas.

(2) The processing allowance deduction on the basis of an individual product may not exceed 66 2/3 percent of the value of each gas plant product determined under §1206.142(c). Before you calculate the 66 2/3-percent limit, you must first reduce the value for any transportation allowances related to post-processing transportation authorized under §1206.152.

(3) If ONRR approved your request to take a processing allowance in excess of the limitation in paragraph (c)(2) of this section under former §1206.158(c)(3), that approval is terminated as of January 1, 2017.

(d)(1) ONRR will not allow a processing allowance based upon your or your affiliate's failure to provide documents that ONRR requests under 30 CFR part 1212, subpart B.

(2) If your or your affiliate's arm's-length processing contract includes more than one gas plant product, and you can determine the processing costs for each product based on the contract, then you must determine the processing costs for each gas plant product under the contract.

(3) Depreciation and a return on undepreciated capital investment in accordance with paragraph (h)(1) of this section, or you may elect to use a cost equal to the initial depreciable capital investment in the processing plant under paragraph (h)(2) of this section. After you have elected to use either method for a processing plant, you may not later elect to change to the other alternative without ONRR's approval. If ONRR accepts your request to change methods, you may use your changed method beginning with the production month following the month when ONRR received your change request.

§ 1206.160 How do I determine a processing allowance if I have an arm’s-length processing contract?

(a)(1) If you or your affiliate incur processing costs under an arm’s-length processing contract, you may claim a processing allowance for the reasonable, actual costs incurred, as more fully explained in paragraph (b) of this section, except as provided in paragraphs (a)(3)(i) and (a)(3)(ii) of this section and subject to the limitation in §1206.159(c)(2).

(2) You must be able to demonstrate that your or your affiliate’s processing contract is arm’s-length.

(b)(1) If your or your affiliate’s arm’s-length processing contract includes more than one gas plant product, and you can determine the processing costs for each product based on the contract, then you must determine the processing costs for each gas plant product under the contract.

(2) If your or your affiliate’s arm’s-length processing contract includes more than one gas plant product, and you cannot determine the processing costs attributable to each product from the contract, you must propose an allocation procedure to ONRR.

(3) ONRR will determine your processing allowance unreasonably high if it is 10 percent higher than the highest reasonable measures of processing costs, including, but not limited to, processing allowances reported to ONRR; or

(4) If your or your affiliate’s payments for processing under an arm’s-length contract are not based on a dollar-per-unit basis, you must convert whatever consideration that you or your affiliate paid to a dollar-value equivalent.

(c) If you have no written contract for the arm’s-length processing of gas, then ONRR will determine your processing allowance under §1206.144. You may not use this paragraph (c) if you or your affiliate perform(s) your own processing.

(1) You must propose to ONRR a method to determine the allowance using the procedures in §1206.148(a).

(2) You may use that method to determine your allowance until ONRR issues a determination.

§ 1206.161 How do I determine a processing allowance if I have a non-arm’s-length processing contract?

(a) This section applies if you or your affiliate do(es) not have an arm’s-length processing contract, including situations where you or your affiliate provide your own processing services. You must calculate your processing allowance based on your or your affiliate’s reasonable, actual costs for processing during the reporting period using the procedures prescribed in this section.

(b) Your or your affiliate’s actual costs may include:

(1) Capital costs and operating and maintenance expenses under paragraphs (d), (e), and (f) of this section.

(2) Overhead under paragraph (g) of this section.

(3) Depreciation and a return on undepreciated capital investment in accordance with paragraph (h)(1) of this section.

(4) A return on the reasonable salvage value under paragraph (h)(2)(iii) of this section, after you have depreciated the processing plant to its reasonable salvage value.

(c) You may not use any cost as a deduction that duplicates all or part of any other cost that you use under this section.

(d) Allowable capital investment costs are generally those for depreciable fixed assets (including costs of delivery and installation of capital equipment), which are an integral part of the processing plant.
(e) Allowable operating expenses include the following:
(1) Operations supervision and engineering
(2) Operations labor
(3) Fuel
(4) Utilities
(5) Materials
(6) Ad valorem property taxes
(7) Rent
(8) Supplies
(9) Any other directly allocable and attributable operating expense that you can document

(f) Allowable maintenance expenses may include the following:
(1) Maintenance of the processing plant
(2) Maintenance of equipment
(3) Maintenance labor
(4) Other or directly allocable and attributable maintenance expenses that you can document

(g) Overhead, directly allocable and allocable to the operation and maintenance of the processing plant, is an allowable expense. State and Federal income taxes and severance taxes and other fees, including royalties, are not allowable expenses.

(h)(1) To calculate depreciation and a return on undepreciated capital investment, you may elect to use either a straight-line depreciation method based on the life of equipment or on the life of the reserves that the processing plant services, or you may elect to use a unit-of-production method. After you make an election, you may not change it without ONRR’s approval. If ONRR accepts your request to change methods, you may use your changed method beginning with the production month following the month when ONRR received your change request.
(i) A change in ownership of a processing plant will not alter the depreciation schedule that the original processor/lessee established for purposes of the allowance calculation.

(ii) You may depreciate a processing plant only once with or without a change in ownership.

(iii) A To calculate a return on undepreciated capital investment, you may use an amount equal to the undepreciated capital investment in the processing plant multiplied by the rate of return that you determine under paragraph (h)(3) of this section.

(B) After you have depreciated a processing plant to its reasonable salvage value, you may continue to include in the allowance calculation a cost equal to the reasonable salvage value multiplied by a rate of return under paragraph (h)(3) of this section.

(2) You may use as a cost an amount equal to the allowable initial capital investment in the processing plant multiplied by the rate of return determined under paragraph (b)(3) of this section. You may not include depreciation in your allowance.

(3) The rate of return is the industrial rate associated with Standard & Poor’s BBB rating.

(d) Other or directly allocable and attributable maintenance expenses that you can document

(1) You must determine the reasonable and actual cost of processing the gas. You must base your allocation of costs to each gas plant product upon generally accepted accounting principles.

(2) You may not take an allowance for processing lease production that is not royalty-bearing.

(j) You may apply for an exception from the requirement to calculate actual costs under paragraphs (a) and (b) of this section.

(1) ONRR will grant the exception if:

(i) You have or your affiliate has arm’s-length contracts for processing other gas production at the same processing plant; and

(ii) At least 50 percent of the gas processed annually at the plant is processed under arm’s-length processing contracts.

(2) If ONRR grants the exception, you must use as your processing allowance the volume-weighted average prices charged to other persons under arm’s-length contracts for processing at the same plant.

§ 1206.162 What are my reporting requirements under an arm’s-length processing contract?

(a) You must use a separate entry on form ONRR–2014 to notify ONRR of an allowance based on arm’s-length processing costs that you or your affiliate incur(s).
(b) For new non-arm’s-length processing facilities or arrangements, you must base your initial deduction on estimates of allowable gas processing costs for the applicable period.

(2) You must use your or your affiliate’s most recently available operations data for the processing plant as your estimate, if available. If such data is not available, you must use estimates based on data for similar processing plants.

(3) Section 1206.165 applies when you amend your report based on your actual costs.

(c) ONRR may require you or your affiliate to submit all data used to calculate the allowance deduction. You can find recordkeeping requirements in parts 1207 and 1212 of this chapter.

(d) If you are authorized under § 1206.161(j) to use an exception to the requirement to calculate your actual processing costs, you must follow the reporting requirements of § 1206.162.

§ 1206.164 What interest and penalties apply if I improperly report a processing allowance?

(a) If ONRR determines that you took an unauthorized processing allowance, then you must pay any additional royalties due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter.

(b) If you understated your processing allowance, you may be entitled to a credit, with interest.

(c) If you improperly net a processing allowance against the sales value of a processed product, you must pay late payment interest on the excess allowance amount taken from the date when that amount is taken until the date when you pay the additional royalties due.

(d) If you improperly report a processing allowance against the sales value of a gas plant product instead of reporting the allowance as a separate entry on form ONRR–2014, ONRR may assess a civil penalty under 30 CFR part 1241.

§ 1206.165 What reporting adjustments must I make for processing allowances?

(a) If your actual processing allowance is less than the amount that you claimed on form ONRR–2014 for each month during the allowance reporting period, you must pay additional royalties due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter from the date when you took the deduction to the date when you repay the difference.

(b) If the actual processing allowance is greater than the amount that you
Subpart F—Federal Coal

§ 1206.250 What is the purpose and scope of this subpart?

(a) This subpart applies to all coal produced from Federal coal leases. It explains how you, as the lessee, must calculate the value of production for royalty purposes consistent with the mineral leasing laws, other applicable laws, and lease terms.

(b) The terms “you” and “your” in this subpart refer to the lessee.

(c) If the regulations in this subpart are inconsistent with §1205: Federal Register

§ 1206.251 How do I determine royalty quantity and quality?

(a) You must calculate royalties based on the quantity and quality of coal at the royalty measurement point that ONRR expects, at least, would approximate the value established under this subpart; or express provision of a coal lease contract subject to this subpart, then the statute, settlement agreement, written agreement, or lease provision will govern to the extent of the inconsistency.

(d) ONRR may audit and order you to adjust all royalty payments.

§ 1206.252 How do I calculate royalty value for coal that I or my affiliate sell(s) under an arm’s-length or non-arm’s-length contract?

(a) The value of coal under this section for royalty purposes is the gross proceeds accruing to you or your affiliate under the first arm’s-length contract, less an applicable transportation allowance determined under §§ 1206.260 through 1206.262 and washing allowance under §§ 1206.267 through 1206.269. You must use this paragraph (a) to value coal when:

(1) You sell under an arm’s-length contract; or

(2) You sell to your affiliate or another person under a non-arm’s-length contract, and that affiliate or person, or another affiliate of either of them, then sells the coal under an arm’s-length contract.

(b) If you have no contract for the sale of coal subject to this section because you or your affiliate used the coal in a power plant that you or your affiliate own(s) for the generation and sale of electricity, one of the following applies:

(1) You or your affiliate sell(s) the electricity, then the value of the coal subject to this section, for royalty purposes, is the gross proceeds accruing to you for the power plant’s arm’s-length sales of the electricity less applicable transportation and washing deductions determined under §§ 1206.260 through 1206.262 and §§ 1206.267 through 1206.269 of this subpart and, if applicable, transmission and generation deductions determined under §§ 1206.353 and 1206.354 of subpart H.

(2) You or your affiliate do(es) not sell the electricity at arm’s-length (for example you or your affiliate deliver(s) the electricity directly to the grid), then ONRR will determine the value of the coal under §1206.254.

(i) You must propose to ONRR a method to determine the value using the procedures in §1206.258(a).

(ii) You may use that method to determine value, for royalty purposes, until ONRR issues a determination.
(iii) After ONRR issues a determination, you must make the adjustments under § 1206.253(a)(2).
(c) If you are a coal cooperative, or a member of a coal cooperative, one of the following applies:
(1) You sell or transfer coal to another member of the coal cooperative, and that member of the coal cooperative then sells the coal under an arm's-length contract, then you must value the coal under paragraph (a) of this section.
(2) You sell or transfer coal to another member of the coal cooperative, and you, the coal cooperative, or another member of the coal cooperative use the coal in a power plant for the generation and sale of electricity, then you must value the coal under paragraph (b) of this section.
(d) If you are entitled to take a washing allowance and transportation allowance for royalty purposes under this section, under no circumstances may the washing allowance plus the transportation allowance reduce the royalty value of the coal to zero.
(e) The values in this section do not apply if ONRR decides to value your coal under § 1206.254.

§ 1206.253 How will ONRR determine if my royalty payments are correct?
(a)(1) ONRR may monitor, review, and audit the royalties that you report. If ONRR determines that your reported value is inconsistent with the requirements of this subpart, ONRR will direct you to use a different measure of royalty value, or decide your value, under § 1206.254.
(2) If ONRR directs you to use a different royalty value, you must either pay any underpaid royalties due, plus late payment interest calculated under § 1218.202 of this chapter, or report a late payment interest calculated under § 1206.252 for any reason, including, but not limited to, your or your affiliate's failure to provide documents to ONRR under 30 CFR part 1212, subpart E.
(b) You have the burden of demonstrating that your or your affiliate's contract is arm's-length.
(c) ONRR may require you to certify that the provisions in your or your affiliate's contract include(s) all of the consideration that the buyer paid to you or your affiliate, either directly or indirectly, for the coal.
(d) Absent any contract revisions or amendments, if you or your affiliate fails to take proper or timely action to receive prices or benefits to which you or your affiliate are entitled, you must pay royalty based upon that obtainable price or benefit.
(e) ONRR may require you to certify that the provisions in your or your affiliate's contract include(s) all of the consideration that the buyer paid to you or your affiliate, either directly or indirectly, for the coal.
(f)(1) Absent any contract revisions or amendments, if you or your affiliate fails to take proper or timely action to receive prices or benefits to which you or your affiliate are entitled, you must pay royalty based upon that obtainable price or benefit.
(2) If you or your affiliate apply in a timely manner for a price increase or benefit allowed under your or your affiliate's contract, but the purchaser refuses, and you or your affiliate take reasonable, documented measures to force purchaser compliance, you will not owe additional royalties unless or until you or your affiliate receive additional consideration resulting from the price increase. You may not construe this paragraph to permit you to avoid your royalty payment obligation in situations where a purchaser fails to pay in whole or in part, or in a timely manner, for a quantity of coal.
(g)(1) You or your affiliate must make all contracts, contract revisions, or amendments in writing, and all parties to the contract must sign the contract, contract revisions, or amendments.
(2) If you or your affiliate fail(s) to comply with paragraph (g)(1) of this section, ONRR may decide to value your coal under § 1206.254.
(3) This provision applies notwithstanding any other provisions in this title 30 to the contrary.

§ 1206.254 How will ONRR determine the value of my coal for royalty purposes?
If ONRR decides to value your coal for royalty purposes under § 1206.253, or any other provision in this subpart, then ONRR will determine value by considering any information that we deem relevant, which may include, but is not limited to:
(a) The value of like-quality coal from the same mine, nearby mines, the same region, other regions, or washed in the same or nearby wash plant.
(b) Public sources of price or market information that ONRR deems reliable, including, but not limited to, the price of electricity.
(c) Information available to ONRR and information reported to us, including, but not limited to, on form ONRR-4430.
(d) Costs of transportation or washing, if ONRR determines that they are applicable.
(e) Any other information that ONRR deems relevant regarding the particular lease operation or the salability of the coal.

§ 1206.255 What records must I keep in order to support my calculations of royalty under this subpart?
If you value your coal under this subpart, you must retain all data relevant to the determination of the royalty that you paid. You can find recordkeeping requirements in parts 1207 and 1212 of this chapter.
(a) You must show:
(1) How you calculated the royalty value, including all allowable deductions; and
(2) How you complied with this subpart.
(b) Upon request, you must submit all data to ONRR. You must comply with any such requirement within the time that ONRR specifies.

§ 1206.256 What are my responsibilities to place production into marketable condition and to market production?
(a) You must place coal into marketable condition and market the coal for the mutual benefit of the lessee and the lessor at no cost to the Federal Government.
(b) If you use gross proceeds under an arm's-length contract in order to determine royalty, you must increase those gross proceeds to the extent that the purchaser, or any other person, provides certain services that you normally are responsible to perform in order to place the coal in marketable condition or to market the coal.

§ 1206.257 When is an ONRR audit, review, reconciliation, monitoring, or other like process considered final?
Notwithstanding any provision in these regulations to the contrary, ONRR will not consider any audit, review, reconciliation, monitoring, or other like process that results in ONRR re-determining royalty due, under this subpart, final or binding as against the
Federal government or its beneficiaries unless ONRR chooses to, in writing, formally close the audit period.

§ 1206.258 How do I request a valuation determination?

(a) You may request a valuation determination from ONRR regarding any coal produced. Your request must:

(1) Be in writing;

(2) Identify specifically all leases involved, all interest owners of those leases, and the operator(s) for those leases;

(3) Completely explain all relevant facts. You must inform ONRR of any changes to relevant facts that occur before we respond to your request;

(4) Include copies of all relevant documents;

(5) Provide your analysis of the issue(s), including citations to all relevant precedents (including adverse precedents);

(6) Suggest a proposed valuation method.

(b) In response to your request, ONRR may:

(1) Request that the Assistant Secretary for Policy, Management and Budget issue a determination;

(2) Decide that ONRR will issue guidance or determine;

(3) Inform you in writing that ONRR will not provide a determination or guidance. Situations in which ONRR typically will not provide any determination or guidance include, but are not limited to:

(i) Requests for guidance on hypothetical situations; or

(ii) Matters that are the subject of pending litigation or administrative appeals.

(c)(1) A determination that the Assistant Secretary for Policy, Management and Budget signs is the final action of the Department and is subject to judicial review under 5 U.S.C. 701–706.

(2) If you receive an order requiring you to pay royalty on the same basis as the guidance, you may appeal that order under 30 CFR part 1290.

(d) Guidance that ONRR issues may use any of the applicable criteria in this subpart to provide guidance or to make a determination.

(e) A change in an applicable statute or regulation on which ONRR based any guidance, or the Assistant Secretary based any determination, takes precedence over the determination or guidance after the effective date of the statute or regulation, regardless of whether ONRR or the Assistant Secretary modifies or rescinds the guidance or determination.

(f) ONRR may make requests and replies under this section available to the public, subject to the confidentiality requirements under § 1206.259.

§ 1206.259 Does ONRR protect information that I provide?

(a) Certain information that you or your affiliate submit(s) to ONRR regarding royalties on coal, including deductions and allowances, may be exempt from disclosure.

(b) To the extent that applicable laws and regulations permit, ONRR will keep confidential any data that you or your affiliate submit(s) that is privileged, confidential, or otherwise exempt from disclosure.

(c) You and others must submit all requests for information under the Freedom of Information Act regulations of the Department of the Interior at 43 CFR part 2.

§ 1206.260 What general transportation allowance requirements apply to me?

(a)(1) ONRR will allow a deduction for the reasonable, actual costs to transport coal from the lease to the point of the lease or mine as determined under § 1206.261 or § 1206.262, as applicable.

(2) You do not need ONRR's approval before reporting a transportation allowance for costs incurred.

(b) You may take a transportation allowance when:

(1) You value coal under § 1206.252 of this part;

(2) You transport the coal from a Federal lease to a sales point, which is remote from both the lease and mine; or

(3) You transport the coal from a Federal lease to a wash plant when that plant is remote from both the lease and mine and, if applicable, from the wash plant to a remote sales point.

(c) You may not take an allowance for:

(1) Transporting lease production that is not royalty-bearing;

(2) In-mine movement of your coal; or

(3) Costs to move a particular tonnage of production for which you did not incur those costs.

(d) You may only claim a transportation allowance when you sell the coal and pay royalties.

(e) You must allocate transportation allowances to the coal attributed to the lease from which it was extracted.

(1) If you commingle coal produced from Federal and non-Federal leases, you may not disproportionately allocate transportation costs to Federal lease production. Your allocation must use the same proportion as the ratio of the tonnage from the Federal lease production to the tonnage from all production.

(2) If you commingle coal produced from more than one Federal lease, you must allocate transportation costs to each Federal lease, as appropriate. Your allocation must use the same proportion as the ratio of the tonnage of each Federal lease production to the tonnage of all production.

(3) For washed coal, you must allocate the total transportation allowance only to washed products.

(4) For unwashed coal, you may take a transportation allowance for the total coal transported.

(5)(i) You must report your transportation costs on form ONRR–4430 as clean coal short tons sold during the reporting period multiplied by the sum of the per-short-ton cost of transporting the raw tonnage to the wash plant and, if applicable, the per-short-ton cost of transporting the clean coal tons from the wash plant to a remote sales point.

(ii) You must determine the cost per short ton of clean coal transported by dividing the total applicable transportation cost by the number of clean coal tons resulting from washing the raw coal transported.

(f) You must express transportation allowances for coal as a dollar-value equivalent per short ton of coal transported. If you do not base your or your affiliate's payments for transportation under a transportation contract on a dollar-per-unit basis, you must convert whatever consideration that you or your affiliate paid to a dollar-value equivalent.

(g) ONRR may determine your transportation allowance under § 1206.254 because:

(1) There is misconduct by or between the contracting parties;

(2) ONRR determines that the consideration that you or your affiliate
paid under an arm’s-length transportation contract does not reflect the reasonable cost of the transportation because you breached your duty to market the coal for the mutual benefit of yourself and the lessor by transporting your coal at a cost that is unreasonably high. We may consider a transportation allowance unreasonably high if it is 10 percent higher than the highest reasonable measures of transportation costs, including, but not limited to, transportation allowances reported to ONRR and the cost to transport coal through the same transportation system; or

(3) ONRR cannot determine if you properly calculated a transportation allowance under §1206.261 or §1206.262 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents that ONRR requests under 30 CFR part 1212, subpart E.

§1206.261 How do I determine a transportation allowance if I have an arm’s-length transportation contract or no written arm’s-length contract?

(a) If you or your affiliate incur(s) transportation costs under an arm’s-length transportation contract, you may claim a transportation allowance for the reasonable, actual costs incurred for transporting the coal under that contract.

(b) You must be able to demonstrate that your or your affiliate’s contract is at arm’s-length.

(c) If you have no written contract for the arm’s-length transportation of coal, then ONRR will determine your transportation allowance under §1206.254. You may not use this paragraph (c) if you or your affiliate perform(s) your own transportation.

(1) You must propose to ONRR a method to determine the allowance using the procedures in §1206.258(a).

(2) You may use that method to determine your allowance until ONRR issues a determination.

§1206.262 How do I determine a transportation allowance if I do not have an arm’s-length transportation contract?

(a) This section applies if you or your affiliate do(es) not have an arm’s-length transportation contract, including situations where you or your affiliate provide your own transportation services. You must calculate your transportation allowance based on your or your affiliate’s reasonable, actual costs for transportation during the reporting period using the procedures prescribed in this section.

(b) Your or your affiliate’s actual costs may include:

(1) Capital costs and operating and maintenance expenses under paragraphs (d), (e), and (f) of this section.

(2) Overhead under paragraph (g) of this section.

(3) Depreciation under paragraph (h) of this section and a return on undepreciated capital investment under paragraph (i) of this section, or you may elect to use a cost equal to a return on the initial undepreciated capital investment in the transportation system under paragraph (j) of this section. After you have elected to use either method for a transportation system, you may not later elect to change to the other alternative without ONRR’s approval. If ONRR accepts your request to change methods, you may use your changed method beginning with the production month following the month when ONRR received your change request.

(4) A return on the reasonable salvage value, under paragraph (l) of this section, after you have depreciated the transportation system to its reasonable salvage value.

(c) You may not use any cost as a deduction that duplicates all or part of any other cost that you use under this section.

(d) Allowable capital investment costs are generally those for depreciable fixed assets (including costs of delivery and installation of capital equipment), which are an integral part of the transportation system.

(e) Allowable operating expenses include the following:

(1) Operations supervision and engineering

(2) Operations labor

(3) Fuel

(4) Utilities

(5) Materials

(6) Ad valorem property taxes

(7) Rent

(8) Supplies

(9) Any other directly allocable and attributable operating expenses that you can document

(f) Allowable maintenance expenses include the following:

(1) Maintenance of the transportation system

(2) Maintenance of equipment

(3) Maintenance labor

(4) Other directly allocable and attributable maintenance expenses that you can document

(g) Overhead, directly allocable and allocable to the operation and maintenance of the transportation system, is an allowable expense. State and Federal income taxes and severance taxes and other fees, including royalties, are not allowable expenses.

(h)(1) To calculate depreciation, you may elect to use either (i) a straight-line depreciation method based on the life of the transportation system or the life of the reserves that the transportation system services, or you may elect to use (ii) a unit-of-production method. After you make an election, you may not change methods without ONRR’s approval. If ONRR accepts your request to change methods, you may use your changed method beginning with the production month following the month when ONRR received your change request.

(2) A change in ownership of a transportation system will not alter the depreciation schedule that the original transporter/lessee established for the purposes of the allowance calculation.

(3) You may depreciate a transportation system only once with or without a change in ownership.

(i)(1) To calculate a return on undepreciated capital investment, you must multiply the remaining undepreciated capital balance as of the beginning of the period for which you are calculating the transportation allowance by the rate of return provided in paragraph (k) of this section.

(ii) For a transportation system, you may not elect to use the reserves that the transportation system or the life of the transportation system will not alter the depreciation schedule that the original transporter/lessee established for the purposes of the allowance calculation.

(j) As an alternative to using depreciation and a return on undepreciated capital investment, as provided under paragraph (b)(3) of this section, you may use as a cost an amount equal to the allowable initial capital investment in the transportation system multiplied by the rate of return determined under paragraph (k) of this section.

(k) The rate of return is the industrial rate associated with Standard & Poor’s BBB rating.

(1) You must use the monthly average BBB rate that Standard & Poor’s publishes for the first month for which the allowance is applicable.

(2) You must re-determine the rate at the beginning of each subsequent calendar year.

§1206.263 What are my reporting requirements under an arm’s-length transportation contract?

(a) You must use a separate entry on ONRR—4430 to notify ONRR of an allowance based on transportation costs that you or your affiliate incur(s).

(b) ONRR may require you or your affiliate to submit arm’s-length transportation contracts, production
agreements, operating agreements, and related documents.

(c) You can find recordkeeping requirements in parts 1207 and 1212 of this chapter.

§ 1206.264 What are my reporting requirements under a non-arm’s-length transportation contract?

(a) You must use a separate entry on form ONRR–4430 to notify ONRR of an allowance based on non-arm’s-length transportation costs you or your affiliate incur(s).

(b)(1) For new non-arm’s-length transportation facilities or arrangements, you must base your initial deduction on estimates of allowable transportation costs for the applicable period.

(2) You must use your or your affiliate’s most recently available operations data for the transportation system as your estimate, if available. If such data is not available, you must use estimates based on data for similar transportation systems.

(3) Section 1206.266 applies when you amend your report based on the actual costs.

(c) ONRR may require you or your affiliate to submit all data used to calculate the allowance deduction. You can find recordkeeping requirements in parts 1207 and 1212 of this chapter.

§ 1206.265 What interest and penalties apply if I improperly report a transportation allowance?

(a)(1) If ONRR determines that you took an unauthorized transportation allowance, then you must pay any additional royalties due, plus late payment interest calculated under § 1218.202 of this chapter.

(2) If you understated your transportation allowance, you may be entitled to a credit without interest.

(b) If you improperly net a transportation allowance against the sales value of the coal instead of reporting the allowance as a separate entry on form ONRR–4430, ONRR may assess a civil penalty under 30 CFR part 1241.

§ 1206.266 What reporting adjustments must I make for transportation allowances?

(a) If your actual transportation allowance is less than the amount that you claimed on form ONRR–4430 for each month during the allowance reporting period, you must pay additional royalties due, plus late payment interest calculated under § 1218.202 of this chapter from the date when you took the deduction to the date when you repay the difference.

(b) If the actual transportation allowance is greater than the amount that you claimed on form ONRR–4430 for any month during the period reported on the allowance form, you are entitled to a credit without interest.

§ 1206.267 What general washing allowance requirements apply to me?

(a)(1) If you determine the value of your coal under § 1206.252 of this subpart, you may take a washing allowance for the reasonable, actual costs to wash the coal. The allowance is a deduction when determining coal royalty value for the costs that you incur to wash coal.

(2) You do not need ONRR’s approval before reporting a washing allowance.

(b) You may not:

(1) Take an allowance for the costs of washing lease production that is not royalty bearing.

(2) Disproportionately allocate washing costs to Federal leases. You must allocate washing costs to washed coal attributable to each Federal lease by multiplying the input ratio determined under § 1206.251(e)(2)(i) by the total allowable costs.

(c)(1) You must express washing allowances for coal as a dollar-value equivalent per short ton of coal washed.

(2) If you do not base your or your affiliate’s payments for washing under an arm’s-length contract on a dollar-per-unit basis, you must convert whatever consideration that you or your affiliate paid to a dollar-value equivalent.

(d) ONRR may determine your washing allowance under § 1206.254 because:

(1) There is misconduct by or between the contracting parties;

(2) ONRR determines that the consideration that you or your affiliate paid under an arm’s-length washing contract does not reflect the reasonable cost of the washing because you breached your duty to market the coal for the mutual benefit of yourself and the lessor by washing your coal at a cost that is unreasonably high. We may consider a washing allowance unreasonably high if it is 10 percent higher than the highest other reasonable measures of washing, including, but not limited to, washing allowances reported to ONRR and costs for coal washed in the same plant or other plants in the region; or

(3) ONRR cannot determine if you properly calculated a washing allowance under §§ 1206.267 through 1206.269 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents that ONRR requests under 30 CFR part 1212, subpart E.

(e) You may only claim a washing allowance when you sell the washed coal and report and pay royalties.

§ 1206.268 How do I determine washing allowances if I have an arm’s-length washing contract?

(a) If you or your affiliate incur(s) washing costs under an arm’s-length washing contract, you may claim a washing allowance for the reasonable, actual costs incurred.

(b) You must be able to demonstrate that your or your affiliate’s contract is arm’s-length.

(c) If you have no written contract for the arm’s-length washing of coal, then ONRR will determine your washing allowance under § 1206.254. You may not use this paragraph (c) if you or your affiliate perform(s) your own washing. If you or your affiliate perform(s) the washing, then

(1) You must propose to ONRR a method to determine the allowance using the procedures in § 1206.258(a).

(2) You may use that method to determine your allowance until ONRR issues a determination.

§ 1206.269 How do I determine washing allowances if I do not have an arm’s-length washing contract?

(a) This section applies if you or your affiliate do(es) not have an arm’s-length washing contract, including situations where you or your affiliate provides your own washing services. You must calculate your washing allowance based on your or your affiliate’s reasonable, actual costs for washing during the reporting period using the procedures prescribed in this section.

(b) Your or your affiliate’s actual costs may include:

(1) Capital costs and operating and maintenance expenses under paragraphs (d), (e), and (f) of this section.

(2) Overhead under paragraph (g) of this section.

(3) Depreciation under paragraph (h) of this section and a return on undepreciated capital investment under paragraph (i) of this section, or you may elect to use a cost equal to a return on the initial depreciable capital investment in the wash plant under paragraph (j) of this section. After you have elected to use either method for a wash plant, you may not later elect to change to the other alternative without ONRR’s approval. If ONRR accepts your request to change methods, you may use your changed method beginning with the production month following the month when ONRR received your change request.

(4) A return on the reasonable salvage value, under paragraph (i) of this section, after you have depreciated the wash plant to its reasonable salvage value.
(c) You may not use any cost as a deduction that duplicates all or part of any other cost that you use under this section.

(d) Allowable capital investment costs are generally those for depreciable fixed assets (including costs of delivery and installation of capital equipment), which are an integral part of the wash plant.

(e) Allowable operating expenses include the following:

(1) Operations supervision and engineering
(2) Operations labor
(3) Fuel
(4) Utilities
(5) Materials
(6) Ad valorem property taxes
(7) Rent
(8) Supplies
(9) Any other directly allocable and attributable operating expenses that you can document

(f) Allowable maintenance expenses include the following:

(1) Maintenance of the wash plant
(2) Maintenance of equipment
(3) Maintenance labor
(4) Other directly allocable and attributable maintenance expenses that you can document

(g) Overhead, directly allocable and allocable to the operation and maintenance of the wash plant, is an allowable expense. State and Federal income taxes and severance taxes and other fees, including royalties, are not allowable expenses.

(b) To calculate depreciation, you may elect to use either a straight-line depreciation method based on the life of the wash plant or the life of the reserves that the wash plant services, or you may elect to use a unit-of-production method. After you make an election, you may not change methods without ONRR’s approval. If ONRR accepts your request to change methods, you may use your changed method beginning with the production month following the month when ONRR received your change request.

A change in ownership of a wash plant will not alter the depreciation schedule that the original washer/lessee established for purposes of the allowance calculation.

(3) With or without a change in ownership, you may depreciate a wash plant only once.

(i) To calculate a return on undepreciated capital investment, you must multiply the remaining undepreciated capital balance as of the beginning of the period for which you are calculating the washing allowance by the rate of return provided in paragraph (k) of this section.

(2) After you have depreciated a wash plant to its reasonable salvage value, you may continue to include in the allowance calculation a cost equal to the salvage value multiplied by a rate of return determined under paragraph (k) of this section.

(j) As an alternative to using depreciation and a return on undepreciated capital investment, as provided under paragraph (b)(3) of this section, you may use as a cost an amount equal to the allowable initial capital investment in the wash plant multiplied by the rate of return as determined under paragraph (k) of this section. You may not include depreciation in your allowance.

(k) The rate of return is the industrial rate associated with Standard & Poor’s BBB rating.

(1) You must use the monthly average BBB rate that Standard & Poor’s publishes for the first month for which the allowance is applicable.

(2) You must re-determine the rate at the beginning of each subsequent calendar year.

§ 1206.270 What are my reporting requirements under an arm’s-length washing contract?

(a) You must use a separate entry on form ONRR–4430 to notify ONRR of an allowance based on washing costs that you or your affiliate incur(s).

(b) ONRR may require you or your affiliate to submit arm’s-length washing contracts, production agreements, operating agreements, and related documents.

(c) You can find recordkeeping requirements in parts 1207 and 1212 of this chapter.

§ 1206.271 What are my reporting requirements under a non-arm’s-length washing contract?

(a) You must use a separate entry on form ONRR–4430 to notify ONRR of an allowance based on washing costs that you or your affiliate incur(s).

(b) ONRR may require you or your affiliate to submit non-arm’s-length washing contracts, production agreements, operating agreements, and related documents.

(c) You can find recordkeeping requirements in parts 1207 and 1212 of this chapter.

§ 1206.272 What interest and penalties apply if I improperly net a washing allowance?

(a) If ONRR determines that you took an unauthorized washing allowance, then you must pay any additional royalties due, plus late payment interest calculated under § 1218.202 of this chapter.

(b) If you understated your washing allowance, you may be entitled to a credit without interest.

§ 1206.273 What reporting adjustments must I make for washing allowances?

(a) If your actual washing allowance is less than the amount that you claimed on form ONRR–4430 for each month during the allowance reporting period, you must pay additional royalties due, plus late payment interest calculated under § 1218.202 of this chapter.

(b) If the actual washing allowance is greater than the amount that you claimed on form ONRR–4430 for any month during the period reported on the allowance form, you are entitled to a credit without interest.

9. Revise subpart J to read as follows:

Subpart J—Indian Coal

1206.450 What is the purpose and scope of this subpart?

1206.451 How do I determine royalty quantity and quality?

1206.452 How do I calculate royalty value for coal that I or my affiliate sell(s) under an arm’s-length or non-arm’s-length contract?

1206.453 How will ONRR determine if my royalty payments are correct?

1206.454 How will ONRR determine the value of my coal for royalty purposes?

1206.455 What records must I keep in order to support my calculations of royalty under this subpart?

1206.456 What are my responsibilities to place production into marketable condition and to market production?

1206.457 When is an ONRR audit, review, reconciliation, monitoring, or other like process considered final?

1206.458 How do I request a valuation determination?

1206.459 Does ONRR protect information that I provide?

1206.460 What general transportation allowance requirements apply to me?

1206.461 How do I determine a transportation allowance if I have an
arm’s-length transportation contract or no written arm’s-length contract?

1206.462 How do I determine a transportation allowance if I do not have an arm’s-length transportation contract?

1206.465 What are my reporting requirements under an arm’s-length transportation contract?

1206.464 What are my reporting requirements under a non-arm’s-length transportation contract or no written arm’s-length contract?

1206.463 What am I required to do if I do not have an arm’s-length contract?

1206.461 What interest and penalties apply if I improperly report a transportation allowance?

1206.466 What reporting adjustments must I make for transportation allowances?

1206.467 What general washing allowance requirements apply to me?

1206.468 How do I determine washing allowances if I have an arm’s-length washing contract or no written arm’s-length contract?

1206.469 How do I determine washing allowances if I do not have an arm’s-length washing contract?

1206.470 What are my reporting requirements under an arm’s-length washing contract?

1206.471 What are my reporting requirements under a non-arm’s-length washing contract or no written arm’s-length contract?

1206.472 What interest and penalties apply if I improperly report a washing allowance?

1206.473 What are my reporting requirements under an arm’s-length washing contract?

1206.474 What are my reporting requirements under a non-arm’s-length washing contract or no written arm’s-length contract?

1206.475 What interest and penalties apply if I improperly report a washing allowance?

Subpart J—Indioal Coal

§ 1206.450 What is the purpose and scope of this subpart?

(a) This subpart applies to all coal produced from Indian Tribal coal leases and coal leases on land held by individual Indian mineral owners. It explains how you, as the lessee, must calculate the value of production for royalty purposes consistent with the mineral leasing laws, other applicable laws, and lease terms (except leases on the Osage Indian Reservation, Osage County, Oklahoma).

(b) The terms “you” and “your” in this subpart refer to the lessee.

(c) If the regulations in this subpart are inconsistent with a(n): Federal statute; settlement agreement between the United States and a lessee resulting from administrative or judicial litigation; written agreement between the lessee and ONRR’s Director establishing a method to determine the value of production from any lease that ONRR expects, at least, would approximate the value established under this subpart; or express provision of a coal lease subject to this subpart, then the statute, settlement agreement, written agreement, or lease provision will govern to the extent of the inconsistency.

(d) ONRR may audit and order you to adjust all royalty payments.

(e) The regulations in this subpart, intended to ensure that the trust responsibilities of the United States with respect to the administration of Indian coal leases, are discharged under the requirements of the governing mineral leasing laws, treaties, and lease terms.

§ 1206.451 How do I determine royalty quantity and quality?

(a) You must calculate royalties based on the quantity and quality of coal at the royalty measurement point that ONRR and BLM jointly determine.

(b) You must measure coal in short tons using the methods that BLM prescribes for Indian coal leases. You must report coal quantity on appropriate forms required in 30 CFR part 1210.

(c)(1) You are not required to pay royalties on coal that you produce and add to stockpiles or inventory until you use, sell, or otherwise finally dispose of such coal.

(2) ONRR may request that BLM require you to increase your lease bond if BLM determines that stockpiles or inventory are excessive such that they increase the risk of resource degradation.

(d) You must pay royalty at the rate specified in your lease at the time when you use, sell, or otherwise finally dispose of the coal.

(e) You must allocate washed coal by attributing the washed coal to the leases from which it was extracted.

(1) If the wash plant washes coal from only one lease, the quantity of washed coal allocable to the lease is the total output of washed coal from the plant.

(2) If the wash plant washes coal from more than one lease, you must determine the tonnage of washed coal attributable to each lease by:

(i) First, calculating the input ratio of washed coal allocable to each lease by dividing the tonnage of coal input to the wash plant from each lease by the total tonnage of coal input to the wash plant from all leases.

(ii) Second, multiplying the input ratio derived under paragraph (e)(2)(i) of this section by the tonnage of total output of washed coal from the plant.

§ 1206.452 How do I calculate royalty value for coal that I or my affiliate sell(s) under an arm’s-length or non-arm’s-length contract?

(a) The value of coal under this section for royalty purposes is the gross proceeds accruing to you or your affiliate under the first arm’s-length contract less an applicable transportation allowance determined under §§ 1206.460 through 1206.462 and washing allowance under §§ 1206.467 through 1206.469. You must use this paragraph (a) to value coal when:

(1) You sell under an arm’s-length contract; or

(2) You sell or transfer to your affiliate or another person under a non-arm’s-length contract, and that affiliate or person, or another affiliate of either of them, then sells the coal under an arm’s-length contract.

(b) If you have no contract for the sale of coal subject to this section because you or your affiliate used the coal in a power plant that you or your affiliate own(s) for the generation and sale of electricity, one of the following applies:

(1) You or your affiliate sell(s) the electricity at arm’s-length (for example you or your affiliate deliver(s) the electricity directly to the grid), then ONRR will determine the value of the coal under § 1206.454.

(i) You must propose to ONRR a method to determine the value using the procedures in § 1206.453(a)(2).

(ii) You may use that method to determine value, for royalty purposes, until ONRR issues a determination.

(iii) After ONRR issues a determination, you must make the adjustments under § 1206.453(a)(2).

(c) If you are a coal cooperative, or a member of a coal cooperative, one of the following applies:

(1) You sell or transfer coal to another member of the coal cooperative, and that member of the coal cooperative then sells the coal under an arm’s-length contract, then you must value the coal under paragraph (a) of this section.

(2) You sell or transfer coal to another member of the coal cooperative, and you, the coal cooperative, or another member of the coal cooperative use the coal in a power plant for the generation and sale of electricity, then you must value the coal under paragraph (b) of this section.

(d) If you are entitled to take a transportation allowance and transportation allowance for royalty purposes under this section, under no circumstances...
may the washing allowance plus the transportation allowance reduce the royalty value of the coal to zero.

(e) The values in this section do not apply if ONRR decides to value your coal under § 1206.454.

§ 1206.453 How will ONRR determine if my royalty payments are correct?

(a)(1) ONRR may monitor, review, and audit the royalties that you report. If ONRR determines that your reported value is inconsistent with the requirements of this subpart, ONRR will direct you to use a different measure of royalty value, or decide your value, under § 1206.454.

(2) If ONRR directs you to use a different royalty value, you must either pay any underpaid royalties plus late payment interest calculated under § 1218.202 of this chapter or report a credit for, or request a refund of, any overpaid royalties.

(b) When the provisions in this subpart refer to gross proceeds, in conducting reviews and audits, ONRR will examine if your or your affiliate’s contract reflects the total consideration actually transferred, either directly or indirectly, from the buyer to you or your affiliate for the coal. If ONRR determines that a contract does not reflect the total consideration, ONRR may decide your value under § 1206.454.

(c) ONRR may decide to value your coal under § 1206.454, if ONRR determines that the gross proceeds accruing to you or your affiliate under a contract do not reflect reasonable consideration because:

(1) There is misconduct by or between the contracting parties;

(2) You breached your duty to market the coal for the mutual benefit of yourself and the lessor by selling your coal at a value that is unreasonably low.

ONRR may consider a sales price unreasonably low, if it is 10 percent less than the lowest other reasonable measures of market price, including, but not limited to, prices reported to ONRR for like-quality coal; or

(3) ONRR cannot determine if you properly valued your coal under § 1206.452 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents to ONRR under 30 CFR part 1212, subpart E.

(d) You have the burden of demonstrating that your or your affiliate’s contract is arm’s-length.

(e) ONRR may require you to certify that the coal in your or your affiliate’s contract include(s) all of the consideration that the buyer paid to you or your affiliate, either directly or indirectly, for the coal.

(f)(1) Absent contract revision or amendment, if you or your affiliate fail(s) to take proper or timely action to receive prices or benefits to which you are entitled under your contract, you must pay royalty based upon that obtainable price or benefit.

(2) If you or your affiliate apply in a timely manner for price increase or benefit allowed under your or your affiliate’s contract, but the purchaser refuses, and you or your affiliate take reasonable, documented measures to force purchaser compliance, you will not owe additional royalties unless or until you or your affiliate receive additional monies or consideration resulting from the price increase. You may not construe this paragraph to permit you to avoid your royalty payment obligation in situations where a purchaser fails to pay, in whole or in part, or in a timely manner, for a quantity of coal.

(g)(1) You or your affiliate must make all contracts, contract revisions, or amendments in writing, and all parties to the contract must sign the contract, contract revisions, or amendments.

(2) If you or your affiliate fail(s) to comply with paragraph (g)(1) of this section, ONRR may decide to value your coal under § 1206.454.

(3) This provision applies notwithstanding any other provisions in this title 30 to the contrary.

§ 1206.454 How will ONRR determine the value of my coal for royalty purposes?

If ONRR decides to value your coal for royalty purposes under § 1206.454, or any other provision in this subpart, then ONRR will determine value by considering any information that we deem relevant, which may include, but is not limited to:

(a) The value of like-quality coal from the same mine, nearby mines, same region, other regions, or washed in the same or nearby wash plant.

(b) Public sources of price or market information that ONRR deems reliable, including, but not limited to, the price of electricity.

(c) Information available to ONRR and information reported to us, including but not limited to, on form ONRR–4430.

(d) Costs of transportation or washing, if ONRR determines they are applicable.

(e) Any other information that ONRR deems to be relevant regarding the particular lease operation or the salability of the coal.

§ 1206.455 What records must I keep in order to support my calculations of royalty due?

If you value your coal under this subpart, you must retain all data relevant to the determination of the royalty that you paid. You can find recordkeeping requirements in parts 1207 and 1212 of this chapter. (a) You must show:

(1) How you calculated the royalty value, including all allowable deductions; and

(2) How you complied with this subpart.

(b) Upon request, you must submit all data to ONRR, the representative of the Indian lessor, the Inspector General of the Department of the Interior, or other persons authorized to receive such information. Such data may include arm’s-length sales and sales quantity data for like-quality coal that you or your affiliate sold, purchased, or otherwise obtained from the same mine, nearby mines, same region, or other regions. You must comply with any such requirement within the time that ONRR specifies.

§ 1206.456 What are my responsibilities to place production into marketable condition and to market production?

(a) You must place coal in marketable condition and market the coal for the mutual benefit of the lessee and the lessor at no cost to the Indian lessor.

(b) If you use gross proceeds under an arm’s-length contract to determine royalty, you must increase those gross proceeds to the extent that the price increase, or any other person, provides certain services that you normally are responsible to perform in order to place the coal in marketable condition or to market the coal.

§ 1206.457 When is an ONRR audit, review, reconciliation, monitoring, or other like process considered final?

Notwithstanding any provision in these regulations to the contrary, ONRR will not consider any audit, review, reconciliation, monitoring, or other like process that results in ONRR re-determining royalty due, under this subpart, final or binding as against the Federal government or its beneficiaries unless ONRR chooses to, in writing, formally close the audit period.

§ 1206.458 How do I request a valuation determination?

(a) You may request a valuation determination from ONRR regarding any coal produced. Your request must:

(1) Be in writing;

(2) Identify specifically all leases involved, all interest owners of those
leases, and the operator(s) for those leases;
(3) Completely explain all relevant facts. You must inform ONRR of any changes to relevant facts that occur before we respond to your request;
(4) Include copies of all relevant documents;
(5) Provide your analysis of the issue(s), including citations to all relevant precedents (including adverse precedents); and
(6) Suggest a proposed valuation method.
(b) In response to your request, ONRR may:
(1) Request that the Assistant Secretary for Policy, Management and Budget issue a determination;
(2) Decide that ONRR will issue guidance; or
(3) Inform you in writing that ONRR will not provide a determination or guidance. Situations in which ONRR typically will not provide any determination or guidance include, but are not limited to:
(i) Requests for guidance on hypothetical situations; or
(ii) Matters that are the subject of pending litigation or administrative appeals.
(c)(1) A determination that the Assistant Secretary for Policy, Management and Budget signs is binding on both you and ONRR until the Assistant Secretary modifies or rescinds it.
(2) After the Assistant Secretary issues a determination, you must make any adjustments in royalty payments that follow from the determination and, if you owe additional royalties, you must pay any additional royalties due, plus late payment interest calculated under § 1206.495.
(3) A determination that the Assistant Secretary signs is the final action of the Department and is subject to judicial review under 5 U.S.C. 701–706.
(d) Guidance that ONRR issues is not binding on ONRR, Tribes, individual Indian mineral owners, or you with respect to the specific situation addressed in the guidance.
(ii) Guidance and ONRR’s decision whether or not to issue guidance or to request an Assistant Secretary determination, or neither, under paragraph (b) of this section, are not appealable decisions or orders under 30 CFR part 1290.
(2) If you receive an order requiring you to pay royalty on the same basis as the guidance, you may appeal that order under 30 CFR part 1290.
(e) ONRR or the Assistant Secretary may use any of the applicable criteria in this subpart to provide guidance or to make a determination.
(f) A change in an applicable statute or regulation on which ONRR based any guidance, or the Assistant Secretary based any determination, takes precedence over the determination or guidance after the effective date of the statute or regulation, regardless of whether ONRR or the Assistant Secretary modifies or rescinds the guidance or determination.
(g) ONRR may make requests and replies under this section available to the public, subject to the confidentiality requirements under § 1206.459.
§ 1206.459 Does ONRR protect information that I provide?
(a) Certain information that you or your affiliate submit(s) to ONRR regarding royalties on coal, including deductions and allowances, may be exempt from disclosure.
(b) To the extent that applicable laws and regulations permit, ONRR will keep confidential any data that you or your affiliate submit(s) that is privileged, confidential, or otherwise exempt from disclosure.
(c) You and others must submit all requests for information under the Freedom of Information Act regulations of the Department of the Interior at 43 CFR part 2.
§ 1206.460 What general transportation allowance requirements apply to me?
(a)(1) ONRR will allow a deduction for the reasonable, actual costs to transport coal from the lease to the point off of the lease or mine as determined under § 1206.461 or § 1206.462, as applicable.
(2) Before you may take any transportation allowance, you must submit a completed page 1 of the Coal Transportation Allowance Report (Form ONRR–4293), under §§ 1206.463 and 1206.464 of this subpart. You may claim a transportation allowance retroactively for a period of not more than three months prior to the first day of the month when ONRR receives your form ONRR–4293.
(3) You may not use a transportation allowance that was in effect before January 1, 2017. You must use the provisions of this subpart to determine your transportation allowance.
(b) You may take a transportation allowance when:
(1) You value coal under § 1206.452 of this part;
(2) You transport the coal from an Indian lease to a sales point that is remote from both the lease and mine; or
(3) You transport the coal from an Indian lease to a wash plant when that plant is remote from both the lease and mine and, if applicable, from the wash plant to a remote sales point.
(c) You may not take an allowance for:
(1) Transportation lease production that is not royalty-bearing;
(2) In-mine movement of your coal; or
(3) Costs to move a particular tonnage of production for which you did not incur those costs.
(d) You may only claim a transportation allowance when you sell the coal and pay royalties.
(e) You must allocate transportation allowances to the coal attributed to the lease from which it was extracted.
(1) If you commingle coal produced from Indian and non-Indian leases, you may not disproportionate transport costs to Indian lease production. Your allocation must use the same proportion as the ratio of the tonnage from the Indian lease production to the tonnage from all production.
(2) If you commingle coal produced from more than one Indian lease, you must allocate transportation costs to each Indian lease, as appropriate. Your allocation must use the same proportion as the ratio of the tonnage of each Indian lease’s production to the tonnage of all production.
(3) For washed coal, you must allocate the total transportation allowance only to washed products.
(4) For unwashed coal, you may take a transportation allowance for the total coal transported.
(5)(i) You must report your transportation costs on form ONRR–4430 as clean coal short tons sold during the reporting period multiplied by the sum of the per short-ton cost of transporting the raw tonnage to the wash plant and, if applicable, the per short-ton cost of transporting the clean coal tons from the wash plant to a remote sales point.
(ii) You must determine the cost per short ton of clean coal transported by dividing the total applicable transportation cost by the number of clean coal tons resulting from washing the raw coal transported.
(f) You must express transportation allowances for coal as a dollar-value equivalent per short ton of coal transported. If you do not base your or your affiliate’s payments for transportation under a transportation contract on a dollar-per-unit basis, you must convert whatever consideration that you or your affiliate paid into a dollar-value equivalent.
(g) ONRR may determine your transportation allowance under § 1206.454 because:
(1) There is misconduct by or between the contracting parties;
(2) ONRR determines that the consideration that you or your affiliate
paid under an arm’s-length transportation contract does not reflect the reasonable cost of the transportation because you breached your duty to market the coal for the mutual benefit of yourself and the lessor by transporting your coal at a cost that is unreasonably high. We may consider a transportation allowance unreasonably high if it is 10 percent higher than the highest reasonable measures of transportation costs, including, but not limited to, transportation allowances reported to ONRR and the cost to transport coal through the same transportation system; or

(3) ONRR cannot determine if you properly calculated a transportation allowance under §1206.461 or §1206.462 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents that ONRR requests under 30 CFR part 1212, subpart E.

§1206.461 How do I determine a transportation allowance if I have an arm’s-length transportation contract or no written arm’s-length contract?

(a) If you or your affiliate incur(s) transportation costs under an arm’s-length transportation contract, you may claim a transportation allowance for the reasonable, actual costs incurred for transporting the coal under that contract.

(b) You must be able to demonstrate that your or your affiliate’s contract is at arm’s length.

(c) If you have no written contract for the arm’s-length transportation of coal, then ONRR will determine your transportation allowance under §1206.454. You may not use this paragraph (c) if you or your affiliate perform(s) your own transportation.

(1) You must propose to ONRR a method to determine the allowance using the procedures in §1206.458(a).

(2) You may use that method to determine your allowance until ONRR issues a determination.

§1206.462 How do I determine a transportation allowance if I do not have an arm’s-length transportation contract?

(a) This section applies if you or your affiliate do(es) not have an arm’s-length transportation contract, including situations where you or your affiliate provide your own transportation services. Calculate your transportation allowance based on your or your affiliate’s reasonable, actual costs for transportation during the reporting period using the procedures prescribed in this section.

(b) Your or your affiliate’s actual costs may include:

1. Capital costs and operating and maintenance expenses under paragraphs (d), (e), and (f) of this section.

2. Overhead under paragraph (g) of this section.

3. Depreciation under paragraph (h) of this section and a return on undepreciated capital investment under paragraph (i) of this section, or you may elect to use a cost equal to a return on the initial depreciable capital investment in the transportation system under paragraph (j) of this section. After you have elected to use either method for a transportation system, you may not later elect to change to the other alternative without ONRR’s approval. If ONRR accepts your request to change methods, you may use your changed method beginning with the production month following the month when ONRR received your change request.

(c) You may not use any cost as a deduction that duplicates all or part of any other cost that you use under this section.

(d) Allowable capital investment costs are generally those for depreciable fixed assets (including costs of delivery and installation of capital equipment), which are an integral part of the transportation system.

(e) Allowable operating expenses include the following:

1. Operations supervision and engineering

2. Operations labor

3. Fuel

4. Utilities

5. Materials

6. Ad valorem property taxes

7. Rent

8. Supplies

9. Any other directly allocable and attributable operating expense that you can document

(f) Allowable maintenance expenses include the following:

1. Maintenance of the transportation system

2. Maintenance of equipment

3. Maintenance labor

4. Other directly allocable and attributable maintenance expenses that you can document

(g) Overhead, directly allocable and allocable to the operation and maintenance of the transportation system, is an allowable expense. State and Federal income taxes and Indian Tribal severance taxes and other fees, including royalties, are not allowable expenses.

(h)(1) To calculate depreciation, you may elect to use either a straight-line depreciation method based on the life of the transportation system or the life of the reserves that the transportation system services, or you may elect to use a unit-of-production method. After you make an election, you may not change methods without ONRR’s approval. If ONRR accepts your request to change methods, you may use your changed method beginning with the production month following the month when ONRR received your change request.

(2) A change in ownership of a transportation system will not alter the depreciation schedule that the original transporter/lessee established for the purposes of the allowance calculation.

(i) You may depreciate a transportation system only once with or without a change in ownership.

(j) As an alternative to using depreciation and a return on undepreciated capital investment, as provided under paragraph (b)(3) of this section, you may use as a cost an amount equal to the allowable initial capital investment in the transportation system multiplied by the rate of return determined under paragraph (k) of this section. You may not include depreciation in your allowance.

(k) The rate of return is the industrial rate associated with Standard & Poor’s BBB rating.

(1) You must use the monthly average BBB rate that Standard & Poor’s publishes for the first month for which the allowance is applicable.

(2) You must re-determine the rate at the beginning of each subsequent calendar year.

§1206.463 What are my reporting requirements under an arm’s-length transportation contract?

(a) You must use a separate entry on form ONRR–4293 to notify ONRR of an allowance based on transportation costs you or your affiliate incur(s).

(b) ONRR may require you or your affiliate to submit arm’s-length transportation contracts, production agreements, operating agreements, and related documents.

(c) You can find recordkeeping requirements in parts 1207 and 1212 of this chapter.

(d)(1) You must submit page 1 of the initial form ONRR–4293 prior to, or at the same time as, you report the transportation allowance determined under an arm’s-length contract on form ONRR–4430.

(2) The initial form ONRR–4293 is effective beginning with the production
month when you are first authorized to deduct a transportation allowance and continues until the end of the calendar year, or until the termination, modification, or amendment of the applicable contract or rate, whichever is earlier.

(3) After the initial period when ONRR first authorized you to deduct a transportation allowance and for succeeding periods, you must submit the entire form ONRR–4293 by the earlier of the following:
   (i) Within three months after the end of the calendar year
   (ii) After the termination, modification, or amendment of the applicable contract or rate

(4) You may request to use an allowance for a longer period than that required under paragraph (d)(2) of this section.

(i) You may use that allowance beginning with the production month following the month when ONRR received your request to use the allowance for a longer period until ONRR decides whether to approve the longer period.

(ii) ONRR’s decision whether or not to approve a longer period is not appealable under 30 CFR part 1290.

(iii) If ONRR does not approve the longer period, you must adjust your transportation allowance under § 1206.466.

§ 1206.464 What are my reporting requirements under a non-arm’s-length transportation contract or no written arm’s-length contract?

(a) You must use a separate entry on form ONRR–4430 to notify ONRR of an allowance based on non-arm’s-length transportation costs that you or your affiliate incur(s).

(b) ONRR may require you or your affiliate to submit all data used to calculate the allowance deduction. You can find recordkeeping requirements in parts 1207 and 1212 of this chapter.

(c) (1) You must submit an initial form ONRR–4293 prior to, or at the same time as, the transportation allowance determined under a non-arm’s-length contract or no written arm’s-length contract situation that you report on form ONRR–4430. If ONRR receives a form ONRR–4293 by the end of the month when the form ONRR–4430 is due, ONRR will consider the form to be received in a timely manner. You may base the initial form on estimated costs.

(2) The initial form ONRR–4293 is effective beginning with the production month when you are first authorized to deduct a transportation allowance and continues until the end of the calendar year or termination, modification, or amendment of the applicable contract or rate, whichever is earlier.

(3) (i) At the end of the calendar year for which you submitted a form ONRR–4293 based on estimates, you must submit another, completed form ONRR–4293 containing the actual costs for that calendar year.

(ii) If the transportation continues, you must include on form ONRR–4293 your estimated costs for the next calendar year.

(A) You must base the estimated transportation allowance on the actual costs for the previous reporting period plus or minus any adjustments based on your knowledge of decreases or increases that will affect the allowance.

(B) ONRR must receive form ONRR–4293 within three months after the end of the previous calendar year.

(d)(1) For new non-arm’s-length transportation facilities or arrangements, on your initial ONRR–4293 form, you must include estimates of the allowable transportation costs for the applicable period.

(2) You must use your or your affiliate’s most recently available operations data for the transportation system as your estimate, if available. If such data is not available, you must use estimates based on data for similar transportation systems.

(e) Upon ONRR’s request, you must submit all data used to prepare your ONRR–4293 form. You must provide the data within a reasonable period of time, as ONRR determines.

(f) Section 1206.466 applies when you amend your form ONRR–4293 based on the actual costs.

§ 1206.465 What interest and penalties apply if I improperly report a transportation allowance?

(a)(1) If ONRR determines that you took an unauthorized transportation allowance, then you must pay any additional royalties due, plus late payment interest calculated under § 1218.202 of this chapter from the date when you took the deduction to the date when you repay the difference.

(b) If the actual transportation allowance is greater than the amount that you claimed on form ONRR–4430 for any month during the period reported on the allowance form, you are entitled to a credit without interest.

§ 1206.467 What general washing allowance requirements apply to me?

(a)(1) If you determine the value of your coal under § 1206.452 of this subpart, you may take a washing allowance for the reasonable, actual costs to wash coal. The allowance is a deduction when determining coal royalty value for the costs that you incur to wash coal.

(2) Before you may take any deduction, you must submit a completed page 1 of the Coal Washing Allowance Report (Form ONRR–4292), under §§ 1206.470 and 1206.471 of this subpart. You may claim a washing allowance retroactively for a period of not more than three months prior to the first day of the month when you have filed form ONRR–4292 with ONRR.

(3) You may not use a washing allowance that was in effect before January 1, 2017. You must use the provisions of this subpart to determine your washing allowance.

(b) You may not:

(1) Take an allowance for the costs of washing lease production that is not royalty bearing.

(2) Disproportionately allocate washing costs to Indian leases. You must allocate washing costs to washed coal attributable to each Indian lease by multiplying the input ratio determined under § 1206.451(e)(2)(i) by the total allowable costs.

(c)(1) You must express washing allowances for coal as a dollar-value equivalent per short ton of coal washed.

(2) If you do not base your or your affiliate’s payments for washing under an arm’s-length contract on a dollar-per-unit basis, you must convert whatever consideration that you or your affiliate paid into a dollar-value equivalent.

(d) ONRR may determine your washing allowance under § 1206.454 because:

(1) There is misconduct by or between the contracting parties;

(2) ONRR determines that the consideration that you or your affiliate paid under an arm’s-length washing contract does not reflect the reasonable cost of the washing because you breached your duty to market the coal
for the mutual benefit of yourself and
the lessor by washing your coal at a cost
that is unreasonably high. We may
consider a washing allowance to be
unreasonably high if it is 10 percent
higher than the highest other reasonable
measures of washing, including, but not
limited to, washing allowances reported
to ONRR and costs for coal washed in
the same plant or other plants in the
region; or
(3) ONRR cannot determine if you
properly calculated a washing
allowance under §§ 1206.557 through
1206.469 for any reason, including, but
not limited to, your or your affiliate’s
failure to provide documents that ONRR
requests under 30 CFR part 1212,
subpart E.
(e) You may only claim a washing
allowance if you sell the washed coal
and report and pay royalties.
§ 1206.468 How do I determine washing
allowances if I have an arm’s-length
washing contract or no written arm’s-length
contract?
(a) If you or your affiliate incur(s)
washing costs under an arm’s-length
washing contract, you may claim a
washing allowance for the reasonable,
actual costs incurred.
(b) You must be able to demonstrate
that your or your affiliate’s contract is
arm’s-length.
(c) If you have no contract for the
washing of coal, then ONRR will
determine your transportation
allowance under § 1206.454. You may
not use this paragraph (c), if you or your
affiliate perform(s) your own washing. If
you or your affiliate perform(s) the
washing, then:
(1) You must propose to ONRR a
method to determine the allowance
using the procedures in § 1206.456(a).
(2) You may use that method to
determine your allowance until ONRR
issues a determination.
§ 1206.469 How do I determine washing
allowances if I do not have an arm’s-length
washing contract?
(a) This section applies if you or your
affiliate do(es) not have an arm’s-length
washing contract, including situations
where you or your affiliate provides
your own washing services. Calculate
your washing allowance based on your
or your affiliate’s reasonable, actual
costs for washing during the reporting
period using the procedures prescribed
in this section.
(b) Your or your affiliate’s actual costs
may include:
(1) Capital costs and operating and
maintenance expenses under paragraphs
(d), (e), and (f) of this section.
(2) Overhead under paragraph (g) of
this section.
(3) Depreciation under paragraph (h)
of this section and a return on
undepreciated capital investment under
paragraph (i) of this section, or a cost
equal to a return on the initial
depreciable capital investment in the
wash plant under paragraph (j) of this
section. After you have elected to use
either method for a wash plant, you may
not later elect to change to the other
alternative without ONRR’s approval. If
ONRR accepts your request to change
methods, you may use your changed
method beginning with the production
month following the month when ONRR
received your change request.
(c) You may not use any cost as a
deduction that duplicates all or part of
any other cost that you use under this
section.
(d) Allowable capital investment costs
are generally those for depreciable fixed
assets (including costs of delivery and
installation of capital equipment),
which are an integral part of the wash
plant.
(e) Allowable operating expenses
include the following:
(1) Operations supervision and
engineering
(2) Operations labor
(3) Fuel
(4) Utilities
(5) Materials
(6) Ad valorem property taxes
(7) Rent
(8) Supplies
(9) Any other directly allocable and
attributable operating expenses that
you can document
(f) Allowable maintenance expenses
include the following:
(1) Maintenance of the wash plant
(2) Maintenance of equipment
(3) Maintenance labor
(4) Other directly allocable and
attributable maintenance expenses
that you can document
(g) Overhead, directly allocatable and
allocable to the operation and
maintenance of the wash plant is an
allowable expense. State and Federal
income taxes and Indian Tribal
severance taxes and other fees,
including royalties, are not allowable
expenditures.
(h)(1) To calculate depreciation, you
can elect to use either (i) a straight-line
depreciation method based on the life of
the wash plant or the life of the reserves
that the wash plant services, or you may
elect to use (ii) a unit-of-production
method. After you make an election,
you may not change methods without
ONRR’s approval. If ONRR accept your
request to change methods, you may use
your changed method beginning with
the production month following the
month when ONRR received your
change request.
(2) A change in ownership of a wash
plant will not alter the depreciation
schedule that the original washer/lessee
established for the purposes of the
allowance calculation.
(3) With or without a change in
ownership, you may depreciate a wash
plant only once.
(i) To calculate a return on
undepreciated capital investment,
multiply the remaining undepreciated
capital balance as of the beginning of
the period for which you are calculating
the washing allowance by the rate of
return provided in paragraph (k) of this
section.
(j) As an alternative to using
depreciation and a return on
undepreciated capital investment, as
provided under paragraph (b)(3) of this
section, you may use as a cost an
amount equal to the allowable initial
capital investment in the wash plant
multiplied by the rate of return as
determined under paragraph (k) of this
section. You may not include
depreciation in your allowance.
(k) The rate of return is the industrial
rate associated with Standard & Poor’s
BBB rating.
(1) You must use the monthly average
BBB rate that Standard & Poor’s
publishes the first month for which
the allowance is applicable.
(2) You must re-determine the rate
at the beginning of each subsequent
calendar year.
§ 1206.470 What are my reporting
requirements under an arm’s-length
washing contract?
(a) You must use a separate entry on
form ONRR–4293 to notify ONRR of an
allowance based on washing costs that
you or your affiliate incur(s).
(b) ONRR may require you or your
affiliate to submit arm’s-length washing
contracts, production agreements,
operating agreements, and related
documents.
(c) You can find recordkeeping
requirements in parts 1207 and 1212 of
this chapter.
(d)(1) You must file an initial form
ONRR–4292 prior to, or at the same time
as, the washing allowance determined
under an arm’s-length contract or no
written arm’s-length contract situation
that you report on form ONRR–4293. If
ONRR receives a form ONRR–4292 by
the end of the month when the form
ONRR–4430 is due, ONRR will consider
the form to be received in a timely
manner.
(2) The initial form ONRR–4292 is
effective beginning with the production
month when you are first authorized to
deduct a washing allowance and continues until the end of the calendar year, or until the termination, modification, or amendment of the applicable contract or rate, whichever is earlier.

(3) After the initial period that ONRR first authorized you to deduct a washing allowance, and for succeeding periods, you must submit the entire form ONRR–4292 by the earlier of the following:

(i) Within three months after the end of the calendar year.

(ii) After the termination, modification, or amendment of the applicable contract or rate.

(4) You may request to use an allowance for a longer period than that required under paragraph (d)(2) of this section.

(i) You may use that allowance beginning with the production month following the month when ONRR received your request to use the allowance for a longer period until ONRR decides whether to approve the longer period.

(ii) ONRR’s decision whether or not to approve a longer period is not appealable under 30 CFR part 1290.

(iii) If ONRR does not approve the longer period, you must adjust your transportation allowance under § 1206.466.

§1206.471 What are my reporting requirements under a non-arm’s-length washing contract or no written arm’s-length contract?

(a) You must use a separate entry on form ONRR–4430 to notify ONRR of an allowance based on non-arm’s-length washing costs that you or your affiliate incur(s).

(b) ONRR may require you or your affiliate to submit all data used to calculate the allowance deduction. You can find recordkeeping requirements in parts 1207 and 1212 of this chapter.

(c)(1) You must submit an initial form ONRR–4292 prior to, or at the same time as, the washing allowance determined under a non-arm’s-length contract or no written arm’s-length contract situation that you report on form ONRR–4430. If ONRR receives a form ONRR–4292 by the end of the month when the form ONRR–4430 is due, ONRR will consider the form to be received in a timely manner. You may base the initial reporting on estimated costs.

(2) The initial form ONRR–4292 is effective beginning with the production month when you are first authorized to deduct a washing allowance and continues until the end of the calendar year or termination, modification, or amendment of the applicable contract or rate, whichever is earlier.

(3)(i) At the end of the calendar year for which you submitted a form ONRR–4292, you must submit another, completed form ONRR–4292 containing the actual costs for that calendar year.

(ii) If coal washing continues, you must include on form ONRR–4292 your estimated costs for the next calendar year.

(A) You must base the estimated coal washing allowance on the actual costs for the previous period plus or minus any adjustments based on your knowledge of decreases or increases that will affect the allowance.

(B) ONRR must receive form ONRR–4292 within three months after the end of the previous calendar year.

(d)(1) For new non-arm’s-length washing facilities or arrangements on your initial form ONRR–4292, you must include estimates of allowable washing costs for the applicable period.

(2) You must use your or your affiliate’s most recently available operations data for the wash plant as your estimate, if available. If such data is not available, you must use estimates based on data for similar wash plants.

(e) Upon ONRR’s request, you must submit all data that you used to prepare your forms ONRR–4293. You must provide the data within a reasonable period of time, as ONRR determines.

(f) Section 1206.472 applies when you amend your form ONRR–4292 based on the actual costs.

§1206.472 What interest and penalties apply if I improperly report a washing allowance?

(a)(1) If ONRR determines that you took an unauthorized washing allowance, then you must pay any additional royalties due, plus late payment interest calculated under § 1218.202 of this chapter.

(2) If you understated your washing allowance, you may be entitled to a credit without interest.

(b) If you improperly net a washing allowance against the sales value of the coal instead of reporting the allowance as a separate entry on form ONRR–4430, ONRR may assess a civil penalty under 30 CFR part 1241.

§1206.473 What reporting adjustments must I make for washing allowances?

(a) If your actual washing allowance is less than the amount that you claimed on form ONRR–4430 for each month during the allowance reporting period, you may pay additional royalties due, plus late payment interest calculated under § 1218.202 of this chapter from the date when you took the deduction to the date when you repay the difference.

(b) If the actual washing allowance is greater than the amount that you claimed on form ONRR–4430 for any month during the period reported on the allowance form, you are entitled to a credit without interest.

[FR Doc. 2020–20560 Filed 9–30–20; 8:45 am]
ONRR 2020 Valuation Reform and Civil Penalty Rule; Proposed Rule
DEPARTMENT OF THE INTERIOR  
Office of Natural Resources Revenue  

30 CFR Parts 1206 and 1241  
[Docket No. ONRR–2020–0001; DS63644000 DRT000000.CH7000 201D1113RT]  
RIN 1012–AA27  
ONRR 2020 Valuation Reform and Civil Penalty Rule  

AGENCY: Department of the Interior, Office of the Secretary, Office of Natural Resources Revenue.  

ACTION: Proposed rule.  

SUMMARY: The Office of Natural Resources Revenue (“ONRR”) is publishing this proposed rule to seek comment on measures to amend portions of ONRR’s regulations for valuing oil and gas produced from Federal leases for royalty purposes, valuing coal produced from Federal and Indian leases, and assessing civil penalties for violations of certain statutes, regulations, leases, and orders associated with mineral leases.  

DATES: You must submit comments on or before November 30, 2020.  

ADDRESSES: You may submit comments to ONRR using any of the following three methods. Please reference Regulation Identifier Number (RIN) 1012–AA27 in any comment:  

- Electronically submit at http://www.regulations.gov. In the search bar titled “SEARCH for: Rules, Comments, Adjudications or Supporting Documents:” enter “ONRR–2020–0001,” and then click “Search.” Follow the instructions to submit public comments.  
- Email comments to Dane Templin, Regulations Supervisor, at Dane.Templin@onrr.gov and Luis Aguilar, Regulatory Specialist, at Luis.Aguilar@onrr.gov. Include RIN 1012–AA27 in the subject line of the message.  
- Hand-carry or mail comments to the Office of Natural Resources Revenue, Building 85, Entrance N–1, Denver Federal Center, West 6th Ave. and Kipling St., Denver, Colorado 80225.  

Instructions: All comments must include the agency name and docket number or RIN for this rulemaking. All comments, including any personal identifying information or confidential business information contained in a comment, will be posted without change to https://www.onrr.gov/Laws_R_D/FRNotices/AA27.htm. See also Public Availability of Comments under the Procedural Matters section of this document.  

Docket: For access to the docket to read background documents or comments received, go to https://regulations.gov or https://www.onrr.gov/Laws_R_D/FRNotices/AA27.htm.  

FOR FURTHER INFORMATION CONTACT: For questions on procedural issues, contact Dane Templin at (303) 231–3149, or by email addressed to Dane.Templin@onrr.gov. For comments or questions on technical issues, contact Amy Lunt, Supervisor Royalty Valuation Team A, at (303) 231–3746, or by email addressed to Amy.Lunt@onrr.gov, or Peter Christnacht, Supervisor Royalty Valuation Team B, at (303) 231–3651, or by email addressed to Peter.Christnacht@onrr.gov.  

SUPPLEMENTARY INFORMATION:  

I. Executive Summary  

ONRR is proposing, for multiple reasons, targeted amendments to 30 CFR part 1206 (most recently amended by the 2016 Consolidated Federal Oil & Gas and Federal & Indian Coal Valuation Reform Rule (“2016 Valuation Rule”)). First, the 2016 Valuation Rule added certain provisions that are inconsistent with multiple executive orders that have been issued after the 2016 Valuation Rule’s effective date, including Executive Order on Promoting Energy Independence and Economic Growth (Executive Order 13783), which directs agencies to “identify existing regulations that potentially burden the development or use of domestically produced energy resources and appropriately suspend, revise, or rescind those that unduly burden the development of domestic energy resources beyond the degree necessary to protect the public interest or otherwise comply with the law.” Second, ONRR, after defending its amendments to the Federal and Indian coal valuation rules in 2016 Valuation Rule litigation, and upon consideration of the parties’ briefs and receiving the Court’s ruling, has determined that it should propose a revision to the most controversial coal valuation rules. Third, the proposed amendments would update ONRR’s regulations to simplify certain processes, provide early clarity regarding royalties owed, and better explain ONRR’s civil penalty practices. Finally, this proposed rule would return the relationship between the Federal government, States, Tribes, and regulated parties to the longstanding and familiar valuation framework that existed under POGGMA for many years prior to the 2016 Valuation Rule. The agency finds that these reasons, collectively and individually, warrant amending ONRR’s valuation and civil penalty regulations. In addition, ONRR proposes to amend 30 CFR part 1241 (most recently amended by the 2016 Amendments to Civil Penalty Regulations (“2016 Civil Penalty Rule”)) to conform that part with a decision recently issued by a federal district court and to clarify that the 2016 Civil Penalty Rule conforms with ONRR’s long-standing practice. ONRR believes that regulatory certainty will be best served by amending targeted portions of 30 CFR part 1206 that the 2016 Valuation Rule also addressed, including recodifying certain pre-2017 regulations to achieve a more rational balance between the government’s interest in effective regulation of royalties and the burden on the regulated entities. Though ONRR recognizes that the regulations in place prior to the 2016 Valuation Rule pose certain implementation challenges, the agency finds that restoring those prior regulations is preferable to maintaining ONRR’s rules, as modified by 2016 Valuation Rule, because returning to some of the prior regulations would reinstate a longstanding, nationwide regulatory framework that is better understood by the parties interpreting and applying the regulations (ONRR and the regulated entities). The proposed rule would also meet policy objectives stated in certain Executive Orders, including Executive Order 13783, “Promoting Energy Independence and Economic Growth,” Executive Order 13795, “Implementing an America-First Offshore Energy Strategy,” and would support Secretarial Order 3350, which promotes the America-First Offshore Energy Strategy.  

In July 2016, ONRR published the 2016 Valuation Rule, amending, in a number of significant respects, the valuation regulations applicable to Federal oil and gas and Federal and Indian coal. 81 FR 43338, July 1, 2016 (https://www.onrr.gov/Laws_R_D/FRNotices/AA13.htm). The effective date of the 2016 Valuation Rule was January 1, 2017. ONRR is reissuing the 2016 Valuation Rule in the Rule and Regulations section of this issue of the Federal Register.  

With respect to Federal oil and gas, this proposed rule would alter or reverse some of the changes brought about by the 2016 Valuation Rule in order to return to the definitions and practices that had been in place since the 1980s. The proposed changes to return to historical practices include: (1) Reinstating the ability of a lessee to request to exceed the 500-pound regulatory limit for transportation costs; (2) reinstating the ability of a lessee to...
request to exceed the 66 2/3-percent regulatory limit for processing costs; (3) allowing a lessee producing offshore to claim, without requesting case-by-case approval, certain gathering costs as a transportation allowance in waters 200 meters and deeper; (4) allowing a lessee producing offshore to request ONRR’s approval to claim certain gathering costs as a transportation allowance in waters shallower than 200 meters where “deepwater-like” subsea movement occurs; (5) removing the misconduct definition (also applies to Federal and Indian coal); (6) removing the default provision and all references thereto (also applies to Federal and Indian coal); (7) eliminating the requirement that written contracts be signed by all parties (also applies to Federal and Indian coal); and (8) eliminating the requirement that companies cite legal precedent when seeking a valuation determination (also applies to Federal and Indian coal). In addition, this proposed rule would expand concepts first adopted in the 2016 Valuation Rule. The proposed expansion to those 2016 Valuation Rule concepts includes extending the index-based valuation option to all Federal gas dispositions. Finally, this proposed rule would change a few index-based valuation concepts in the 2016 Valuation Rule, including changing the index-based option for unprocessed and residue gas from the highest bidweek price to an average bidweek price; updating the index-based transportation deductions based on more current data; expressly stating that a lessee cannot report royalty values of zero or less; and expressing that ONRR can request production of a variety of records from lessees who report under an index-based option.

By reverting to certain pre-2016 Valuation Rule practices, this rule would reintroduce one ONRR-quantified administrative cost that the 2016 Valuation Rule eliminated—accounting for deepwater gathering costs that may be claimed as part of a transportation allowance. Described further in Section E, ONRR estimates that Federal lessees would incur an additional $3.136 million in administrative costs in order to increase reported transportation allowances by $30.5 to $41.3 million per year related to deepwater gathering.

With respect to Federal and Indian coal, this proposed rule would eliminate some of the changes brought about by the 2016 Valuation Rule in order to address deficiencies in the 2016 Valuation Rule identified by the United States District Court for the District of Wyoming in Cloud Peak Energy, Inc., v. U.S. Dep’t of the Interior, 415 F. Supp. 3d 1034 (D. Wy. 2019). Specifically, this proposed rule would remove the requirement that coal be valued based on sales of electricity and eliminate the definition of coal cooperative.

In August 2016, ONRR published the 2016 Civil Penalty Rule, 81 FR 50306, August 1, 2016 (https://www.onrr.gov/Laws_R_D/FRNotices/AA05.htm). This proposed rule would require companies to calculate a fine or penalty for violating the 2016 Valuation Rule in order to increase the fine or penalty for violating the 2016 Valuation Rule by $30.5 to $41.3 million per year related to deepwater gathering.

In response to the repeal, the court found that ONRR failed to adequately explain the regulatory change. First, the district court held that ONRR did not provide a reasoned explanation as to “why the industry concerns [regarding compliance issues with the 2016 Valuation Rule that ONRR] previously rejected—as well as its prior findings in support of adopting the 2016 Valuation Rule—now justified returning to the pre-[2016 Valuation Rule] regulatory framework. Nowhere in the Final Repeal does the ONRR provide such an explanation.” Id. at 1166 (citation omitted). The district court went on to state that “[a]lthough the ONRR is entitled to change its position, it must provide ‘a reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy.’” Id. at 1168. “ONRR’s conclusory explanation in the Final Repeal fails to satisfy its obligation to explain inconsistencies between its prior findings in enacting the [2016 Valuation Rule] and its decision to repeal such rule.” Id.

Second, the district court held that there was no support for ONRR’s complete repeal of the 2016 Valuation Rule. Id. “When considering revoking a rule, an agency must consider alternatives in lieu of complete repeal, such as by addressing the deficiencies individually.” Id. The court found that such action was arbitrary and capricious. Id. at 1169. California v. Bureau of Land Mgmt., 286 F. Supp. 3d 1054, 1066–67 (N.D. Cal. 2018)
(finding that even if the agency had factual evidence to support its claim that the new regulations at issue in that rule burdened small operators, a “blanket suspension” of the regulations was arbitrary and capricious because the suspension was “not properly tailored” to address the allegedly defective provision).

Third, the district court found that ONRR’s citation to Executive Order 13783 as justification for repeal of the 2016 Valuation Rule was not adequately explained and conclusory. Id. at 1169–70. “More fundamentally, the ONRR’s speculation that provisions [in the 2016 Valuation Rule] would be unduly burdensome, difficult to apply and increase costs, directly contradict its previous findings in its promulgation of the [2016 Valuation Rule].” Id. at 1170. The court concluded that an agency’s failure to provide a reasoned explanation for its decision to suspend a rule based on the rule’s costs, while ignoring its benefits, violates the APA. Id.

Fourth, the district court found that ONRR could not rely on potential future findings and recommendations made by its Royalty Policy Committee to justify repeal of the 2016 Valuation Rule, although ONRR stated it was not, in any event, doing so. Id. at 1171. “Predicating a repeal decision on recommendations that may or may not occur in the future is arbitrary and capricious.” Id.

After ONRR reinstated the 2016 Valuation Rule, industry refiled litigation challenging the 2016 Valuation Rule. That litigation is currently proceeding in the United States District Court for the District of Wyoming. Cloud Peak Energy, Inc. v. U.S. Dep’t of the Interior, Case No. 19–CV–120–SWS (D. Wyo.). On October 8, 2019, the Wyoming District Court entered an Order granting in part and denying in part industry’s request for a preliminary injunction of the implementation of the 2016 Valuation Rule. The Court refused to enjoin the portions of the 2016 Valuation Rule applicable to Federal oil and gas but stayed the portions of the 2016 Valuation Rule applicable to Federal and Indian coal. Cloud Peak, 415 F. Supp. 3d at 1053. Thus, the 1989 Federal and Indian Coal Valuation Regulations continue to govern coal valuation produced from Federal and Indian leases.


2. Civil Penalties

On August 1, 2016, the 2016 Civil Penalty Rule was published. 81 FR 50306 (https://www.onrr.gov/Laws_R_D/FRNotices/AA05.htm). In the API case, supra, the 2016 Civil Penalty Rule withstood industry’s challenge, with the exception of the challenge to 30 CFR 1241.11(b)(5) related to the Department’s administrative law judges’ power to stay civil penalty accruals pending appeal. 366 F. Supp. 3d at 1311. API has appealed the District Judge’s decision on the remaining portions of the 2016 Civil Penalty Rule and that appeal is pending in the United States Court of Appeals for the Tenth Circuit. API v. U.S. Dep’t of the Interior, Case No. 18–8070 (10th Cir.).

B. Rulemaking Objectives

This rulemaking is not founded upon new factual findings contradicting those upon which the 2016 Valuation Rule was based. Instead, ONRR is implementing this rulemaking because policy directives issued after July 1, 2016, give different weight to the factual findings, and also dictate that a different policy-based outcome be pursued. A revised rulemaking based on “a reevaluation of which policy would be better in light of the facts” is “well within an agency’s discretion.” Nat’l Ass’n of Home Builders v. EPA, 682 F.3d 1032, 1038 (D.C. Cir. 2012) (citing FCC v. Fox Television Stations, Inc., 556 U.S. 502, 514–15 (2009)). Further, “[a] change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency’s reappraisal of the costs and benefits of its programs and regulations.” Id. at 1043 (quoting Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 59 (1983) (Rehnquist, J., concurring in part and dissenting in part)). An “agency is entitled to have second thoughts, and to sustain action which it considers in the public interest upon whatever basis more mature reflection suggests.” Dana Corp. v. ICC, 703 F.2d 1297, 1305 (D.C. Cir. 1983). An agency is entitled to give more weight to socioeconomic concerns than it may have under a different administration. Organized Vill. of Kake v. U.S. Dep’t of Agric., 795 F.3d 956, 968 (9th Cir. 2015) (en banc).

In determining that ONRR should reconsider its rule, it considered Executive Order 13783, “Implementing an America-First Offshore Energy Strategy;” and Secretarial Orders 3350 and 3360, which promote the America-First Offshore Energy Strategy and require a review of regulations that “potentially burden the development or utilization of domestically produced energy resources,” respectively. These Executive and Secretarial Orders directed review of various agency actions, without directing specific outcomes for rulemakings.


In Executive Order 13738, the President emphasized that “[i]t is in the national interest to promote clean and safe development of our Nation’s vast energy resources, while at the same time avoiding regulatory burdens that unnecessarily encumber energy production, constrain economic growth, and prevent job creation.” The President further directed executive departments and agencies to immediately review existing regulations that potentially burden the development or use of domestically produced energy resources and appropriately suspend, revise, or rescind those that unduly burden the development of domestic energy resources beyond the degree necessary to protect the public interest or otherwise comply with the law. Pursuant to Executive Order 13783, agency heads are required to review all existing regulations that potentially burden the development or use of domestically produced energy resources, “with particular attention to oil, natural gas, coal, and nuclear energy resources.” Executive Order 13783 further explained that “burden” means to unnecessarily obstruct, delay, curtail, or otherwise impose significant costs on the siting, permitting, production, utilization, transmission, or delivery of energy resources.

2. Executive Order 13795, Implementing an America-First Offshore Energy Strategy, April 28, 2017

Through Executive Order 13795, the President stated his policy goal of emphasizing “the energy needs of American families and businesses first” and to “continue implementing a plan that ensures energy security and economic vitality for decades to come.” The Executive Order 13795 stated that “[i]ncreased domestic energy production on Federal lands and waters strengthens the Nation’s security and reduces reliance on imported energy” as well as helping reinvigorate American manufacturing and job growth.
Accordingly, Executive Order 13795 stated that “[i]t shall be the policy of the United States to encourage energy exploration and production, including on the Outer Continental Shelf (OCS), in order to maintain the Nation’s position as a global energy leader and foster energy security and resilience for the benefit of the American people . . . .”

3. Secretarial Orders 3350 and 3360

Two Secretarial Orders are also relevant to this rulemaking. Through Secretarial Order 3350, America-First Offshore Energy Strategy, the Secretary of the Interior (Secretary) took specific steps to implement Executive Order 13795. Significant to the proposed rule, the Secretary specifically stated that Secretarial Order 3350 is designed to implement the President’s directives as set forth in Executive Order 13795 to “ensure that responsible OCS exploration and development is promoted and not unnecessarily delayed or inhibited.” The Order directed the Bureau of Ocean Energy Management and the Bureau of Safety and Environmental Enforcement to take specific actions, but also more generally expressed a desire for active coordination of energy policy in order to enhance opportunities for energy exploration, leasing, and development on the OCS. Secretarial Order 3360 is likewise directed at continuing to implement Executive Order 13793 and the directive to the Department to review existing regulations that “potentially burden the development or utilization of domestically produced energy resources.”

These Executive Orders and Secretarial Orders make clear that it is in the national interest to promote domestic energy development for a variety of reasons, including stimulating the economy, job creation, and national security. They also emphasize the importance of reducing regulatory burdens so that energy producers, and particularly oil, natural gas, and coal producers, can be encouraged to produce more energy. Through this rulemaking, ONRR will attempt to further those policy objectives by two primary means. The first, to provide mechanisms that simplify reporting. The second, to promote new and continued domestic energy production. In Section F below, ONRR requests specific comments on how effectively the proposed rule would implement the policy objectives stated above, and for additional ways in which ONRR could further implement those policy objectives.

ONRR’s royalty program is “a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.” Amoco Prod. Co. v. Watson, 410 F.3d 722, 729 (D.C. Cir. 2005) (internal quotations and citation omitted). FOGRMA grants the Secretary authority to “prescribe such rules and regulations as he deems reasonably necessary to carry out this chapter.” See 30 U.S.C. 1751(a); see also, e.g., 30 U.S.C. 1719. Re-evaluating the best means of balancing these statutory priorities within the bounds of the specific commands of the statute, as called for in the Executive and Secretarial Orders, is well within the scope of authority that Congress delegated to ONRR under FOGRMA.

C. ONRR’s Rulemaking Authority

Congress gave the Secretary authority to promulgate regulations concerning “a comprehensive inspection, collection and fiscal and production accounting and auditing system to provide the capability to accurately determine oil and gas royalties, interest, fines, penalties, fees, deposits, and other payments owed, and to collect and account for such amounts in a timely manner.” 30 U.S.C. 1751(a). The Secretary, in turn, assigned these duties to ONRR’s predecessor, a program within the Minerals Management Service. 47 FR 4751, February 2, 1982; Secretarial Order 3071, as amended on May 10, 1982; see also 30 CFR 201.100 (2006). Secretarial Order 3299, as amended on August 29, 2011, created ONRR and delegated to it the “royalty and revenue management function of the Minerals Management Service.”

ONRR has the authority to amend its rules, consistent in large part with the policy established in the Executive and Secretarial Orders, so long as ONRR: (1) Displays “awareness that it is changing position,” (2) shows that “the new policy is permissible under the statute,” (3) “believes” that the new policy is better than the old, and (4) provides “good reasons” for the new policy, which, if the “new policy rests upon factual findings that contradict those which underlay its prior policy,” must include “a reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy.” Fox, 556 U.S. at 515–16.

Importantly, ONRR is not limited to an analysis of whether facts or circumstances changed since the 2016 Valuation Rule. Instead, ONRR may look to other “good reasons” to adopt new policy—including the objectives of certain Executive and Secretarial Orders and weighing facts differently considering those objectives. ONRR does not need to base a revised decision upon a change of facts or circumstances. A revised rulemaking based “on a reevaluation of which policy would be better in light of the facts” is “well within an agency’s discretion,” and “[a] change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency’s reappraisal of the costs and benefits of its programs and regulations.” Nat’l Ass’n of Home Builders, 682 F.3d at 1036 and 1043 (citations omitted).

D. What This Proposed Rule Does

1. Index-Based Options for Valuing Federal Gas

The 2016 Valuation Rule adopted an index-based valuation option for non-arm’s-length sales (that is, sales under contracts that do not satisfy the “arm-length contract” definition under § 1206.20 or sales that do not occur under a contract) of unprocessed gas, natural gas liquids (“NGLs”), and residue gas. The 2016 Valuation Rule set royalty value at the highest monthly bidweek price (less a specified deduction) for unprocessed gas and residue gas, and the average monthly bidweek price (less a specified deduction) for NGLs, from a publicly-available publication at an accessible index-pricing point. Currently approved publications can be found at https://www.onrr.gov/Valuation/federal-gas-index-option.htm.

In the 2016 Valuation Rule, ONRR explained that the gross proceeds accruing under an arm’s-length transaction is generally the most accurate indicator of value. But given the complexity of non-arm’s-length dispositions, it was appropriate to provide the index-based valuation option to increase simplicity and reduce administrative burdens to ONRR and industry.

Complex valuation situations related to marketable condition, transportation, and processing are not limited to non-arm’s-length dispositions. So similar benefits—notably reductions to industry’s administrative burdens—could be gained by extending the index-based valuation option to arm’s-length dispositions. Further, because industry is in the process of altering its accounting and reporting processes to monitor and use index-based valuation for its non-arm’s-length dispositions, it stands to gain additional efficiencies from applying those same processes to arm’s-length dispositions.
ONRR maintains that arm’s-length dispositions are most often the strongest indicator of market value, and that market value is generally the most appropriate measure for royalty value. This proposed rule would attempt to further the 2016 Valuation Rule’s progress by closing the gap between royalty values determined using the gross proceeds accrued under arm’s-length dispositions and royalty values determined under index-based valuation.

In the 2016 Valuation Rule, ONRR designed the index-based valuation option to result in royalty values that are generally greater than those based on gross proceeds. The greater value protected ONRR’s ability to collect at least as much in royalties using index-based valuation as it would using a non-index method (that is, using gross proceeds). ONRR stated that any increase in royalty value would be offset by the reduced administrative burden that the index-based option’s simplicity and clarity afforded a lessee. Based on a review of data from production months in 2007 through 2010, ONRR determined that the estimated royalty value using an index-based valuation option would result in consistently higher royalties due than the average value received under gross-proceeds-based reporting.

When ONRR uses the term, “published average bidweek price,” or “bidweek average” for short, it refers to what many publications call the “index” or “average” price. For example, the Platts Inside FEHR’s Gas Market Report labels this price as the “index,” while the Natural Gas Intelligence’s (NGI) Bidweek Survey labels this price as the “average.”

ONRR proposes to amend 30 CFR part 1206 to specify that, when a lessee chooses to value unprocessed or residue gas for royalty purposes using the index-based option, the lessee may use the published bidweek average price rather than the bidweek high price. Doing so would more closely match what many lessees would otherwise receive as gross proceeds and would apply a consistent valuation approach to unprocessed gas, residue gas, and NGLs.

ONRR compared the royalties paid based on gross proceeds to the royalties paid using the 2016 Valuation Rule’s index-based valuation option—as well as to the method proposed in this rule. As outlined in the Procedural Matters section, overall royalty values under the 2016 Valuation Rule’s index-based valuation option are still around $0.04/ MMBtu, the prices reported to ONRR for arm’s-length sales. In the proposed rule, the average bidweek price would result in around $0.09 less per MMBtu. But, in certain areas, there could be greater increases (offshore Gulf of Mexico) or decreases (most onshore basins) in royalty value under the index-based valuation option. ONRR is interested in receiving comments on alternatives that more closely match the index-based valuation method to the gross proceeds accruing under arm’s-length dispositions across all Federal oil and gas leases.

Through the proposed rule, ONRR is attempting to address major concerns with the 2016 Valuation Rule’s index-based valuation option for Federal gas and implement certain Administration policies enacted following publication of the 2016 Valuation Rule to encourage domestic oil and gas production and reduce undue regulatory burdens on industry. The proposed rule would: (1) Extend the index-based valuation option to all Federal gas dispositions; (2) change the royalty value under the index-based option for unprocessed and residue gas from the highest bidweek indexed bidweek price; (3) update the index-based transportation deduction to rely on more recent cost data; (4) clarify, in the unprocessed and processed gas sections, that a lessee may not report a product’s value for royalty purposes as zero or less; and (5) add language reinforcing ONRR’s statutory authority to request and receive a lessee’s and its affiliate’s sales and expense records even in instances where the lessee pays royalties under an index-based valuation method.

2. Allowance Limits

For over two decades before the 2016 Valuation Rule, when a lessee submitted a certain form (form ONRR–4393), and documentation showing that it had met certain criteria, ONRR would evaluate the submissions and determine whether to allow that lessee to exceed the regulatory limits for transportation allowances or processing allowances (request-to-exceed, or, under a different process, to claim extraordinary processing costs (request-to-claim)). The 2016 Valuation Rule eliminated those practices by converting the regulatory limits into hard caps, abolishing the request-to-exceed and request-to-claim processes, and terminating all approvals ONRR previously granted.

ONRR has re-evaluated these provisions in light of the Administration’s policy emphasis on domestic energy production and reduction of regulatory burdens and believes it is appropriate to reconsider the approach to dealing with the burdens the 2016 Valuation Rule imposed. The 2016 Valuation Rule’s allowance hard caps increased energy production costs (through increased royalty values) in situations where a lessee previously had a long-standing ability to deduct certain costs under the 1988 valuation rule after justifying its request for an allowance. Providing a lessee with a method to request and receive approval to exceed the regulatory limits removes a disincentive for the limited number of lessees that produce from Federal lands that are less desirable due to the high costs associated with transportation, processing, or both. In particular, reintroducing the request-to-exceed and request-to-claim processes could remove a hard cap’s disincentive to produce in remote areas (high movement costs) or from low quality reservoirs (high treatment costs, processing costs, or both). It could also provide a lessee an incentive to continue producing through uncommon or unavoidable circumstances affecting costs and value.

ONRR proposes to remove the undue burden on energy production that the 2016 Valuation Rule’s hard caps created when the rule eliminated the approval burden for ONRR. The proposed rule would revert to the historical practices with respect to regulatory limits on transportation costs (50 percent for Federal oil and Federal gas) and processing costs (66 2/3 percent for Federal gas), and allow a lessee to request extraordinary processing-cost allowance approvals. As before the 2016 Valuation Rule, ONRR would only approve a lessee’s request after reviewing a lessee’s documentation for adequacy, reasonableness, and accuracy.

3. Transportation Allowance for Certain Offshore Gathering Costs

After the publication of 2016 Valuation Rule, the Administration adopted policies through certain Executive and Secretarial Orders to encourage Federal oil and gas production. In response, ONRR is reexamining its historical practice (1999 through 2016) with respect to allowing a transportation deduction for certain costs that the regulations define to be gathering costs. Specifically, ONRR proposes to reinstate the May 20, 1999, memorandum titled “Guidance for Determining Transportation Allowances for Production from Leases in Water Depths Greater Than 200 Meters.”

In 1988, the Minerals Management Service (MMS) defined “gathering” in regulations for the first time (and it has remained substantively unchanged since): “Gathering means the movement of lease production to a central accumulation and/or treatment point on the lease, unit or
communitized area, or to a central accumulation or treatment point off the lease, unit or communitized area as approved by BLM or MMS OCS operations personnel for onshore and OCS leases, respectively.” See 53 FR 1273, January 15, 1988.

In effect, those regulations authorized a lessee to deduct certain costs incurred for transportation off the lease—other than gathering—as a transportation allowance. In the final rule, MMS rejected an industry-group’s comment to remove the “excluding gathering” language because “MMS [believed] that gathering is a cost of making oil marketable, which must be borne exclusively by the lessee.” 53 FR 1184 at 1190–1191, January 15, 1988.

MMS also considered numerous comments from industry concerning the phrase “or to a central accumulation or treatment point off the lease, unit or communitized area as approved by BLM or MMS OCS operations personnel for onshore and OCS leases, respectively.” The commenters stated that the phrase was unclear and that it should be removed from the definition. Several industry commenters recommended that gathering be limited to the lease or unit area so a transportation allowance could be obtained for all off lease movement. But MMS kept the proposed rule’s definition intact.

The operational regulations of both BLM and MMS required that a lessee place all production in a marketable condition, if economically feasible, and that a lessee also properly measure all production in a manner acceptable to those agencies’ authorized officials. Unless specifically approved otherwise, the regulations’ requirements were to be met prior to the production leaving the lease. Thus, MMS did not believe that any allowances should be granted for costs incurred by a lessee when approval was granted for the removal of production from the lease, unit, or communitized area when the purpose was to treat production or accumulate production for delivery to a purchaser prior to meeting the requirements of any operational regulations. 53 FR 1184 at 1193, January 15, 1988.

MMS published the 1988 rule prohibiting the deduction of all gathering costs with knowledge of the costs of deepwater gathering. While the 1987 draft final rule that preceded the 1988 rule contemplated allowing deductions for deepwater gathering costs, the 1988 rule rejected any deduction for deepwater gathering costs. The 1987 draft final rule provided that if a lessee incurred extraordinary costs for gathering from frontier or deepwater areas, and those costs related to unusual or unconventional operations, it may apply to MMS for an allowance. Such an allowance would only be granted if the costs were associated with offshore leases located in water depths in excess of 400 meters. 52 FR 30826 at 30858, August 17, 1987.

But in the preamble to the 1988 rule MMS concluded that it would not allow a deduction of any gathering costs, including deepwater gathering. MMS concluded that the burdens placed on the lessee by the environment in which it operates were matters considered at the time the lease was issued, and reflected in the amount of bonus bids and, in some cases, the royalty rate. MMS determined that if a lessee was entitled to further economic relief, it would be inappropriate to provide that relief through an adjustment to the value of the production using methods that were inconsistent with historical practice and interpretation of a lessee’s express obligation to place production in marketable condition at no cost to the Federal lessor. 53 FR 1184 at 1205 (January 15, 1988).

In sum, ONRR and its predecessor, MMS, by regulation prohibited the deduction of all gathering, even for deepwater, with gathering defined to include all movement upstream of any “central accumulation point and/or treatment point.” Preamble language clarified upstream of a “central accumulation point and/or treatment point” to mean upstream of the point at which oil and gas is in marketable condition and metered for royalty purposes.

In 1998, MMS published two Federal Register Notices (63 FR at 38355 and 63 FR 56217) requesting input on whether MMS should change the “gathering” definition to allow a lessee to deduct costs associated with moving bulk production from subsea wellheads to offshore floating platforms. MMS requested further comments on what criteria to use when differentiating between the movement that is gathering and the movement that is transportation.

MMS chose not to amend its regulations after receiving comments on those Federal Register notices. Instead, the Associate Director for MMS’s Royalty Management Program implemented policy on deepwater gathering through a May 20, 1999, memorandum titled “Guidance for Determining Transportation Allowances for Production from Leases in Water Depths Greater Than 200 Meters” (Deepwater Policy).

The Deepwater Policy provided that production from a lease, any part of which lies in water deeper than 200 meters, may qualify for a transportation allowance. The following guidelines also applied:

- The transportation allowance was to be determined in accordance with then-current regulations.
- The costs of movement was allocated between the royalty bearing and non-royalty bearing substances.
- Movement prior to a central accumulation point was considered gathering. A central accumulation point may be a single well, a subsea manifold, the last well in a group of wells connected in series, or a platform extending above the surface of the water. Movement beyond the point was considered transportation.
- Leases and units were treated similarly.
- To qualify for a transportation allowance, the movement had to be to a facility not located on a lease adjacent to the lease on which the production originated. An adjacent lease was defined as any lease within at least one point of contact with the producing lease/unit. Typically, for a single lease, there would be eight leases adjacent to a qualifying deep-water lease.
- Allowances for subsea completions not located in water deeper than 200 meters could be considered on a case-by-case basis.

In the proposed 2016 Valuation Rule (80 FR 608), ONRR proposed to rescind the Deepwater Policy because, “Under Kerr-McGee Corp., 147 IBLA 277, 282 (Jan. 29, 1999) almost all of the movement the [Deepwater] Policy allows as a transportation allowance is, in actuality, non-deductible ‘gathering’ under ONRR’s current valuation regulations. We determined that the Deep-Water Policy is inconsistent with our regulatory definition of “gathering” and Departmental decisions interpreting that term.” Id. at 624.

In the 2016 Valuation Rule’s preamble, ONRR included language that rescinded the Deepwater Policy, explaining that MMS intended for the Deepwater Policy to incentivize deepwater leasing by allowing lessees to deduct broader transportation costs than the regulations allowed. ONRR then concluded that the Deepwater Policy had served its purpose and was no longer necessary.

In the 2017 Repeal Rule, ONRR stated that by reinstating the prior regulations, ONRR’s longstanding Deepwater Policy would remain in effect, and that ONRR would continue to implement the Deepwater Policy to the extent that it is consistent with the prior regulations. ONRR also asserted that Deepwater Policy is a matter that is appropriate to revisit and reconsider.
would state that: ‘‘For oil produced on
Federal oil regulations under § 1206.110
than 200 meters. For example, the
water shall be treated as transportation.’’ ONRR proposes to
movement of [production] from the
§§ 1206.110(a)(2)(ii) and
transportation allowance sections under
Valuation Rule added in the
Deepwater Policy and permitted a lessee to
1206.152(a)(2)(ii) that provides ‘‘[f]or
production from the OCS, the
Deepwater Policy allowed, in the form
the wellhead—where separation,
production, and the Secretarial Orders
where the wellhead is located on a
wellhead to the first platform is
complex—than a topside completion,
transportation allowance for certain
before production reaches the platform.

The proposed rule would effectively
the best indicator of value). While the
regulated scheme (which include, for
misconduct may be eliminated in
‘‘misconduct’’ since the definition of
Industry stakeholders have argued that
the ‘‘misconduct’’ definition in the
30 CFR 1207.5, 1206.104(g)(1),
ONRR did not address how we might
ONRR would evaluate a
purpose of the default provision was to
transportation for which a
transportation allowance may be
On a case-by-case basis, you may apply to ONRR to have your
actual, reasonable and necessary costs of
movement of oil produced on the
USCS in waters shallower than 200
meters from the wellhead to the first
platform to be treated as transportation
for which a transportation allowance
may be claimed.’’ and ‘‘On a case-by-case basis,
you may apply to ONRR to have your
actual, reasonable and necessary costs of
movement of oil produced on the
USCS in waters shallower than 200
meters from the wellhead to the first
platform to be treated as transportation
for which a transportation allowance
may be claimed.’’

4. Misconduct, the Default Provision, and Contract Signature Requirement
ONRR proposes to amend certain
sections under 30 CFR part 1206 to
effectively return the requirements for
the following topics, for Federal oil
industry and Indian Coal, to the
practices in place prior to the 2016
Valuation Rule. The proposed rule
would delete: (1) The definition of
‘‘misconduct’’ from § 1206.20; (2) the
default provision from §§ 1206.105,
1206.144, 1206.254, and 1206.454, as
well as references in other sections; and
(3) the requirement that all contracts be
signed by all parties to the contract from
30 CFR 1207.5, 1206.104(g)(1),
1206.143(g)(3), 1206.253(g)(1), and
1206.453(g)(1).

In the 2015 Proposed Valuation Rule
and 2016 Valuation Rule, ONRR
distinguished between the
‘‘misconduct’’ definition in the civil
penalty regulations and the
‘‘misconduct’’ definition in the
valuation regulations at § 1206.20.
Industry stakeholders have argued that the
‘‘misconduct’’ definition in the valuation
regulations is too broad and could be
misapplied.

Under § 1210.30, ONRR requires
lessees to ‘‘submit accurate, complete,
and timely information,’’ which means
lessees are required to correct
simple reporting errors when the lessee or
ONRR discovers them—regardless of
whether the errors constitute
misconduct. ONRR therefore agrees that
the new definition of misconduct is
unduly burdensome and duplicative. As
noted below, ONRR is requesting
comments on further revisions to its
rules to replace the usage of the term
‘‘misconduct’’ since the definition of
misconduct may be eliminated in
§ 1206.20.

Like the ‘‘misconduct’’ definition, industry believes that ONRR could
misapply the default provision in ways
that undermine the other pillars of our
regulatory scheme (which include, for
example, basing allowances on
reasonable actual costs, identifying
where royalties are calculated, and
looking to arm’s-length transactions as
the best indicator of value). While the

ONRR did not address how we might
fulfill that statutory mandate without
the signature requirement in the 2017
Repeal Rule because ONRR has fulfilled
that mandate for decades without an
additional requirement. If finalized as
proposed, ONRR would evaluate a
party’s course of performance under all
contracts—signed and unsigned—consistent with its historical practice.

ONRR proposes to eliminate the requirement that a lessee create, maintain, and provide contracts signed by all parties, but would keep the requirement that has existed since 1988 that contracts be in written form. The requirement that lessees place contracts in writing is found under 30 CFR § 1207.5, 1206.104(g)(1), 1206.143(g)(3), 1206.253(g)(1), and 1206.453(g)(1).

Here, ONRR, in an effort to relieve certain regulatory burdens the 2016 Valuation Rule places on industry, is reevaluating the requirement for a lessee to maintain signed contracts. Without a requirement to maintain signed contracts, ONRR possesses broad authority to investigate and question the validity of any contract. For example, ONRR may choose to exercise that authority in situations where ONRR suspects that an arm’s-length or non-arm’s-length contract: (1) Fails to reflect actual performance, (2) shows a breach of the lessee’s duty to market for the benefit of the lessor, or (3) shows lessee misconduct. Thus, ONRR estimates little, if any, impact on our methods for determining compliance. Moreover, ONRR recognizes that contracts may be valid and enforceable, as a matter of law, despite the absence of one or more signatures.

5. Citation to Legal Precedent With Valuation Determination Requests

ONRR proposes to eliminate the requirements under 30 CFR §§ 1206.108(a)(5), 1206.148(a)(5), 1206.258(a)(5) and 1206.458(a)(5) for a lessee to include citations to legal precedents when requesting a valuation determination.

ONRR encourages a lessee to provide, along with the lessee’s valuation request, any citations to precedent that it believes are persuasive. At the same time, ONRR is familiar with, and commonly a party to, matters that generate precedent for Federal oil and gas, Federal coal, and Indian coal royalty valuation. So, although citations might expedite the processing time for an industry request, it is not necessary to require industry to provide citations to precedent. Further, ONRR believes that it would be unproductive to attempt to enforce or litigate such a requirement, especially because a failure to include a citation to precedent may not, on its own, provide a sufficient reason to deny an otherwise valid request for a valuation determination. Finally, ONRR is reevaluating whether it inadvertently created an undue burden on industry by requiring lessees to provide legal precedents with valuation determination requests because that requirement might require a lessee to retain legal counsel instead of allowing a lessee’s non-legal staff to more expeditiously communicate with ONRR regarding a valuation determination request.

6. Coal Valued as Electricity

ONRR proposes to amend 30 CFR part 1206 to remove the “coal cooperative” definition under § 1206.20 and all other references thereto. ONRR is attempting to relieve concerns with the definition’s applicability and meaning. While the Court, in Cloud Peak, did not find the coal cooperative definition to be arbitrary and capricious, the Court offered strong criticism of the definition. Accordingly, this amendment would harmonize the ONRR’s rules with the Court’s statements in Cloud Peak, supra.

8. Civil Penalties for Payment Violations

ONRR proposes to amend § 1241.70 to clarify that—for payment violations only—ONRR would consider the monetary impact of the entity’s conduct when assessing a civil penalty. Section 1241.70(b) arguably created an ambiguity as to whether ONRR considers the unpaid, underpaid, or late-paid amounts when assessing a penalty for a payment violation under § 1241.50. Clarifying this ONRR civil penalty practice would support Executive Order 13892—Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication.

9. Aggravating and Mitigating Circumstances

ONRR proposes to amend § 1241.70 to clarify that ONRR may consider aggravating and mitigating circumstances to determine an appropriate penalty. ONRR considers aggravating and mitigating circumstances on a case-by-case basis to increase or decrease the penalty amount in a Failure to Correct Civil Penalty Notice (FCCP) or Immediate Liability Civil Penalty Notice (ILCP). Potential aggravating circumstances may include, but are not limited to, when the violation may also be a criminal act, when the violation occurs because a violator calculated the cost of compliance is more than the cost of a penalty, or when a violator has no history of noncompliance for the violation at hand but has an extensive history of noncompliance for other violation types. Mitigating circumstances are generally conditions where a lessee has limited control including, but not limited to, operational impacts resulting from the unexpected illness or death of an employee, natural disasters, pandemics, acts of terrorism, civil unrest, or armed conflict or delays caused by government action or inaction, including as a result of a government shutdown or ONRR-system downtime. Consistent with the general approach of Executive Order 13924 “Regulatory Relief to Support Economic Recovery” and Executive Order 13892 “Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication,” the failure of a lessee to conform to formal or informal agency guidance does not, in itself, establish a violation, while good faith efforts to comply with formal or informal agency guidance constitute mitigating circumstances and may serve as a rationale to decline issuing enforcement penalties entirely.
When ONRR adopted the 2016 Civil Penalty Rule, § 1241.11(b)(5) was added. When API challenged the 2016 Civil Penalty Rule, the challenge was rejected except as to § 1241.11(b)(5). API, 366 F. Supp. 3d at 1310. Because § 1241.11(b)(5) was invalidated through a judicial proceeding and ONRR is not pursuing a review of this portion of the Court’s ruling in API’s ongoing appeal, ONRR proposes to remove the paragraph from the 2016 Civil Penalty Rule.

E. Economic Analysis

ONRR summarized the estimated changes to royalties and regulatory costs the proposed rule may have on potentially affected groups, including industry, the Federal Government, and State and local governments. A number of the proposed Federal oil and gas amendments would result in decreased royalty collections.

ONRR notes that changes to royalties are transfers that are distinguishable from regulatory costs (or cost savings). The estimated changes in royalties assessed will change both the private cost to the lessee and the amount of revenue collected by the Federal government and disbursed to State and local governments. The net impact of the proposed amendments is an estimated $42.1 million annual decrease in royalty collections. This represents a decrease of less than one-half of one percent of the total Federal oil and gas royalties ONRR collected in 2018. However, the financial impact, as evident in the total annual estimate reflected above, does impact the royalty disbursements for the Treasury and States who are stakeholders and recipients of ONRR’s distributions.

Increased domestic energy production protects the United States from supply disruptions abroad and may also lead to an overall increase in royalty collections. Further, an industry more focused on domestic capital expenditures may create jobs and increase cash circulation in the United States’ economy. As such, ONRR recognizes that the United States benefits from domestic energy production beyond the production’s royalty value. In the instances where this rule proposes to alter royalties, ONRR is particularly interested in public comments on whether, and to what extent, the proposed amendments would impact domestic energy exploration and energy production, create economic opportunity, or otherwise provide justification to alter—or not—those transfer payments between the United States and its lessees.

ONRR also estimates that the Federal oil and gas industry would experience increased annual administrative costs of $2.58 million if ONRR adopts the entirety of this rule as proposed. As discussed below, this is the net impact of various cost increasing and cost saving proposals.

ONRR estimates that the proposed rule would have no economic impact on Federal and Indian coal. Please note that, unless otherwise indicated, numbers in the tables in this section are rounded to the nearest thousand, and that the totals may not match due to rounding.

1. Federal Oil and Gas

This table shows the change in royalties by rule provision for the first year and each year thereafter:

<table>
<thead>
<tr>
<th>Rule provision</th>
<th>Net change in royalties paid by lessees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index-Based Valuation Option Extended to Gas Dispositions</td>
<td>$5,620,000</td>
</tr>
<tr>
<td>Index-Based Valuation Option Extended to NGL Dispositions</td>
<td>21,141,000</td>
</tr>
<tr>
<td>High to Midpoint Index Price for Non-Arm’s-Length Gas Dispositions</td>
<td>(4,488,000)</td>
</tr>
<tr>
<td>Transportation Deduction Non-Arm’s-Length Index-Based Valuation Option</td>
<td>(7,121,000)</td>
</tr>
<tr>
<td>Gas Transportation Allowances</td>
<td>(279,000)</td>
</tr>
<tr>
<td>Oil Transportation Allowances</td>
<td>(11,000)</td>
</tr>
<tr>
<td>Gas Processing Allowances</td>
<td>(9,942,000)</td>
</tr>
<tr>
<td>Extraordinary Processing Allowances</td>
<td>(11,131,000)</td>
</tr>
<tr>
<td>Deepwater Policy</td>
<td>21,141,000</td>
</tr>
<tr>
<td>Total</td>
<td>(42,111,000)</td>
</tr>
</tbody>
</table>

ONRR also estimates industry will incur a one-time administrative cost savings of $4.5 million from the simplification of reporting process and transportation allowances associated with the optional use of the index-based valuation method. These costs are only calculated one time and then used to break out allowed from disallowed costs in reported transportation and processing allowances.

<table>
<thead>
<tr>
<th>Rule provision</th>
<th>Cost (cost savings)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative Benefit for Index-Based Valuation Option for Gas &amp; NGLs</td>
<td>($1,356,000)</td>
</tr>
<tr>
<td>Administrative Cost for Deepwater Policy</td>
<td>3,936,000</td>
</tr>
<tr>
<td>Total</td>
<td>2,580,000</td>
</tr>
</tbody>
</table>

ONRR also estimates industry will incur a one-time administrative cost savings of $4.5 million from the simplification of reporting process and transportation allowances associated with the optional use of the index-based valuation method. These costs are only calculated one time and then used to break out allowed from disallowed costs in reported transportation and processing allowances.
To perform this economic analysis, ONRR reviewed royalty data for Federal oil, condensate, residue gas, unprocessed gas, fuel gas, gas lost—flared or vented, carbon dioxide, sulfur, coalbed methane, and natural gas products (product codes 03, 04, 15, 16, 17, 19, 39, 07, 01, 02, 61, 62, 63, 64, and 65) from the last five calendar years, 2014–2018. ONRR believes that the vast majority of that reporting was made in compliance with the rules in place prior to the 2016 Valuation Rule. ONRR used five calendar years of royalty data because this longer time period helps smooth data to reduce volatility caused by fluctuations in commodity pricing and volume swings. ONRR used these data without adjusting for previous rulemakings because at the time of this analysis, a significant number of lessees and operators had not yet complied with the 2016 Valuation Rule’s provisions due to its implementation delays, including the 2017 Repeal Rule, the subsequent 2019 Vacatur, and ONRR’s two dear reporter letters providing industry with additional time to come into compliance with the 2016 Valuation following its reinstatement. ONRR adjusted the historical data in this analysis to 2018 dollars using the Consumer Price Index (all items in U.S. city average, all urban consumers) published by the Bureau of Labor Statistics (BLS). Based on ONRR’s auditing experience, some companies aggregate their volumes (reported in thousand cubic feet (Mcf) and in a metric of energy content—one million British thermal units (MMBtu) for natural gas) in pools, and then sell the natural gas under multiple contracts. Lessees report those sales and dispositions using the “POOL” sales type code. Only a small portion of gas sales were non-arm’s-length. Thus, ONRR used estimates of 10 percent of the POOL volumes in the economic analysis of non-arm’s-length dispositions and 90 percent of the POOL volumes in the economic analysis of arm’s-length dispositions. ONRR requests comments specific to how it could more accurately estimate the allocation between arm’s-length and non-arm’s-length sales.

Change in Royalty 1: Using Index-Based Valuation Option to Value Federal Unprocessed Gas, Residue Gas, Fuel Gas, and Coalbed Methane

To estimate the royalty impact of the option to pay royalties using index-based valuation, ONRR reviewed the reported royalty data for all gas sales except for non-arm’s-length (discussed below), future valuation agreements, and percentage of proceeds sales. ONRR also adjusted the POOL sales down to 90 percent (as described above), which were spread across 10 major geographic areas with active index prices. The 10 areas account for over 95 percent of all Federal gas produced. ONRR assumes the remaining five percent of Federal gas lessees will not likely elect the index-based method as areas outside of major producing basins may have infrastructure limitations or limited access to index pricing. The 10 geographic areas are:

- Offshore Gulf of Mexico
- Big Horn Basin
- Green River Basin
- Permian Basin
- Piceance Basin
- Powder River Basin
- San Juan Basin
- Uinta Basin
- Williston Basin
- Wind River Basin

To calculate the estimated impact, ONRR:

1. Identified the monthly bidweek price index, published by Platts Inside FERC, applicable to each area—Northwest Pipeline Rockies for Green River, Piceance and Uinta basins; El Paso San Juan for San Juan basin; Colorado Interstate Gas for Big Horn, Powder River, Williston, and Wind River basins; El Paso Permian for Permian basin; and Henry Hub for the Gulf of Mexico. ONRR determined price index application based on proximity to the producing area and the frequency by which ONRR’s audit and compliance staff verify these index prices in sales contracts. ONRR is aware that all sales in an area are based off these indices and requests further comment to improve this analysis.

2. Subtracted the transportation deduction as modified by the proposed rule (detailed in the transportation section below) from the midpoint index price identified in step (1).

3. Multiplied the royalty volume by the index price identified per region, less the transportation deduction calculated in step (2).

4. Totaled the reported royalties less allowances reported on the monthly royalty report (form ONRR–2014) and the estimated royalties based on the index-based valuation option calculated in step (3).

5. Calculated the annual average of reported royalties and estimated index-based royalties calculated in step (4) by dividing by five (number of years in the analysis).

6. Subtracted the difference between the totals calculated in step (5).

ONRR anticipates that some lessees will choose to report to ONRR using this simpler method, saving administrative costs (described in detail below in Cost Savings 1 and Cost Savings 2), while other lessees will continue to calculate and deduct the actual costs they incur. ONRR cannot accurately estimate how many lessees will elect to use the index valuation method since many factors that are currently unquantifiable will drive a lessee’s decision. For the purposes of this analysis, ONRR assumed that half of lessees would choose the alternative index-based valuation method to value dispositions eligible for the election. ONRR invites public comment on this assumption, and on other methods ONRR could use to more accurately estimate the economic impact of this election. ONRR’s assumption of a 50 percent reduction is an attempt to simplify the myriad factors such as, simpler accounting methods for industry, company-specific break-even analysis, and simplified allowance unbundling administrative calculations. ONRR also broke out the Gulf of Mexico from the other onshore basins listed above because it accounts for approximately 30 percent of the total Federal gas sales used in this analysis, as well as having different complexities related to offshore gas production, when compared to onshore areas.

ONRR estimates that this change will increase annual royalty payments by approximately $5.3 million. This estimate represents an average increase of approximately one percent, or $0.04 per MMBtu, based on an annualized royalty volume of 296,440,024 MMBtu. ONRR chose not to include POP sales in the above methodology because the sales are reported inclusive of the NGL value and net of transportation and

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**ONE-TIME ADMINISTRATIVE IMPACTS TO INDUSTRY**

<table>
<thead>
<tr>
<th>Rule provision</th>
<th>Cost savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative Cost-savings in lieu of Unbundling related to Index-Based Valuation Option for Gas &amp; NGLs</td>
<td>$4,520,000</td>
</tr>
</tbody>
</table>
processing costs. To try to account for the change in value associated with POP contracts, ONRR applied the $0.04 per MMBtu calculated above to the royalty volume for APOP sales of 158,772,452 MMBtu. The total estimated annual average impact is a $5.6 million increase in royalties. ONRR recognizes that it is not accounting for the value of APOP NGLs, however ONRR does not have a reasonable method to break out those components from the available data and would welcome comment on this matter.

### ANNUAL NET CHANGE IN ROYALTIES PAID USING INDEX OPTION FOR GAS DISPOSITIONS

<table>
<thead>
<tr>
<th>Region</th>
<th>Gulf of Mexico</th>
<th>Onshore basins</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annualized Reported Royalties</td>
<td>$235,065,000</td>
<td>$541,124,000</td>
<td>$776,189,000</td>
</tr>
<tr>
<td>Royalties Estimated using Index-Based Valuation Option</td>
<td>$250,183,000</td>
<td>$564,360,000</td>
<td>$814,523,000</td>
</tr>
<tr>
<td>Difference</td>
<td>$15,118,000</td>
<td>$(4,560,000)</td>
<td>10,558,000</td>
</tr>
<tr>
<td>Change per MMBtu</td>
<td>0.18</td>
<td>(0.02)</td>
<td>0.04</td>
</tr>
<tr>
<td>% Change</td>
<td>6</td>
<td>(1)</td>
<td>1</td>
</tr>
<tr>
<td>Annualized POP Royalties using Index-Based Valuation Option</td>
<td></td>
<td></td>
<td>(681,768)</td>
</tr>
<tr>
<td>50% of lessees choose this option</td>
<td></td>
<td></td>
<td>5,620,000</td>
</tr>
</tbody>
</table>

Change in Royalties 2: Using the Index-Based Valuation Option To Value Sales of Federal NGLs

Similar to the changes to Federal unprocessed gas, residue gas, pipeline fuel, and coaled methane, a lessee will have the option to pay royalties on Federal NGLs using an index-based value less a theoretical processing allowance and be allowed an adjustment for transportation costs and fractionation costs, which account for the prices realized at the various NGL hubs. ONRR used the same 2014–2018 calendar years for all NGL sales except for non-arm’s-length and future

### Platts Conway Basket

- Ethane-propane (EP mix) 40% .......................................................... Ethane 42%
- Propane 28% .................................................................................... Non-TET Propane 28%
- Isobutane 10% .................................................................................. Non-TET Isobutane 6%
- Normal Butane 7% ............................................................................ Normal Butane 11%
- Natural Gasoline 15% ...................................................................... Natural Gasoline 13%

### OPIS Mont Belvieu Basket

(3) Subtracted the current theoretical allowance for processing deductions, as well as fractionation costs and transportation costs referenced in the current regulations and published online at https://www.onrr.gov, as shown in the table below from the NGL basket price calculated in step (2):

### NGL DEDUCTION

[$/gal]

<table>
<thead>
<tr>
<th>Region</th>
<th>Gulf of Mexico</th>
<th>New Mexico</th>
<th>Other areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processing</td>
<td>$0.10</td>
<td>$0.15</td>
<td>$0.15</td>
</tr>
<tr>
<td>Transportation and Fractionation</td>
<td>0.05</td>
<td>0.07</td>
<td>0.12</td>
</tr>
<tr>
<td>Total (/gal)</td>
<td>0.15</td>
<td>0.22</td>
<td>0.27</td>
</tr>
</tbody>
</table>

(4) Multiplied the royalty volume by the index price identified for each region, less the NGL deduction calculated in step (3).

(5) Totaled the royalty value less allowances reported on the monthly royalty report, and the estimated royalties based off the index-based valuation option calculated in step (4).

(6) Calculated the annual average of reported royalties and estimated index-based royalties calculated in step (5) by dividing by five (number of years in this analysis).

(7) Subtracted the difference between the totals calculated in step (6). Because ONRR assumed that 50 percent of lessees would choose this option for eligible dispositions, ONRR reduced the total estimate by 50 percent in the following table, and ONRR invites public comments on this assumption and any other method available to more accurately quantify the economic impact of this election. ONRR estimates that this change will increase annual royalty payments by approximately
$21.1 million. This estimate represents an average increase of approximately 17 percent or $0.0894 per gallon, based on an annualized royalty volume of 475,257,250 gallons.

### ANNUAL NET CHANGE IN ROYALTIES PAID USING INDEX OPTION FOR NGL SALES

<table>
<thead>
<tr>
<th></th>
<th>Gulf of Mexico</th>
<th>New Mexico</th>
<th>Other areas</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annualized Reported Royalties</td>
<td>$74,438,000</td>
<td>$67,637,000</td>
<td>$70,072,000</td>
<td>$212,147,000</td>
</tr>
<tr>
<td>Royalties Estimated using Index-Based Valuation Option</td>
<td>77,068,000</td>
<td>66,397,000</td>
<td>110,962,000</td>
<td>254,428,000</td>
</tr>
<tr>
<td>Difference</td>
<td>2,630,000</td>
<td>(1,240,000)</td>
<td>40,891,000</td>
<td>42,281,000</td>
</tr>
<tr>
<td>Change per gallon</td>
<td>0.0174</td>
<td>(0.0081)</td>
<td>0.2439</td>
<td>0.0894</td>
</tr>
<tr>
<td>% Change</td>
<td>3</td>
<td>(2)</td>
<td>37</td>
<td>17</td>
</tr>
<tr>
<td>50% of lessees choose this option</td>
<td></td>
<td></td>
<td></td>
<td>$21,141,000</td>
</tr>
</tbody>
</table>

### Change in Royalties 3: Using the Published Index Price Versus the Highest Published Index Price to Value Non-Arm’s-Length Federal Unprocessed Gas, Residue Gas, Coalbed Methane, and NGLs

As noted above, index-based valuation will change from using the highest published price for a specific index-pricing point to using the average published bidweek price for the index-pricing point. To estimate the royalty impact of this change to the index-based valuation option, ONRR used reported royalty data using non-arm’s-length (“NARM”) sales and 10 percent of the reported sales type codes based on the assumption above in the same 10 major geographic areas with active index-pricing points, also listed above.

To calculate the estimated impact, ONRR:

1. Identified the Platts Inside FERC published monthly midpoint and high prices for the index applicable to each area—Northwest Pipeline Rockies for Green River, Piceance and Uinta basins; El Paso San Juan for San Juan basin; Colorado Interstate Gas for Big Horn, Powder River, Williston, and Wind River basins; El Paso Permian for Permian basin; and Henry Hub for the Gulf of Mexico.
2. Multiplied the royalty volume by the published index prices identified for each region.
3. Totaled the estimated royalties using the published index prices calculated in step (2).
4. Calculated the annual average index-based royalties for both the high and volume-weighted-average prices calculated in step (3) by dividing by five (number of years in this analysis).
5. Subtracted the difference between the totals calculated in step (4).

Because ONRR assumes that 50 percent of lessees would choose this option, ONRR reduced the total estimate by 50 percent in the following table, but ONRR invites public comment on this assumption and any other method available to more accurately quantify the economic impact. ONRR estimates that the result of this change is a decrease in annual royalty payments of approximately $4.5 million. This estimate represents an average decrease of three percent or nine cents ($0.09) per MMBtu, based on an annualized royalty volume of 93,301,478 MMBtu (for NARM and 10 percent POOL reported sales type codes).

### ANNUAL CHANGE IN ROYALTIES PAID DUE TO HIGH TO MIDPOINT MODIFICATION FOR NON-ARM’S-LENGTH SALES OF NATURAL GAS

<table>
<thead>
<tr>
<th></th>
<th>Gulf of Mexico</th>
<th>Onshore basins</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Royalties Estimated Using High Index Price</td>
<td>$107,736,000</td>
<td>$198,170,000</td>
<td>$305,907,000</td>
</tr>
<tr>
<td>Royalties Estimated Using Published Average Bidweek Price</td>
<td>107,448,000</td>
<td>189,483,000</td>
<td>296,931,000</td>
</tr>
<tr>
<td>Difference</td>
<td>(288,000)</td>
<td>(8,687,000)</td>
<td>(8,975,000)</td>
</tr>
<tr>
<td>Change per MMBtu</td>
<td>(0.01)</td>
<td>(0.14)</td>
<td>(0.10)</td>
</tr>
<tr>
<td>% Change</td>
<td>0</td>
<td>(5)</td>
<td>(3)</td>
</tr>
<tr>
<td>50% of lessees choose this option</td>
<td></td>
<td></td>
<td>(4,488,000)</td>
</tr>
</tbody>
</table>

NARM and 10% of POOL Sales Type Codes.

### Change in Royalties 4: Modifying the Index-Based Valuation Option Transportation Deduction Used to Value Non-Arm’s-Length Federal Unprocessed Gas, Residue Gas, Coalbed Methane, and NGLs

ONRR chose to update the transportation deductions applicable to non-arm’s-length index-based valuation to reflect changes in industry transportation contracts terms and more recent allowance data reported to ONRR. To estimate the royalty impact of the modification to the transportation deduction, ONRR used reported royalty data using NARM and 10 percent of the POOL sales type codes from the same 10 major geographic areas with active index-pricing points listed above.

To calculate the estimated impact, ONRR:

1. Identified appropriate areas using Platts Inside FERC index prices (see list above).
2. Calculated the transportation deduction as published in the current regulations and the deduction outlined in the table below for each area identified in step (1).
TRANSPORTATION DEDUCTION OF INDEX-BASED VALUATION OPTION FOR GAS ($/MMBTU)

<table>
<thead>
<tr>
<th>Element</th>
<th>Current regulations</th>
<th>2019 proposed rule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gulf of Mexico %</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Gulf of Mexico Low Limit</td>
<td>$0.10</td>
<td>$0.10</td>
</tr>
<tr>
<td>Gulf of Mexico High Limit</td>
<td>0.40</td>
<td>0.40</td>
</tr>
<tr>
<td>Other Areas %</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Other Areas Low Limit</td>
<td>0.10</td>
<td>0.10</td>
</tr>
<tr>
<td>Other Areas High Limit</td>
<td>0.50</td>
<td>0.50</td>
</tr>
</tbody>
</table>

(3) Multiplied the royalty volume by the applicable transportation deduction identified for each area calculated in step (2).

(4) Totalled the estimated royalty impact based off both transportation deductions calculated in step (3).

(5) Calculated the annual average royalty impact for both methods calculated in step (4) by dividing by five (number of years in this analysis).

(6) Subtracted the difference between the totals calculated in step (5).

Because ONRR estimates that 50 percent of lessees will choose this option, ONRR reduced the total estimate by 50 percent. Please note that the figures in the table below represent the difference between the current transportation adjustment percentage and the percentage under the index-based valuation option. ONRR estimates the change will result in a decrease in annual royalty payments of approximately $7.1 million. This estimate represents an average decrease of approximately 65 percent or 15 cents per MMBtu, based on an annualized royalty volume of 93,301,478 MMBtu (for NARM and 10 percent POOL reported sales type codes).

ANNUAL CHANGE IN ROYALTIES DUE TO TRANSPORTATION DEDUCTION MODIFICATION FOR NON-ARM’S-LENGTH SALES OF NATURAL GAS

<table>
<thead>
<tr>
<th></th>
<th>Gulf of Mexico</th>
<th>Other areas</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Regulations Transport Deduction</td>
<td>$5,387,000</td>
<td>$16,375,000</td>
<td>$21,762,000</td>
</tr>
<tr>
<td>Estimate using new Transport Deduction</td>
<td>10,346,000</td>
<td>25,659,000</td>
<td>36,005,000</td>
</tr>
<tr>
<td>Difference</td>
<td>4,959,000</td>
<td>9,284,000</td>
<td>14,243,000</td>
</tr>
<tr>
<td>Change per MMBtu</td>
<td>0.15</td>
<td>0.15</td>
<td>0.15</td>
</tr>
<tr>
<td>50% of lessees choose this option</td>
<td>0.05</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>Net change in royalties as a result</td>
<td>7,121,000</td>
<td>7,121,000</td>
<td>(7,121,000)</td>
</tr>
</tbody>
</table>

Change in Royalties 4: Transportation Allowances in Excess of 50 Percent of the Royalty Value Prior to Allowances for Federal Gas

In certain scenarios, a lessee may incur costs to transport Federal gas at a cost that exceeds the regulatory limit of 50 percent of the gas’s royalty value prior to allowances. The proposed rule provides a lessee the ability to request to exceed the 50 percent limit when the lessee’s costs above 50 percent are reasonable, actual, and necessary. To estimate the change in royalties associated with the proposed amendment, ONRR first identified all gas transportation allowances reported on the monthly royalty report exceeding the 50 percent limit for calendar years 2014–2018. Next, ONRR calculated the transportation allowance claimed for each royalty line compared to what the transportation allowance would have been at the 50 percent limit. ONRR then calculated annual totals and averaged them over five years. The result is an annual decrease in royalties paid by industry of approximately $279,000 per year.

Change in Royalties 5: Transportation Allowances in Excess of 50 Percent of the Royalty Value Prior to Allowances for Federal Oil

As described in the section above, a lessee may incur costs to transport Federal oil that exceed the regulatory limit of 50 percent of the oil’s royalty value prior to allowances. This proposed rule would provide a lessee the ability to request to exceed that limit when the lessee’s actual costs are reasonable, actual, and necessary. To estimate the change in royalties associated with this change, ONRR first identified all oil transportation allowances reported on the monthly royalty report that exceeded the 50 percent limit for calendar years 2014–2018. As above, ONRR calculated the transportation allowance claimed for each royalty line compared to what the transportation allowance would have been at the 50 percent limit. ONRR then calculated annual totals and averaged them over five years. The result was an annual decrease in royalties paid by industry of approximately $11,000 per year.

Change in Royalties 6: Processing Allowances in Excess of 66⅔ Percent of the Royalty Value of Federal NGLs Prior to Allowances

As with transportation allowances, a lessee may incur costs required to process gas that exceed the regulatory limit of 66⅔ percent of the royalty value of the NGLs prior to allowances. The proposed rule provides a lessee the ability to request to exceed that limit when the lessee’s costs above 66⅔ percent are reasonable, actual, and necessary. To estimate the change in royalties associated with this change, ONRR completed two separate calculations.

First ONRR identified all NGL processing allowances reported on the monthly royalty report that exceeded the 66⅔ percent limit for calendar years 2014–2018. Next, ONRR calculated the processing allowance claimed for each royalty line compared to what the processing allowance would have been at the 66⅔ percent limit. ONRR then calculated annual totals and averaged them over five years. The result was an annual estimated decrease in royalties
paid by approximately $135,000 per year.

ONRR also calculated and quantified the estimated impact for any allowances and NGLs above the 66⅔% limit for percentage of proceeds (POP) contract sales. When POP sales are reported to ONRR, sales of gas are reported where the value of the unprocessed gas is based on a percentage of the proceeds the purchaser receives for the sales of the processed gas plus the gas plant products attributed to the lessee’s production. Under the 2016 Valuation Rule, a lessee with a POP contract is limited to 66⅔% of the royalty value prior to allowances of the NGLs as a processing allowance even if its actual costs exceed this limit. This proposed rule provides a lessee the ability to request processing allowances in excess of 66⅔% results in an annual royalty payment by $9.8 million, which is a transfer from the lessee’s costs are reasonable, actual, and necessary. For example, a lessee with a 70 percent POP contract receives 70 percent of the value of the residue gas and 70 percent of the value of the NGLs.

The 30 percent of each product that the lessee provides the processing plant in the past cannot, when combined, exceed a value equivalent to 100 percent of the NGLs’ value. Under the proposed rule, the combined value of each product that a lessee gives up to the processing plant could, with approval, exceed two thirds of the NGLs’ value.

Prior to the 2016 Valuation Rule, a lessee reported POP contracts to ONRR using a sales type code that showed whether it was an arm’s-length (an APOP) or non-arm’s-length (an NPOP) POP contract. Because lessees reported APOP sales as unprocessed gas, there are no reported processing allowances available for analysis, and ONRR cannot determine the break between residue gas and NGLs. Lessees report residue gas and NGLs separately for NPOPs. But NPOP volumes constitute only 0.04 percent of all the natural gas royalty volumes that lessees report to ONRR. ONRR deemed the NPOP volume to be too low to adequately assess the impact of this provision on both APOP and NPOP contracts. Thus, ONRR examined the onshore residue gas and NGL royalty data reported for calendar years 2014–2018 and assumed that lessees processed the gas and paid royalties as if they sold the residue gas and NGLs under a POP contract. First, ONRR averaged the total five-year residue gas and NGL royalty values and assumed, based on typical agreement percentage splits observed in compliance activities, that these royalties were subject to a 70–percent POP contract. ONRR’s compliance activities indicate the typical POP contracts split is at a 70/30 percent weighting retained percent of proceeds and cost of processing. ONRR calculated 30 percent of both the value of residue gas and NGLs to approximate a theoretical 30-percent processing deduction and then compared the 30 percent total of residual gas and NGL values to 66⅔ percent of the NGL value (the maximum allowance under the current regulations). The table below summarizes the calculations, rounded to the nearest dollar:

<table>
<thead>
<tr>
<th>POP CONTRACT ALLOWANCE THRESHOLD DETERMINATION</th>
<th>5-year average royalty value prior to allowances</th>
<th>70% proceeds portion of POP contract</th>
<th>30% processing cost portion of POP contract</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residue Gas</td>
<td>$765,199,287</td>
<td>$535,639,501</td>
<td>$229,559,786</td>
</tr>
<tr>
<td>NGLs</td>
<td>274,631,986</td>
<td>192,242,391</td>
<td>82,389,596</td>
</tr>
<tr>
<td>Total</td>
<td>1,039,831,273</td>
<td>727,881,891</td>
<td>311,949,382</td>
</tr>
<tr>
<td>66⅔% Limit</td>
<td>183,087,991</td>
<td>(274,631,986 x %)</td>
<td></td>
</tr>
<tr>
<td>Difference</td>
<td>128,861,391</td>
<td>($311,949,382 – $183,087,991)</td>
<td></td>
</tr>
</tbody>
</table>

ONRR’s analysis shows that, under the theoretical processing allowance and POP contract, 30 percent of residue gas and NGLs ($312 million) would exceed the 66⅔ cap ($183 million). ONRR estimates that this will reduce annual royalty payments by $9.8 million, which is a transfer from the Federal, State, and local governments to industry. ONRR determined this estimate by taking the royalty value exceeding the POP contract allowance ($128.9 million) and dividing it by the annual average non-POP volume (2,254,617,156 MMbtu) to calculate a per-MMbtu rate of $0.06. ONRR then applied the $0.06 rate to the POP contract total volume of 163,455,735 MMbtu to reach the $9.8 million estimate. In this analysis, ONRR assumed all processing costs associated with the 30 percent assumption were allowable.

<table>
<thead>
<tr>
<th>ANNUAL CHANGE IN ROYALTIES FOR REQUESTS TO EXCEED ALLOWANCE THRESHOLD FOR POP CONTRACTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annualized MMbtu Volume</td>
</tr>
<tr>
<td>Rate/MMbtu over limit</td>
</tr>
<tr>
<td>Annualized POP MMbtu Volume</td>
</tr>
<tr>
<td>Estimated Change in Royalties</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

The total impact of both scenarios to allow processing allowances in excess of 66⅔ percent results in an annual estimated decrease in royalties of approximately $9.8 million.

Change in Royalties 7: Extraordinary Cost Gas Processing Allowances for Federal Gas

The proposed rule would allow a lessee to request an extraordinary processing cost allowance. Using the approvals ONRR granted prior to the 2016 Valuation Rule, we identified the 127 leases claiming an extraordinary processing allowance for residue gas, sulfur, and CO₂ for calendar years 2014–2018. The total processing costs are reported across all three products for these unique situations. For these leases, we retrieved all Form ONRR–2014 lines with a processing allowance reported by lessees. For CO₂ and sulfur
produced from these leases, ONRR then calculated the annual average processing allowances which exceeded the 66\(\frac{2}{3}\)% percent limit and found that only two years in the analysis showed that the total allowances exceeded the 66\(\frac{2}{3}\)%-percent limit. Under these unique exceptions, the processing allowances are also reported against residue gas, so we also added the annual average processing allowances taken for those same leases for residue gas. Based on these calculations, ONRR estimates this change will result in a decrease in annual royalty payments of approximately $11.1 million.

**Estimated Annual Change in Royalties Paid**

<table>
<thead>
<tr>
<th>Annual Average Sulfur allowances in excess of 66(\frac{2}{3})%</th>
<th>($348,000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Average Residue Gas Allowance ................................</td>
<td>(10,783,000)</td>
</tr>
<tr>
<td>Estimated Impact on Royalties .......................................</td>
<td>(11,131,000)</td>
</tr>
</tbody>
</table>

Change in Royalties 8: Transportation Allowances for Deepwater Gathering for Federal Oil and Gas

The Deepwater Policy was in effect from 1999 until January 1, 2017 (the 2016 Valuation Rule’s effective date). Under the Deepwater Policy, ONRR allowed a lessee to treat certain expenses for subsea gathering as transportation expenses and to deduct those costs from its royalty payments. The 2016 Valuation Rule rescinded the Deepwater Policy. To analyze the impact to industry of allowing the gathering costs to be treated as deductible transportation costs, ONRR used data from the Bureau of Safety and Environmental Enforcement’s (BSEE’s) Technical Information Management System database to identify 113 current subsea pipeline segments, and potentially 169 eligible leases, which may qualify for an allowance under the Deepwater Policy. ONRR assumed that all segments were similar (in other words, no adjustments were made to account for the size, length, or type of pipeline) and considered only the pipeline segments that were in active status and supporting leases in producing status. To determine the range (shown in the tables at the end of this section as low, mid, and high estimates) of changes to royalties, ONRR estimates a 15 percent error rate in the identification of the 113 eligible pipeline segments. This resulted in a range of 96 to 130 eligible pipeline segments. ONRR’s audit data is available for 13 subsea gathering segments serving 15 leases covering time periods from 1999 through 2010.

The cost to perform this calculation is significant because industry often hires outside consultants to calculate their subsea transportation allowances. ONRR estimates that each lessee with leases eligible for transportation allowances for deepwater gathering systems will allocate one full-time employee annually to perform the calculation. ONRR used data from the BLS to estimate the hourly cost for industry accountants in a metropolitan area [$42.39 mean hourly wage] with a multiplier of 1.4 for industry benefits to equal approximately $59.35 per hour [$42.39 \times 1.4 = 59.35]. Using this fully-burdened labor cost per hour, ONRR estimates that the annual administrative cost to industry would be approximately $3.9 million.

**Annual Estimated Change in Royalties Allowing Deepwater Gathering**

<table>
<thead>
<tr>
<th>Royalty Impact</th>
<th>Low</th>
<th>Mid</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>($30,500,000)</td>
<td>($35,900,000)</td>
<td>($41,300,000)</td>
</tr>
</tbody>
</table>

Cost 1 Transportation Allowances for Deepwater Gathering for Offshore Federal Oil and Gas

The proposed rule, by allowing transportation allowances for deepwater gathering systems, will result in an administrative cost to industry because it requires qualified lessees to monitor their costs and perform calculations.
Cost Savings 1: Administrative Cost Savings From Using Index-Based Valuation Option to Value Federal Unprocessed Gas, Residue Gas, Coalbed Methane, and NGLs

ONRR expects that industry will realize administrative-cost savings if they choose to use the index-based valuation option to value dispositions of Federal unprocessed gas, residue gas, coalbed methane, and NGLs. A lessee will have price certainty when calculating its royalties—saving time it currently spends on verifying gross proceeds. ONRR estimates that 50 percent of lessees will use the index-based valuation option. Further, ONRR estimates that it will shorten the time burden per line reported by 50 percent (to 1.5 minutes per electronic line submission and 3.5 minutes per manual line submission). As with Cost 1, ONRR used tables from the Bureau of Labor Statistics to estimate the fully-burdened hourly cost for an industry accountant in a metropolitan area working in oil and gas extraction. The industry labor cost factor for accountants would be approximately $59.35 per hour = $42.39 [mean hourly wage] × 1.4 [benefits cost factor]. Using a labor cost factor of $59.35 per hour, ONRR estimates the annual administrative cost savings to industry will be approximately $1.4 million.

**ANNUAL ADMINISTRATIVE COST TO INDUSTRY TO CALCULATE DEEPWATER TRANSPORTATION**

<table>
<thead>
<tr>
<th>Deepwater Policy</th>
<th>Annual burden hours per company</th>
<th>Industry labor cost/hour</th>
<th>Companies reporting eligible leases</th>
<th>Estimated cost to industry</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2,080</td>
<td>$59.35</td>
<td>32</td>
<td>$3,936,000</td>
</tr>
</tbody>
</table>

Cost Savings 2: Administrative Cost Savings Using Index-Based Valuation Option to Value Residue Gas and NGLs Simplifying Processing and Transportation Cost Calculations

ONRR expects industry will realize an additional one-time administrative-cost savings if they choose to use the index-based valuation option to value dispositions of Federal residue gas and NGLs, as this method eliminates the need to unbundle and calculate specific cost allocations related to processing and transportation. These cost allocations, referred to as “unbundling,” are segregated portions of a transportation or processing expense or fee attributable to placing production in marketable condition. Industry would unbundle their applicable plants and transportation systems one time in the absence of this rule and then use those unbundled cost allocations for subsequent royalty calculations. Industry is responsible for calculating these costs, however ONRR has published and calculated a limited number of unbundling cost allocations. In ONRR’s experience, it takes approximately 100 hours per gas plant. ONRR calculated the average number of gas plants reported per payor is 3.4, across a total of 448 payors reporting residue gas and NGLs, between 2014–2018. Using the BLS labor cost per hour of $59.35 (described above) and adjusting our assumption to 50 percent of lessees choosing the index-based option, we believe this results in a one-time cost savings to industry of $4.5 million dollars.

i. State and Local Governments

ONRR estimates that the States and certain local governments this rule impacts would receive an overall decrease in royalty share (which, in part, was a reason for California’s and New Mexico’s challenges to the 2017 Repeal Rule) based on the category the lease falls under, including offshore Outer Continental Shelf Lands Act section 8(g) leases (See 43 U.S.C. 1337(g)), Gulf of Mexico Energy Security Act leases (GOMESA) (43 U.S.C. 1337(g)), and onshore Federal lands. ONRR disburses royalties based on where the oil, gas, or coal was produced.

ii. Indian Lessors

The provisions in the proposed rule are not expected to affect Indian lessors.

iii. Federal Government

The impact of the proposed rule to the Federal Government will be a net decrease in royalty collections. ONRR estimates the net yearly impact on the Federal Government (detailed in the next table of this section) would be a loss of $32,239,000 in royalties.

**ANNUAL ADMINISTRATIVE COST SAVINGS FOR INDUSTRY**

<table>
<thead>
<tr>
<th></th>
<th>Time burden per line reported</th>
<th>Estimated lines reported using index option (50%)</th>
<th>Annual burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic Reporting (99%)</td>
<td>1.5 min</td>
<td>892,620</td>
<td>22,315</td>
</tr>
<tr>
<td>Manual Reporting (1%)</td>
<td>3.5 min</td>
<td>9,016</td>
<td>526</td>
</tr>
<tr>
<td>Industry Labor Cost/hour</td>
<td></td>
<td></td>
<td>$59.35</td>
</tr>
<tr>
<td>Total Benefit to Industry</td>
<td></td>
<td></td>
<td>1,356,000</td>
</tr>
</tbody>
</table>

Please visit https://revenuedata.doi.gov/explore/#federal-disbursements to find more information on ONRR’s disbursements to any specific State or local government.

The next table in this section summarizes the State and local government royalty decreases.

**ONRR DISBURSEMENTS BY AREA**

<table>
<thead>
<tr>
<th></th>
<th>Onshore %</th>
<th>Offshore %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal</td>
<td>51</td>
<td>95.2</td>
</tr>
<tr>
<td>State</td>
<td>49</td>
<td>4.8</td>
</tr>
</tbody>
</table>

Please visit https://revenuedata.doi.gov/how-it-works/gomesa/, the following distribution table generally applies:
iv. Summary of Royalty Impacts and Costs to Industry, State and Local Governments, Indian Lessors, and the Federal Government

In the table below, ONRR presents the net change in royalties by rulemaking provision. Changes to royalties are neither costs nor benefits, but transfers. The estimated changes in royalties assessed will change both the private cost to the operator/lessee and the amount of revenue collected by the Federal government and the States.

### ANNUAL ECONOMIC IMPACTS FOR INDUSTRY, THE FEDERAL GOVERNMENT, AND STATES

<table>
<thead>
<tr>
<th>Rule provision</th>
<th>Net change in royalties</th>
<th>Federal proportion</th>
<th>State proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index-Based Valuation Option Extended to Gas Dispositions</td>
<td>$5,620,000</td>
<td>$3,606,000</td>
<td>$2,014,000</td>
</tr>
<tr>
<td>High to Midpoint Index Price for Non-Arm’s-Length Gas Dispositions</td>
<td>(4,488,000)</td>
<td>(2,880,000)</td>
<td>(1,608,000)</td>
</tr>
<tr>
<td>Transportation Deduction Non-Arm’s-Length Index-Based Valuation Option</td>
<td>(7,121,000)</td>
<td>(4,569,000)</td>
<td>(2,552,000)</td>
</tr>
<tr>
<td>Gas Transportation Allowances</td>
<td>(279,000)</td>
<td>(179,000)</td>
<td>(100,000)</td>
</tr>
<tr>
<td>Oil Transportation Allowances</td>
<td>(11,000)</td>
<td>(9,000)</td>
<td>(2,000)</td>
</tr>
<tr>
<td>Gas Processing Allowances</td>
<td>(9,942,000)</td>
<td>(6,379,000)</td>
<td>(3,563,000)</td>
</tr>
<tr>
<td>Extraordinary Processing Allowance</td>
<td>(11,131,000)</td>
<td>(7,142,000)</td>
<td>(3,989,000)</td>
</tr>
<tr>
<td>Deepwater Policy</td>
<td>(35,900,000)</td>
<td>(29,155,000)</td>
<td>(6,745,000)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>(42,111,000)</strong></td>
<td><strong>(32,239,000)</strong></td>
<td><strong>(9,872,000)</strong></td>
</tr>
</tbody>
</table>

**Note:** totals may not add due to rounding.

2. Federal and Indian Coal

ONRR estimates that there will be no economic impact in terms of royalties to ONRR, Tribes, individual Indian mineral owners, States, or industry from the changes to coal valuation in this proposed rule. The changes outlined in this proposed rule should result in coal values for royalty purposes similar to those reported and paid to ONRR under the regulations in effect since 1989. Further, as of this writing, lessees have not submitted reporting under the 2016 Valuation Rule, so ONRR lacks data showing any changes resulting from implementation of the provisions of the 2016 Valuation Rule.

ONRR requests your comments on the economic impact of the changes listed below.

Change 1: Eliminate Reference to Default Provision Requirements for Federal Oil and Gas

ONRR proposed to remove the default provision from its regulations. In instances of misconduct, breach of a lessee’s duty to market, or other situations where royalty value cannot be determined under the rules, ONRR will use statutory authority to determine Federal oil and gas royalty value under lease terms, FOGRMA, and other authorizing legislation in the same manner—as ONRR would have prior to adoption of the 2016 Valuation Rule. ONRR does not believe there is any overall royalty impact from removing the default provision.

Change 2: Eliminating the Use of Arm’s-Length Electricity Sales to Value Non-Arm’s-Length Dispositions of Federal Coal

In the 2016 Valuation Rule, ONRR estimated no impacts to industry for this provision. Further, because lessees have not submitted reporting under the 2016 Valuation Rule, ONRR lacks data showing any changes that may have been attributable to this provision.

Change 3: Using the First Arm’s-Length Sale to Value Non-Arm’s-Length Sales of Indian Coal

ONRR did not estimate any impacts to industry for the proposed change from this provision. Currently, lessees of Indian coal sell their entire production at arm’s-length, so this proposed change would have no royalty impact on lessees or lessors of Indian coal.

Change 4: Eliminating the Sales of Electricity to Value Non-Arm’s-Length Sales of Indian Coal

ONRR did not estimate any impacts to industry for the proposed change for this provision. Currently, lessees of Indian coal sell their entire production at arm’s-length so this proposed change would have no royalty impact on lessees or lessors of Indian coal.

Change 5: Using First Arm’s-Length Sale to Value Sales of Indian Coal Between Parties That Lack Opposing Economic Interests

At the present time, all producers of Indian coal sell the produced coal under arm’s-length transactions. Accordingly, ONRR does not anticipate any impact to royalty collections from the proposed change.

Change 6: Elimination of the Default Provision to Value Federal Oil, Gas, and Coal and Indian Coal

ONRR estimates that the royalty impact would be insignificant because the default provision established a reasonable value of production using market-based transaction data, which has always been, and continues to be, the basis for ONRR’s royalty valuation rules.

### F. Public Comments

1. Federal Oil and Gas

   1. ONRR requests comments identifying the complexities industry could avoid if an index-based valuation option were available for arm’s-length dispositions. Where it can be reasonably determined, ONRR also requests comments quantifying the burden savings that an arm’s-length index-based valuation option would provide, in place of reporting such dispositions using gross proceeds.

   2. ONRR requests comments specific to any unintentional burdens that the 2016 Valuation Rule may have created by providing the index-based valuation option to only the non-arm’s-length dispositions for a lessee with both arm’s-length and non-arm’s-length dispositions.

   3. ONRR also requests comments on whether the 2016 Valuation Rule’s separate arm’s-length and non-arm’s-length valuation methods impacted lessee decision making on whether to use the index-based valuation method for non-arm’s-length dispositions.

4. ONRR requests comments on alternatives that more closely match values under the index-based valuation...
method to the gross proceeds accruing under arm’s-length dispositions across all Federal oil and gas leases.
5. ONRR requests comments on alternatives that would allow a lessee and ONRR to establish a clear and consistent location to determine royalty value under the index-based valuation options.

6. ONRR is proposing to revise the transportation adjustment for the OCS in the Gulf of Mexico to 10 percent per MMBtu, but not less than 10 cents or more than 40 cents per MMBtu, and for all other areas to 15 percent, but not less than 10 cents or more than 50 cents per MMBtu. ONRR requests comments specific to whether the proposed change accomplishes its purpose to more accurately reflect current transportation costs. ONRR is also interested in comments that propose alternative methods for calculating the transportation adjustment in a timely manner, or that would avoid potentially burdensome, controversial rulemakings to update the adjustment.

7. ONRR requests comments on the impacts of the 2016 Valuation Rule’s hard caps and the associated changes proposed in this rule. Specifically, we are interested in any specific data commenters can provide regarding the hard cap’s effect on specific operations or other lessee decision making and arguments that may be made for or against the proposed change.

8. ONRR is interested in receiving comments specific to how codifying the Deepwater Policy would impact energy production and exploration in the OCS now and in the future at depths of 200 meters or deeper; how it would impact revenues to Federal, State, and local governments; and feedback on any efforts that could be anticipated on non-OCS domestic production.

9. ONRR requests comments on the following: (a) In what shallow water situations is the Deepwater Policy currently applicable? (b) In what shallow water situations would it be appropriate or inappropriate to apply the Deepwater Policy in the future? (c) What criteria are appropriate to evaluate when determining whether a shallow water lease with a subsea completion should qualify for the deduction of gathering costs as a transportation allowance? (d) Are there lessons to be learned by how other leasing entities (e.g., State or private landowners) manage such transportation allowances?

10. ONRR requests comments on the following: (a) In what remote-area situations is it uneconomic or unfeasible for a lessee to establish a central separation, treatment, or royalty measurement facilities on or near the lease? (b) What criteria should ONRR use to distinguish between traditional gathering, which generally occurs on or near the lease, and the movement of bulk production in remote areas across lease boundaries to a central separation, treatment, or royalty measurement facilities? (c) How should ONRR distinguish between allowed and disallowed movement in remote areas? (d) How should ONRR define “remote area?” (e) Is there a way for ONRR to develop a coherent policy that distinguishes between remote and non-remote areas in terms of allowing deduction of certain costs to move bulk production? (f) If so, what are the advantages and disadvantages of such an approach to lessees and to the government (as resource owner)?

11. ONRR requests comments on the following: (a) What terms ONRR could use in place of “misconduct” to describe a lessee’s activities that would warrant ONRR establishing royalty value? (b) What specific criteria ONRR could apply to distinguish when a lessee engaged in “misconduct” or the term replacing “misconduct” from a lessee’s mere clerical errors?

12. ONRR requests comments on the following: (a) What criteria could ONRR establish to provide lessees more clarity and certainty on when ONRR would establish royalty value in place of typical methods? (b) What factors and methods should ONRR consider when establishing reasonable royalty values?

13. Without a requirement to maintain signed contracts, ONRR possesses broad authority to investigate and question the validity of any contract. Therefore, ONRR requests comments specific to any additional burdens the 2016 Valuation Rule’s signature requirement placed on lessees.

14. ONRR proposes to eliminate the requirements under §§ 1206.106(a)(5), 1206.148(a)(5), 1206.258(a)(5) and 1206.458(a)(5) for a lessee to include citations to legal precedents when requesting a valuation determination. ONRR requests comments on the burdens the legal precedent requirement placed on industry, and any comments related to the necessity of retaining the requirement.

15. ONRR requests comments on how the proposed rule may or may not fulfill its objective to implement Executive Orders and Secretarial Orders. Moreover, ONRR looks to receive feedback on whether, and to what extent, the proposed amendments would impact domestic energy exploration and energy production, create economic opportunity, or otherwise provide justification to alter—or not—transfer payments between the United States and its lessees in the form of royalties.

2. Federal and Indian Coal

1. ONRR is interested in receiving comments on alternatives that could be used to value non-arm’s-length coal sales and enable a lessee to access the information needed to support royalty reporting while ensuring the Federal and Indian lessors obtain fair market value for the royalty share.

2. ONRR also seeks input on whether the rules should be amended to establish a minimum royalty value to protect the Federal or Indian lessor’s royalty share when production’s value decreases between a lease or mine and where the first arm’s-length sale occurs. Commenters are also encouraged to offer suggestions on the methodology to use to establish a minimum royalty value.

3. ONRR requests your comments on other appropriate alternatives to simplify the method to determine royalty value for coal a lessee does not sell at arm’s-length, before its consumption or other disposition as electricity.

4. ONRR requests your comments on the economic impact of the following: (a) Eliminating the use of arm’s-length electricity sales to value non-arm’s-length dispositions of federal coal. (b) Using the first arm’s-length sale to value non-arm’s-length sales of Indian coal. (c) Eliminating the sales of electricity to value non-arm’s-length sales of Indian coal. (d) Using first arm’s-length sale to value sales of Indian coal between parties that lack opposing economic interests. (e) Elimination of the default provision to value federal oil, gas, and coal and Indian coal.

3. Civil Penalties

1. ONRR proposes to amend § 1241.70 to clarify that, for payment violations only, ONRR would consider the consequence of the unpaid, underpaid, or late payment amount when assessing a civil penalty. ONRR requests comment on how this would impact lessees to which ONRR issues a civil penalty.

2. ONRR proposes to amend § 1241.70 to clarify that ONRR may consider aggravating and mitigating circumstances to increase or decrease a penalty. ONRR requests comment on how this would impact lessees subject to an ONRR-issued civil penalty. ONRR also seeks comment on what facts or situations it should consider to be aggravating and mitigating circumstances.

3. ONRR seeks comment on how removing § 1241.11(b)(5) would affect lessees issued a civil penalty.
4. Other Matters

ONRR requests comment on all other aspects of this proposed rule, including (for instance) whether the proposed regulatory definition of “Affiliate” is too broad or too narrow in any respect. Commenters should provide appropriate reasoning and factual support for all contentions.

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) will review all significant rulemaking. OIRA has determined that the proposed rule is significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866, while calling for improvements in the nation’s regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. This executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We developed this rule in a manner consistent with these requirements.

2. Regulatory Flexibility Act

The Department of the Interior certifies that the proposed rule would 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.). See above for the costs, benefits, and economic analysis.

For the changes to 30 CFR part 1206, this rule would affect lessees of Federal oil and gas leases. For the changes to 30 CFR part 1241, this rule could affect violators of obligations under Federal and Indian mineral leases. Federal and Indian mineral lessees are, generally, companies classified under the North American Industry Classification System (NAICS), as follows:

- Code 211111, which includes companies that extract crude petroleum and natural gas
- Code 212111, which includes companies that extract surface coal
- Code 212112, which includes companies that extract underground coal

For these NAICS code classifications, a small company is one with fewer than 500 employees. Approximately 1,920 different companies submit royalty and production reports from Federal oil and gas leases and other Federal mineral leases to ONRR each month. Of these, approximately 65 companies would be large businesses under the U.S. Small Business Administration definition, because they would have more than 500 employees. The Department estimates that the remaining 1,855 companies that this rule would affect are small businesses. In this context, ONRR defines company size for lessees as follows: large: Average annual royalties over $100 million, medium: $99–$10 million, and small: Less than $10 million.

As stated in the Summary of Royalty Impacts and Costs table, shown above, this rule would benefit industry through a cost savings of approximately $42 million per year. Small businesses account for about 8 percent of the royalties. Applying that percentage to industry costs, we estimate that the changes in the proposed rule would result in a cost savings to small-business lessees by a total of approximately $3.5 million per year, which shared between...
the 1,855 companies totals in an average $1,887 cost savings per company. The amount would vary for each company depending on the volume of production that the small business produces and sells each year.

In sum, we do not estimate that this rule would result in a significant economic impact on a substantial number of small entities because this rule does not impose new costs on the regulated industry anywhere where those entities would not have an opportunity to realize some cost savings. Each small entity would consider the provisions to decide whether it is economically advantageous to incur increases in administrative costs to achieve the cost savings the provision would provide. The rule would benefit affected small businesses a collective total of $3.5 million per year. Thus, an Initial Regulatory Flexibility Act Analysis is not required, and, accordingly, a Small Entity Compliance Guide is not required.

Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and ten Regional Fairness Boards receive comments from small businesses about Federal agency enforcement actions. The Ombudsman annually evaluates the enforcement activities and rates each agency’s responsiveness to small business. If you wish to comment on ONRR’s actions, call 1–(888) 734–3247. You may comment to the Small Business Administration without fear of retaliation. Allegations of discrimination/retaliation filed with the Small Business Administration would be investigated for appropriate action.

3. Small Business Regulatory Enforcement Fairness Act

The proposed rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Will not have an annual effect on the economy of $100 million or more. We estimate that the cumulative effect on all of industry will be a reduction in private cost of nearly $39.52 million per year, which is the sum of $42.1 million in decreased royalty payments and $2.58 million in additional costs due to increased administrative burdens. The net change in royalty payments is a transfer rather than a cost or cost savings. The Summary of Royalty Impacts and Costs table, as shown above, demonstrates that the cumulative economic impact on industry, State and local governments, and the Federal Government will be well below the $100 million threshold that the Federal Government uses to define a rule as having a significant impact on the economy.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. See above.

c. Will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises. The proposed rule would benefit United States-based enterprises. We are the only agency that promulgates rules for royalty valuation on Federal oil and gas leases and Federal and Indian coal leases.

4. Unfunded Mandates Reform Act

The proposed rule would not impose an unfunded mandate on State, local, or Tribal governments, or the private sector of more than $100 million per year. This rule will not have a significant or unique effects on Indian Tribal governments, or the private sector. Therefore, we are not required to provide a statement containing the information that the Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.) requires because this rule is not an unfunded mandate.

5. Takings (Executive Order 12630)

Under the criteria in section 2 of Executive Order 12630, the proposed rule would not have any significant takings implications. This rule would not impose conditions or limitations on the use of any private property. This rule would apply to the valuation of Federal oil and gas and Federal and Indian coal only. The proposed rule would only make minor technical changes to ONRR’s civil penalty regulations that have no expected economic impact. The proposed rule would not require a takings implication assessment.

6. Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, the proposed rule would not have sufficient Federalism implications to warrant the preparation of a Federalism summary impact statement. The management of Federal oil and gas is the responsibility of the Secretary of the Interior, and ONRR distributes all of the royalties that we collect under Federal oil and gas leases as specified in the relevant disbursement statutes. This rule will not impose administrative costs on States or local governments. This rule also will not substantially and directly affect the relationship between the Federal and State governments. Because this rule will not alter that relationship, it does not require a Federalism summary impact statement.

7. Civil Justice Reform (Executive Order 12988)

The proposed rule complies with the requirements of Executive Order 12988. Specifically, this rule:

a. Will meet the criteria of Section 3(a), which requires that we review all regulations to eliminate errors and ambiguity and write them to minimize litigation.

b. Will meet the criteria of Section 3(b)(2), which requires that we write all regulations in clear language using clear legal standards.

8. Consultation With Indian Tribal Governments (Executive Order 13175)

Under the criteria in Executive Order 13175, ONRR evaluated the proposed rule and determined that it will not substantially affect Federally recognized Indian tribes. The proposed rule only affects Federal, not Indian, oil and gas leases. For Indian coal leases, ONRR estimated that the proposed rule would not alter the royalty valuation of Indian coal.

9. Paperwork Reduction Act

The proposed rule:

(a) Will not contain any new information collection requirements.


The proposed rule will leave intact the information collection requirements that OMB has already approved under OMB Control Numbers 1012–0004, 1012–0005, and 1012–0010.

10. National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. ONRR is not required to provide a detailed statement under the National Environmental Policy Act of 1969 (NEPA) because this rule qualifies for a categorical exclusion under 43 CFR 46.210(c) and (i) and the Department of the Interior’s Departmental Manual, part 516, section 15.4.D: “(c) Routine financial transactions including such things as . . . audits, fees, bonds, and royalties . . . [and] (i) [p]olicies, directives, regulations, and guidelines . . . [that are] of an administrative, financial, legal, technical, or procedural nature.” ONRR also determined that this rule is not involved in any of the extraordinary circumstances listed in 43 CFR 46.215 that require further analysis.
under NEPA. The changes resulting from the proposed amendments will have no consequence on the physical environment. The proposed rule does not alter, in any material way, natural resources exploration, production, or transportation.

11. Effects on the Energy Supply (Executive Order 13211)

The proposed rule is not a significant energy action under the definition in Executive Order 13211, and, therefore, does not require a statement of energy effects.

12. Clarity of This Regulation

Executive Orders 12866 (section 1(b)(12), 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and the Presidential Memorandum of June 1, 1998, require us to write all rules in plain language. This means that the rules we publish must use:

(a) Logical organization.
(b) Active voice to address readers directly.
(c) Clear language rather than jargon.
(d) Short sections and sentences.
(e) Lists and tables wherever possible.

If you feel that ONRR has not met these requirements, send your comments to Danel.Templin@onrr.gov. To better help ONRR understand your comments, please make your comments as specific as possible. For example, you should tell ONRR the numbers of the sections or paragraphs that you think were written unclearly, which sections or sentences are too long, the sections where you feel lists or tables would be useful.

13. Public Availability of Comments

ONRR will post all comments we receive, including a respondent’s name and address. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask, in your comment, that your personal identifying information be withheld from public view, ONRR cannot guarantee that we will be able to do so.

List of Subjects

30 CFR Part 1206

Coal, Continental shelf, Geothermal energy, Government contracts, Indians—lands, Mineral royalties, Oil and gas exploration, Public lands—mineral resources, Reporting and recordkeeping requirements

30 CFR Part 1241

Administrative practice and procedure, Coal, Indians—lands, Mineral royalties, Natural gas, Oil and gas exploration, Penalties, Public lands—mineral resources.

Kimbra G. Davis,
Director for Office of Natural Resources Revenue.

Authority and Issuance

For the reasons discussed in the preamble, the Office of Natural Resources Revenue proposes to amend 30 CFR parts 1206 and 1241 as set forth below:

PART 1206—PRODUCT VALUATION

1. The authority citation for part 1206 continues to read as follows:


Subpart A—General Provisions and Definitions

2. Revise § 1206.20 to read as follows:

§ 1206.20 What definitions apply to this part?

The following definitions apply to this part:

Ad valorem lease means a lease where the royalty due to the lessor is based upon a percentage of the amount or value of the coal.

Affiliate means a person who controls, is controlled by, or is under common control with another person. For the purposes of this subpart:

1. Ownership or common ownership of more than 50 percent of the voting securities, or instruments of ownership or other forms of ownership, of another person constitutes control. Ownership of less than 10 percent constitutes a presumption of non-control that ONRR may rebut.

2. If there is ownership or common ownership of 10 through 50 percent of the voting securities or instruments of ownership, or other forms of ownership, of another person, ONRR will consider each of the following factors to determine if there is control under the circumstances of a particular case:

(i) The extent to which there are common officers or directors

(ii) With respect to the voting securities, or instruments of ownership or other forms of ownership: The percentage of ownership or common ownership, the relative percentage of ownership or common ownership compared to the percentage(s) of ownership by other persons, if a person is the greatest single owner, or if there is an opposing voting bloc of greater ownership

(iii) Operation of a lease, plant, pipeline, or other facility

(iv) The extent of other owners’ participation in operations and day-to-day management of a lease, plant, or other facility

(v) Other evidence of power to exercise control over or common control with another person

(3) Regardless of any percentage of ownership or common ownership, relatives, either by blood or marriage, are affiliates.

ANS means Alaska North Slope.

Area means a geographic region at least as large as the limits of an oil and/or gas field, in which oil and/or gas lease products have similar quality and economic characteristics. Area boundaries are not officially designated and the areas are not necessarily named.

Arm’s-length-contract means a contract or agreement between independent persons who are not affiliates and who have opposing economic interests regarding that contract. To be considered arm’s-length for any production month, a contract must satisfy this definition for that month, as well as when the contract was executed.

Audit means an examination, conducted under the generally accepted Governmental Auditing Standards, of royalty reporting and payment compliance activities of lessees, designees or other persons who pay royalties, rents, or bonuses on Federal leases or Indian leases.

BIA means the Bureau of Indian Affairs of the Department of the Interior.

BLM means the Bureau of Land Management of the Department of the Interior.


BSEE means the Bureau of Safety and Environmental Enforcement of the Department of the Interior.

Coal means coal of all ranks from lignite through anthracite.

Coal washing means any treatment to remove impurities from coal. Coal washing may include, but is not limited to, operations, such as flotation, air, water, or heavy media separation; drying; and related handling (or combination thereof).

Compression means the process of raising the pressure of gas.

Condensate means liquid hydrocarbons (normally exceeding 40 degrees of API gravity) recovered at the surface without processing. Condensate
is the mixture of liquid hydrocarbons resulting from condensation of petroleum hydrocarbons existing initially in a gaseous phase in an underground reservoir.

**Constraint** means a reduction in, or elimination of, gas flow, deliveries, or sales required by the delivery system.

**Contract** means any oral or written agreement, including amendments or revisions, between two or more persons, that is enforceable by law and that, with due consideration, creates an obligation.

**Designee** means the person whom the lessee designates to report and pay the lessee's royalties for a lease.

**Exchange agreement** means an agreement where one person agrees to deliver oil to another person at a specified location in exchange for oil deliveries at another location. Exchange agreements may or may not specify prices for the oil involved. They frequently specify dollar amounts reflecting location, quality, or other differentials. Exchange agreements include buy/sell agreements, which specify prices to be paid at each exchange point and may appear to be two separate sales within the same agreement. Examples of other types of exchange agreements include, but are not limited to, exchanges of produced oil for specific types of crude oil (such as West Texas Intermediate); exchanges of produced oil for other crude oil at other locations (Location Trades); exchanges of produced oil for other grades of oil (Grade Trades); and multi-party exchanges.

**FERC** means Federal Energy Regulatory Commission.

**Field** means a geographic region situated over one or more subsurface oil and gas reservoirs and encompassing at least the outermost boundaries of all oil and gas accumulations known within those reservoirs, vertically projected to the land surface. State oil and gas regulatory agencies usually name onshore fields and designate their official boundaries. BOEM names and designates boundaries of OCS fields.

**Gas** means any fluid, either combustible or non-combustible, hydrocarbon or non-hydrocarbon, which is extracted from a reservoir and which has neither independent shape nor volume, but tends to expand indefinitely. It is a substance that exists in a gaseous or rarefied state under standard temperature and pressure conditions.

**Gas plant products** means separate marketable elements, compounds, or mixtures, whether in liquid, gaseous, or solid form, resulting from processing gas, excluding residue gas.

**Gathering** means the movement of lease production to a central accumulation or treatment point on the lease, unit, or communitized area, or to a central accumulation or treatment point off of the lease, unit, or communitized area that BLM or BSEE approves for onshore and offshore leases, respectively. Excluded from this definition is the movement of bulk production from a wellhead to an offshore platform which may, for valuation purposes, be considered a function for which a Transportation Allowance is properly taken pursuant to § 1206.110(a)(1).

**Geographic region** means, for Federal gas, an area at least as large as the defined limits of an oil and/or gas field in which oil and/or gas lease products have similar quality and economic characteristics.

**Gross proceeds** means the total monies and other consideration accruing for the disposition of any of the following:

1. **Oil**. Gross proceeds also include, but are not limited to, the following examples:
   - Payments for services such as dehydration, marketing, measurement, or gathering which the lessee must perform at no cost to the Federal Government
   - The value of services, such as salt water disposal, that the producer normally performs but that the buyer performs on the producer's behalf
   - Reimbursements for harbor fees, royalties, and any other reimbursements
   - Tax reimbursements, even though the Federal royalty interest may be exempt from taxation
   - Payments made to reduce or buy down the purchase price of oil produced in later periods by allocating such payments over the production whose price that the payment reduces and including the allocated amounts as proceeds for the production as it occurs
   - Monies and all other consideration to which a seller is contractually or legally entitled, but does not seek to collect through reasonable efforts
   - Monies and all other consideration to which a seller is contractually or legally entitled, but does not seek to collect through reasonable efforts

2. **Gas, residue gas, and gas plant products**. Gross proceeds also include, but are not limited to, the following examples:
   - Payments for services such as dehydration, marketing, measurement, or gathering that the lessee must perform at no cost to the Federal Government
   - Reimbursements for royalties, fees, and any other reimbursements

3. **Coal**. Gross proceeds also include, but are not limited to, the following examples:
   - Payments for services such as crushing, sizing, screening, storing, mixing, loading, treatment with substances including chemicals or oil, and other preparation of the coal that the lessee must perform at no cost to the Federal Government or Indian lessor
   - Reimbursements for royalties, fees, and any other reimbursements

FDRF means any Indian for whom minerals or interest in minerals are held in trust by the United States or who holds title by the United States or who holds title subject to Federal restriction against alienation.

**Indian Tribe** means any Indian Tribe, band, nation, pueblo, community, rancheria, colony, or other group of Indians for which any minerals or interest in minerals is held in trust by the United States or is subject to Federal restriction against alienation.

**Keep whole contract** means a processing agreement under which the processor delivers to the lessee a quantity of gas after processing that is equivalent to the quantity of gas that the processor received from the lessee prior to processing, normally based on heat.

**Index pricing point** means any point on a pipeline for which there is an index, which ONRR-approved publications may refer to as a trading location.

**Index zone** means a field or an area with an active spot market and published indices applicable to that field or an area that is acceptable to ONRR under § 1206.141(d)(1).


**Price** means any point on a pipeline for which there is an index, which ONRR-approved publications may refer to as a trading location.

**Royalty** means any oral or written agreement, including amendments or revisions, between two or more persons, that is enforceable by law and that, with due consideration, creates an obligation.

**Specified location** means the equivalent to the quantity of gas that the processor delivers to the lessee a quantity of gas after processing that is equivalent to the quantity of gas that the processor received from the lessee prior to processing, normally based on heat.

**Transportation agreement** means any oral or written agreement, including amendments or revisions, between two or more persons, that is enforceable by law and that, with due consideration, creates an obligation.

**Valuation** means any oral or written agreement, including amendments or revisions, between two or more persons, that is enforceable by law and that, with due consideration, creates an obligation.

**Volume** means any point on a pipeline for which there is an index, which ONRR-approved publications may refer to as a trading location.
content, less gas used as plant fuel and gas unaccounted for and/or lost. This includes, but is not limited to, agreements under which the processor retains all NGLs that it recovered from the lessee’s gas.

*Lease* means any contract, profit-sharing arrangement, joint venture, or other agreement issued or approved by the United States under any mineral leasing law, including the Indian Mineral Development Act, 25 U.S.C. 2101–2108, that authorizes exploration for, extraction of, or removal of lease products. Depending on the context, lease may also refer to the land area that the authorization covers.

*Lease products* mean any leased minerals, attributable from, or allocated to a lease or produced in association with a lease.

*Lessee* means any person to whom the United States, an Indian Tribe, and/or Individual Indian minerlal owner issues a lease, and any person who has been assigned all or a part of record title, operating rights, or an obligation to make royalty or other payments required by the lease. Lessee includes:

1. Any person who has an interest in a lease.
2. In the case of leases for Indian coal or Federal coal, an operator, payor, or other person with no lease interest who makes royalty payments on the lessee’s behalf.

*Like quality* means similar chemical and physical characteristics.

*Location differential* means an amount paid or received (whether in money or in barrels of oil) under an exchange agreement that results from differences in location between oil delivered in exchange and oil received in the exchange. A location differential may represent all or part of the difference between the price received for oil delivered and the price paid for oil received under a buy/sell exchange agreement.

*Market center* means a major point that ONRR recognizes for oil sales, refining, or transshipment. Market centers generally are locations where ONRR-approved publications publish oil spot prices.

*Marketable condition* means lease products which are sufficiently free from impurities and otherwise in a condition that they will be accepted by a purchaser under a sales contract, typical for the field or area for Federal oil and gas, and region for Federal and Indian coal.

*Mine* means an underground or surface excavation or series of excavations or the surface or underground support facilities that contribute directly or indirectly to mining, production, preparation, and handling of lease products.

*Net output* means the quantity of:

1. For gas, residue gas and each gas plant product that a processing plant produces.
2. For coal, the quantity of washed coal that a coal wash plant produces.

*Netting* means reducing the reported sales value to account for an allowance instead of reporting the allowance as a separate entry on the Report of Sales and Royalty Remittance (Form ONRR–2014) or the Solid Minerals Production and Royalty Report (Form ONRR–4430).

*NGLs* means Natural Gas Liquids.

*NYMEX price* means the average of the New York Mercantile Exchange (NYMEX) settlement prices for light sweet crude oil delivered at Cushing, Oklahoma, calculated as follows:

1. First, sum the prices published for each day during the calendar month of production (excluding weekends and holidays) for oil to be delivered in the prompt month corresponding to each such day.
2. Second, divide the sum by the number of days on which those prices are published (excluding weekends and holidays).

*Oil* means a mixture of hydrocarbons that existed in the liquid phase in natural underground reservoirs, remains liquid at atmospheric pressure after passing through surface separating facilities, and is marketed or used as a liquid. Condensate recovered in lease separators or field facilities is oil.

*ONRR* means the Office of Natural Resources Revenue of the Department of the Interior.

*ONRR-approved commercial price bulletin* means a publication that ONRR approves for determining NGLs prices.

*ONRR-approved publication* means:

1. For oil, a publication that ONRR approves for determining ANS spot prices or WTI differentials.
2. For gas, a publication that ONRR approves for determining index pricing points.

*Outer Continental Shelf (OCS)* means all submerged lands lying seaward and outside of the area of lands beneath navigable waters, as defined in Section 2 of the Submerged Lands Act (43 U.S.C. 1301), and of which the subsoil and seabed appertain to the United States and are subject to its jurisdiction and control.

*Payor* means any person who reports and pays royalties under a lease, regardless of whether that person also is a lessee.

*Person* means any individual, firm, corporation, association, partnership, consortium, or joint venture (when established as a separate entity).

*Processing* means any process designed to remove elements or compounds (hydrocarbon and non-hydrocarbon) from gas, including absorption, adsorption, or refrigeration. Field processes which normally take place on or near the lease, such as natural pressure reduction, mechanical separation, heating, cooling, dehydration, and compression, are not considered processing. The changing of pressures and/or temperatures in a reservoir is not considered processing. The use of a Joule-Thomson (JT) unit to remove NGLs from gas is considered processing regardless of where the JT unit is located, provided that you market the NGLs as NGLs.

*Processing allowance* means a deduction in determining royalty value for the reasonable, actual costs the lessee incurs for processing gas.

*Prompt month* means the nearest month of delivery for which NYMEX futures prices are published during the trading month.

*Quality differential* means an amount paid or received under an exchange agreement (whether in money or in barrels of oil) that results from differences in API gravity, sulfur content, viscosity, metals content, and other quality factors between oil delivered and oil received in the exchange. A quality differential may represent all or part of the difference between the price received for oil delivered and the price paid for oil received under a buy/sell agreement.

*Region for coal* means the eight Federal coal production regions, which the Bureau of Land Management designates as follows: Denver-Raton Mesa Region, Fort Union Region, Green River-Hams Fork Region, Powder River Region, San Juan River Region, Southern Appalachian Region, Uinta-Southwestern Utah Region, and Western Interior Region. See 44 FR 65197 (1979).

*Residue gas* means that hydrocarbon gas consisting principally of methane resulting from processing gas.

*Rocky Mountain Region* means the States of Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming, except for those portions of the San Juan Basin and other oil-producing fields in the “Four Corners” area that lie within Colorado and Utah.

*Roll* means an adjustment to the NYMEX price that is calculated as follows:

\[ R = 0.6667 \times (P_0 - P_1) + 0.3333 \times (P_0 - P_2), \]

where \( P_0 \) = the average of the daily NYMEX settlement prices for deliveries during the prompt month that is the same as the month of production, as
published for each day during the trading month for which the month of production is the prompt month; \( P_1 \) is the average of the daily NYMEX settlement prices for deliveries during the month following the month of production, published for each day during the trading month for which the month of production is the prompt month; and \( P_2 \) is the average of the daily NYMEX settlement prices for deliveries during the second month following the month of production, as published for each day during the trading month for which the month of production is the prompt month. Calculate the average of the daily NYMEX settlement prices using only the days on which such prices are published (excluding weekends and holidays).

(1) Example 1. Prices in Out Months are Lower Going Forward: The month of production for which you must determine royalty value is December. December was the prompt month (for year 2011) from October 21 through November 18. January was the first month following the month of production, and February was the second month following the month of production. \( P_0 \), therefore, is the average of the daily NYMEX settlement prices for deliveries during December published for each business day between October 21 and November 18. \( P_1 \) is the average of the daily NYMEX settlement prices for deliveries during January published for each business day between October 21 and November 18. \( P_2 \) is the average of the daily NYMEX settlement prices for deliveries during February published for each business day between October 21 and November 18. In this example, assume that \( P_0 = $91.28 \) per bbl, \( P_1 = $91.65 \) per bbl, and \( P_2 = $92.10 \) per bbl. In this example (a rising market), Roll = \( .6667 \times (\$91.28 - \$91.65) + .3333 \times (\$91.28 - \$92.10) = (\$0.25) + (\$0.07) = (\$0.32) \). You add this negative number to the NYMEX price (effectively, a subtraction from the NYMEX price).

**Sale** means a contract between two persons where:
(1) The seller unconditionally transfers title to the oil, gas, gas plant product, or coal to the buyer and does not retain any related rights, such as the right to buy back similar quantities of oil, gas, gas plant product, or coal from the buyer elsewhere;
(2) The buyer pays money or other consideration for the oil, gas, gas plant product, or coal; and
(3) The parties’ intent is for a sale of the oil, gas, gas plant product, or coal to occur.

**Section 6 lease** means an OCS lease subject to section 6 of the Outer Continental Shelf Lands Act, as amended, 43 U.S.C. 1335.

**Short ton** means 2,000 pounds.

**Spot price** means the price under a spot sales contract where:
(1) A seller agrees to sell to a buyer a specified amount of oil at a specified price over a specified period of short duration.
(2) No cancellation notice is required to terminate the sales agreement.
(3) There is no obligation or implied intent to continue to sell in subsequent periods.

**Tonnage** means tons of coal measured in short tons.

**Trading month** means the period extending from the second business day before the 25th day of the second calendar month preceding the delivery month (or, if the 25th day of that month is a non-business day, the second business day before the last business day preceding the 25th day of that month) through the third business day before the 25th day of the calendar month preceding the delivery month (or, if the 25th day of that month is a non-business day, the third business day before the last business day preceding the 25th day of that month), unless the NYMEX publishes a different definition or different dates on its official website, www.cmegroup.com, in which case, the NYMEX definition will apply.

**Transportation allowance** means a deduction in determining royalty value for the reasonable, actual costs that the lessee incurs for moving:
(1) Oil to a point of sale or delivery off of the lease, unit area, or communitized area. The transportation allowance does not include gathering costs.
(2) Unprocessed gas, residue gas, or gas plant products to a point of sale or delivery off of the lease, unit area, or communitized area, or away from a processing plant. The transportation allowance does not include gathering costs.
(3) Coal to a point of sale remote from the mine or wash plant.

**Washing allowance** means a deduction in determining royalty value for the reasonable, actual costs the lessee incurs for coal washing.

**WTI differential** means the average of the daily mean differentials for location and quality between a grade of crude oil at a market center and West Texas Intermediate (WTI) crude oil at Cushing published for each day for which price publications perform surveys for deliveries during the production month, calculated over the number of days on which those differentials are published (excluding weekends and holidays). Calculate the daily mean differentials by averaging the daily high and low differentials for the month in the selected publication. Use only the daily differentials and corresponding differentials for which such differentials are published.

Subpart C—Federal Oil

3. Revise § 1206.101 to read as follows:

§ 1206.101 How do I calculate royalty value for oil I or my affiliate sell(s) under an arm’s-length contract?

(a) The value of oil under this section for royalty purposes is the gross proceeds accruing to you or your affiliate under the arm’s-length contract less applicable allowances determined under § 1206.111 or 1206.112. This value does not apply if you exercise an option to use a different value provided in paragraph (c)(1) or (c)(2)(i) of this section, or if one of the exceptions in paragraph (d) of this section applies. You must use this paragraph (a) to value oil when:
(1) You sell under an arm’s-length sales contract; or
(2) You sell or transfer to your affiliate or another person under a non-arm’s-length contract and that affiliate or person, or another affiliate of either of them, then sells the oil under an arm’s-length contract, unless you exercise the
option provided in paragraph (c)(2)(i) of this section.

(b) If you have multiple arm’s-length contracts to sell oil produced from a lease that is valued under paragraph (a) of this section, the value of the oil is the volume-weighted average of the values established under this section for each contract for the sale of oil produced from that lease.

(c)(1) If you enter into an arm’s-length exchange agreement, or multiple sequential arm’s-length exchange agreements, and following the exchange(s) that you or your affiliate sell(s) the oil received in the exchange(s) under an arm’s-length contract, then you may use either paragraph (a) of this section or § 1206.102 to value your production for royalty purposes. If you fail to make the election required under this paragraph, you may not make a retroactive election.

(i) If you use paragraph (a) of this section, your gross proceeds are the gross proceeds under your or your affiliate’s arm’s-length sales contract after the exchange(s) occur(s). You must adjust your gross proceeds for any location or quality differential, or other adjustments, that you received or paid under the arm’s-length exchange agreement(s). If ONRR determines that any arm’s-length exchange agreement does not reflect reasonable location or quality differentials, ONRR may require you to value the oil under § 1206.102. You may not otherwise use the price or differential specified in an arm’s-length exchange agreement to value your production.

(ii) When you elect under § 1206.101(c)(1) to use paragraph (a) of this section or § 1206.102, you must make the same election for all of your production from the same unit, communitization agreement, or lease (if the lease is not part of a unit or communitization agreement) sold under arm’s-length contracts following arm’s-length exchange agreements. You may not change your election more often than once every two years.

(2) If you sell or transfer your oil production to your affiliate, and that affiliate or another affiliate then sells the oil under an arm’s-length contract, you may use either paragraph (a) of this section or § 1206.102 to value your production for royalty purposes.

(ii) When you elect under paragraph (c)(2)(i) of this section to use paragraph (a) of this section or § 1206.102, you must make the same election for all of your production from the same unit, communitization agreement, or lease (if the lease is not part of a unit or communitization agreement) that your affiliates resell at arm’s-length. You may not change your election more often than once every two years.

(d) This paragraph contains exceptions to the valuation rule in paragraph (a) of this section. Apply these exceptions on an individual contract basis.

(1) In conducting reviews and audits, if ONRR determines that any arm’s-length sales contract does not reflect the total consideration actually transferred either directly or indirectly from the buyer to the seller, ONRR may require that you value the oil sold under that contract either under § 1206.102 or at the total consideration received.

(2) You must value the oil under § 1206.102 if ONRR determines that the value under paragraph (a) of this section does not reflect the reasonable value of the production due to either:

(i) Misconduct by or between the parties to the arm’s-length contract; or

(ii) Breach of your duty to market the oil for the mutual benefit of yourself and the lessor.

4. Revise § 1206.102 to read as follows:

§ 1206.102 How do I value oil not sold under an arm’s-length contract?

This section explains how to value oil that you may not value under § 1206.101 or that you elect under § 1206.101(c)(1) to value under this section. First, determine if paragraph (a), (b), or (c) of this section applies to production from your lease, or if you may apply paragraph (d) or (e) with ONRR’s approval.

(a) Production from leases in California or Alaska. Value is the average of the daily mean ANS spot prices published in any ONRR-approved publication during the trading month most concurrent with the production month. For example, if the production month is June, calculate the average of the daily mean prices using the daily ANS spot prices published in the ONRR-approved publication for all of the business days in June.

(1) To calculate the daily mean spot price, you must average the daily high and low prices for the month in the selected publication.

(2) You must use only the days and corresponding spot prices for which such prices are published.

(3) You must adjust the value for applicable location and quality differentials, and you may adjust it for transportation costs, under § 1206.111.

(4) After you select an ONRR-approved publication, you may not select a different publication more often than once every two years, unless the publication you use is no longer published or ONRR revokes its approval of the publication. If you must change publications, you must begin a new two-year period.

(b) Production from leases in the Rocky Mountain Region. This paragraph provides methods and options for valuing your production under different factual situations. You must consistently apply paragraph (b)(2) or (3) of this section to value all of your production from the same unit, communitization agreement, or lease (if the lease or a portion of the lease is not part of a unit or communitization agreement) that you cannot value under § 1206.101 or that you elect under § 1206.101(c)(1) to value under this section.

(1) You may elect to value your oil under either paragraph (b)(2) or (3) of this section. After you select either paragraph (b)(2) or (3) of this section, you may not change to the other method more often than once every two years, unless the method you have been using is no longer applicable and you must apply the other paragraph. If you change methods, you must begin a new two-year period.

(2) Value is the volume-weighted average of the gross proceeds accruing to the seller under your or your affiliate’s arm’s-length contracts for the purchase or sale of production from the field or area during the production month.

(i) The total volume purchased or sold under those contracts must exceed 50 percent of your and your affiliate’s production from both Federal and non-Federal leases in the same field or area during that month.

(ii) Before calculating the volume-weighted average, you must normalize the quality of the oil in your or your affiliate’s arm’s-length purchases or sales to the same gravity as that of the oil produced from the lease.

(3) Value is the NYMEX price (without the roll), adjusted for applicable location and quality differentials and transportation costs under § 1206.113.

(4) If you demonstrate to ONRR’s satisfaction that paragraphs (b)(2) through (3) of this section result in an unreasonable value for your production as a result of circumstances regarding that production, ONRR’s Director may establish an alternative valuation method.

(c) Production from leases not located in California, Alaska, or the Rocky Mountain Region. (1) Value is the NYMEX price, plus the roll, adjusted for applicable location and quality differentials and transportation costs under § 1206.113.
(2) If ONRR’s Director determines that the use of the roll no longer reflects prevailing industry practice in crude oil sales contracts or that the most common formula that industry uses to calculate the roll changes, ONRR may terminate or modify the use of the roll under paragraph (c)(1) of this section at the end of each two-year period as of January 1, 2017, through a notice published in the Federal Register not later than 60 days before the end of the two-year period. ONRR will explain the rationale for terminating or modifying the use of the roll in this notice.

(d) Unreasonable value. If ONRR determines that the NYMEX price or ANS spot price does not represent a reasonable royalty value in any particular case, ONRR may establish a reasonable royalty value based on other relevant matters.

(e) Production delivered to your refinery and the NYMEX price or ANS spot price is an unreasonable value. (1) Instead of valuing your production under paragraph (a), (b), or (c) of this section, you may apply to ONRR to establish a value representing the market at the refinery if:

(i) You transport your oil directly to your or your affiliate’s refinery, or exchange your oil for oil delivered to your or your affiliate’s refinery; and

(ii) You must value your oil under this section at the NYMEX price or ANS spot price; and

(iii) You believe that use of the NYMEX price or ANS spot price results in an unreasonable royalty value.

(2) You must provide adequate documentation and evidence demonstrating the market value at the refinery. That evidence may include, but is not limited to:

(i) Costs of acquiring other crude oil at or for the refinery;

(ii) How adjustments for quality, location, and transportation were factored into the price paid for other oil;

(iii) Volumes acquired for and refined at the refinery; and

(iv) Any other appropriate evidence or documentation that ONRR requires.

(3) If ONRR establishes a value representing market value at the refinery, you may not take an allowance representing market value at the refinery; and

(b) You may take any additional royalties due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter, or request a refund of—any overpaid royalties.

(2) ONRR may examine whether your or your affiliate’s contract reflects the total consideration transferred for Federal oil, either directly or indirectly, from the buyer to you or your affiliate. If ONRR determines that additional consideration beyond that reflected in the contract was transferred, or that any portion of the consideration was not included in gross proceeds reported, ONRR may establish a reasonable royalty value based on other relevant matters.

(c) ONRR may establish a reasonable royalty value based on other relevant matters if ONRR determines that the gross proceeds accruing to you or your affiliate under a contract do not reflect reasonable consideration because:

(1) There is misconduct by or between the contracting parties;

(2) You have breached your duty to market the oil for the mutual benefit of yourself and the lessor; or

(3) ONRR cannot determine if you properly valued your oil under § 1206.101 or § 1206.102 for any reason including—but not limited to—you or your affiliate’s failure to provide documents that ONRR requests under 30 CFR part 1212, subpart B.

(d) You have the burden of demonstrating that your or your affiliate’s contract is arm’s-length.

(e) ONRR may require you to certify that the provisions in your or your affiliate’s contract include all of the consideration that the buyer paid to you or your affiliate, either directly or indirectly, for the oil.

(f)(1) Absent contract revision or amendment, if you or your affiliate fail(s) to take proper or timely action to receive prices or benefits to which you or your affiliate are entitled, you must pay royalty based upon that obtainable price or benefit.

(2) If you or your affiliate apply in a timely manner for a price increase or benefit allowed under your or your affiliate’s contract, but the purchaser refuses and you or your affiliate take reasonable documented measures to force purchaser compliance, you will not owe additional royalties unless or until you or your affiliate receive additional money or consideration resulting from the price increase. You may not construe this paragraph to permit you to avoid your royalty payment obligation in situations where a purchaser fails to pay, in whole or in part or in a timely manner, for a quantity of oil.

(g)(1) You or your affiliate must put all contracts, contract revisions, or amendments in writing.

(2) If you or your affiliate fail(s) to comply with paragraph (g)(1) of this section, ONRR may establish a reasonable royalty value based on other relevant matters.

(3) This provision applies notwithstanding any other provisions in this title 30 to the contrary.

5. Revise § 1206.104 to read as follows:

§ 1206.104 How will ONRR determine if my royalty payments are correct?

(a) ONRR may monitor, review, and audit the royalties that you report, and, if ONRR determines that your reported value is inconsistent with the requirements of this subpart, ONRR may establish a reasonable royalty value based on other relevant matters.

(2) If ONRR directs you to use a different royalty value, you must either pay any additional royalties due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter, or request a refund of—any overpaid royalties.

(b) ONRR may examine whether your or your affiliate’s contract reflects the total consideration transferred for Federal oil, either directly or indirectly, from the buyer to you or your affiliate. If ONRR determines that additional consideration beyond that reflected in the contract was transferred, or that any portion of the consideration was not included in gross proceeds reported, ONRR may establish a reasonable royalty value based on other relevant matters.

(c) ONRR may establish a reasonable royalty value based on other relevant matters if ONRR determines that the gross proceeds accruing to you or your affiliate under a contract do not reflect reasonable consideration because:

(1) There is misconduct by or between the contracting parties;

(2) You have breached your duty to market the oil for the mutual benefit of yourself and the lessor; or

(3) ONRR cannot determine if you properly valued your oil under § 1206.101 or § 1206.102 for any reason including—but not limited to—you or your affiliate’s failure to provide documents that ONRR requests under 30 CFR part 1212, subpart B.

(d) You have the burden of demonstrating that your or your affiliate’s contract is arm’s-length.

(e) ONRR may require you to certify that the provisions in your or your affiliate’s contract include all of the consideration that the buyer paid to you or your affiliate, either directly or indirectly, for the oil.

(f)(1) Absent contract revision or amendment, if you or your affiliate fail(s) to take proper or timely action to receive prices or benefits to which you or your affiliate are entitled, you must pay royalty based upon that obtainable price or benefit.

(2) If you or your affiliate apply in a timely manner for a price increase or benefit allowed under your or your affiliate’s contract, but the purchaser refuses and you or your affiliate take reasonable documented measures to force purchaser compliance, you will not owe additional royalties unless or until you or your affiliate receive additional money or consideration resulting from the price increase. You may not construe this paragraph to permit you to avoid your royalty payment obligation in situations where a purchaser fails to pay, in whole or in part or in a timely manner, for a quantity of oil.

(g)(1) You or your affiliate must put all contracts, contract revisions, or amendments in writing.

(2) If you or your affiliate fail(s) to comply with paragraph (g)(1) of this section, ONRR may establish a reasonable royalty value based on other relevant matters.

(3) This provision applies notwithstanding any other provisions in this title 30 to the contrary.

6. Remove and reserve § 1206.105.

§ 1206.105 [Reserved]

7. Revise § 1206.108 to read as follows:

§ 1206.108 How do I request a valuation determination?

(a) You may request a valuation determination from ONRR regarding any oil produced. Your request must comply with all of the following:

(1) Be in writing.

(2) Identify, specifically, all leases involved, all interest owners of those leases, the designee(s), and the operator(s) for those leases.

(3) Completely explain all relevant facts; you must inform ONRR of any changes to relevant facts that occur before we respond to your request.

(4) Include copies of all relevant documents.

(5) Provide your analysis of the issue(s).

(6) Suggest your proposed valuation method.

(b) In response to your request, ONRR may:

(1) Request that the Assistant Secretary for Policy, Management, and Budget issue a valuation determination;

(2) Decide that ONRR will issue guidance; or

(3) Inform you in writing that ONRR will not provide a determination or guidance. Situations in which ONRR typically will not provide any determination or guidance include, but are not limited to, the following:

(i) Requests for guidance on hypothetical situations.

(ii) Matters that are the subject of pending litigation or administrative appeals.

(c)(1) A valuation determination that the Assistant Secretary for Policy, Management and Budget signs is binding on both you and ONRR until the Assistant Secretary modifies or rescinds it.

(2) After the Assistant Secretary for Policy, Management and Budget issues
a valuation determination, you must make any adjustments to royalty payments that follow from the determination and, if you owe additional royalties, you must pay the additional royalties due, plus late payment interest calculated under §§1218.54 and 1218.102 of this chapter.

(3) A valuation determination that the Assistant Secretary for Policy, Management and Budget signs is the final action of the Department and is subject to judicial review under 5 U.S.C. 701–706.

(d) Guidance that ONRR issues is not binding on ONRR, delegated States, or you with respect to the specific situation addressed in the guidance.

(1) Guidance and ONRR’s decision whether or not to issue guidance or request an Assistant Secretary for Policy, Management and Budget determination, or neither, under paragraph (b) of this section, are not appealable decisions or orders under 30 CFR part 1290.

(e) ONRR or the Assistant Secretary for Policy, Management and Budget may use any of the applicable valuation criteria in this subpart to provide guidance or to make a determination.

(f) A change in an applicable statute or regulation on which ONRR or the Assistant Secretary for Policy, Management and Budget based any determination or guidance takes precedence over the determination or guidance, regardless of whether ONRR or the Assistant Secretary modifies or rescinds the determination or guidance.

(g) ONRR or the Assistant Secretary for Policy, Management and Budget generally will not retroactively modify or rescind a valuation determination issued under paragraph (d) of this section, unless:

(1) There was a misstatement or omission of material facts; or

(2) The facts subsequently developed are materially different from the facts on which the guidance was based.

(h) ONRR may make requests and replies under this section available to the public, subject to the confidentiality requirements under §1206.109.

§ 1206.110 What general transportation allowance requirements apply to me?

(a) ONRR will allow a deduction for the reasonable, actual costs to transport oil from the lease to the point off of the lease under §§1206.110, 1206.111, or 1206.112, as applicable. You may not deduct transportation costs that you incur to move a particular volume of production to reduce royalties that you owe on production for which you did not incur those costs. This paragraph applies when:

(1) The movement to the sales point is not gathering except

(2) For oil produced on the OCS in waters deeper than 200 meters, the movement of oil from the wellhead to the first platform is transportation for which a transportation allowance may be claimed; and

(3) On a case-by-case basis, you may apply to ONRR to have your actual, reasonable and necessary costs of the movement of oil produced on the OCS in waters shallower than 200 meters from the wellhead to the first platform to be treated as transportation for which a transportation allowance may be claimed.

(2) You value oil under §1206.101 based on a sale at a point off of the lease, unit, or communitized area where the oil is produced; or

(3) You do not value your oil under §1206.102(a)(3) or (b)(3).

(b) You must calculate the deduction for transportation costs based on your or your affiliate’s cost of transporting each product through each individual transportation system. If your or your affiliate’s transportation contract includes more than one liquid product, you must allocate costs consistently and equitably to each of the liquid products that are transported. Your allocation must use the same proportion as the ratio of the volume of each liquid product (excluding waste products with no value) to the volume of all liquid products (excluding waste products with no value).

(1) You may not take an allowance for transporting lease production that is not royalty-bearing.

(2) You may propose to ONRR a prospective cost allocation method based on the values of the liquid products transported. ONRR will approve the method if it is consistent with the purposes of the regulations in this subpart.

(3) You may use your proposed procedure to calculate a transportation allowance beginning with the production month following the month when ONRR received your proposed procedure until ONRR accepts or rejects your cost allocation. If ONRR rejects your cost allocation, you must amend your Form ONRR–2014 for the months that you used the rejected method and pay any additional royalty and interest due.

(c) You may use your proposed procedure to calculate a transportation allowance until ONRR accepts or rejects your cost allocation. If ONRR rejects your cost allocation, you must amend your Form ONRR–2014 for the months when you used the rejected method and pay any additional royalty and interest due.

(3) You must submit your initial proposal, including all available data, within three months after you first claim the allocated deductions on Form ONRR–2014.

(d)(1) Your transportation allowance may not exceed 50 percent of the value of the oil, as determined under §1206.101, except as provided in paragraph (d)(2) of this section.

(2) You may ask ONRR to approve a transportation allowance in excess of the limitation in paragraph (d)(1) of this section. You must demonstrate that the transportation costs incurred were reasonable, actual, and necessary. Your application for exception (using Form ONRR–4393, Request to Exceed Regulatory Allowance Limitation) must contain all relevant and supporting documentation necessary for ONRR to make a determination. You may never reduce the royalty value of any production to zero.

(e) You must express transportation allowances for oil as a dollar-value equivalent. If your or your affiliate’s payment for transportation under a contract are not on a dollar-per-unit basis, you must convert whatever consideration you or your affiliate are paid to a dollar-value equivalent.

(f) ONRR may direct you to modify your transportation allowance if:

(1) There is misconduct by or between the contracting parties;

(2) ONRR determines that the consideration that you or your affiliate paid under an arm’s-length transportation contract does not reflect the reasonable cost of the transportation because you breached your duty to market the oil for the mutual benefit of yourself and the lessor by transporting your oil at a cost that is unreasonably high; or

(3) ONRR cannot determine if you properly calculated a transportation allowance under §1206.111 or 1206.112 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents that ONRR requests under 30 CFR part 1212, subpart B.
You do not need ONRR's approval before reporting a transportation allowance.

9. Revise §1206.111 to read as follows:

§1206.111 How do I determine a transportation allowance if I have an arm’s-length transportation contract?

(a)(1) If you or your affiliate incur transportation costs under an arm’s-length transportation contract, you may claim a transportation allowance for the reasonable, actual costs incurred, as stated in paragraph (b) of this section, except as provided in §1206.110(f) and subject to the limitation in §1206.110(d).

(2) You must be able to demonstrate that your or your affiliate’s contract is at arm’s length.

(b) Subject to the requirements of paragraph (c) of this section, you may include, but are not limited to, the following costs to determine your transportation allowance under paragraph (a) of this section:

(1) The amount that you pay under your arm’s-length transportation contract or tariff.

(2) Fees paid (either in volume or in value) for actual or theoretical line losses.

(3) Fees paid for administration of a quality bank.

(4) Fees paid to a terminal operator for loading and unloading of crude oil into or from a vessel, vehicle, pipeline, or other conveyance.

(5) Fees paid for short-term storage (30 days or less) incidental to transportation as a transporter requires.

(6) Fees paid to pump oil to another carrier’s system or vehicles as required under a tariff.

(7) Transfer fees paid to a hub operator associated with physical movement of crude oil through the hub when you do not sell the oil at the hub. These fees do not include title transfer fees.

(8) Payments for a volumetric deduction to cover shrinkage when high-gravity petroleum (generally in excess of 51 degrees API) is mixed with lower gravity crude oil for transportation.

(9) Costs of securing a letter of credit, or other surety, that the pipeline requires you, as a shipper, to maintain.

(10) Hurricane surcharges that you or your affiliate actually pay(s).

The cost of carrying on your books as inventory a volume of oil that the pipeline operator requires you, as a shipper, to maintain and that you do maintain in the line as line fill. You must calculate this cost as follows:

(i) First, multiply the volume that the pipeline requires you to maintain—and that you do maintain—in the pipeline by the value of that volume for the current month calculated under §1206.101 or 1206.102, as applicable.

(ii) Second, multiply the value calculated under paragraph (b)(11)(i) of this section by the monthly rate of return, calculated by dividing the rate of return specified in §1206.112(3) by 12.

(c) You may not include any of the following costs to determine your transportation allowance under paragraph (a) of this section:

(1) Fees paid for long-term storage (more than 30 days).

(2) Administrative, handling, and accounting fees associated with terminaling.

(3) Title and terminal transfer fees.

(4) Fees paid to track and match receipts and deliveries at a market center or to avoid paying title transfer fees.

(5) Fees paid to brokers.

(6) Fees paid to a scheduling service provider.

(7) Internal costs, including salaries and related costs, rent/space costs, office equipment costs, legal fees, and other costs to schedule, nominate, and account for sale or movement of production.

(8) Gauging fees.

(d) (1) If you have no written contract for the arm’s-length transportation of oil, you must propose to ONRR a method to determine the allowance using the procedures in §1206.108(a).

(2) You may use that method to determine your allowance until ONRR issues its determination.

10. Revise §1206.117 to read as follows:

§1206.117 What interest and penalties apply if I improperly report a transportation allowance?

(a) If you deduct a transportation allowance on Form ONRR–2014 that exceeds 50 percent of the value of the oil transported without obtaining ONRR’s prior approval under §1206.110(d)(2), you must pay additional royalties due, plus late payment interest calculated under §§1218.54 and 1218.102 of this chapter, on the excess allowance amount taken from the date when that amount is taken to the date when you file an exception request that ONRR approves. If you do not file an exception request, or if ONRR does not approve your request, you must pay late payment interest on the excess allowance amount taken from the date that amount is taken until the date you pay the additional royalties owed.

(b) If you improperly net a transportation allowance against the oil instead of reporting the allowance as a separate entry on Form ONRR–2014, ONRR may assess a civil penalty under 30 CFR part 1241.

Subpart D—Federal Gas

11. Revise §1206.141 to read as follows:

§1206.141 How do I calculate royalty value for unprocessed gas that I or my affiliate sell(s) under an arm’s-length or non-arm’s-length contract?

(a) This section applies to unprocessed gas. Unprocessed gas is:

(1) Gas that is not processed;

(2) Any gas that you are not required to value under §1206.142;

(3) Any gas that you sell prior to processing based on a price per MMBtu or Mcf when the price is not based on the residue gas and gas plant products.

(b) The value of gas under this section for royalty purposes is the gross proceeds accruing to you or your affiliate under the first arm’s-length contract less a transportation allowance determined under §1206.152. This value does not apply if you exercise the option in paragraph (c) of this section. Unless you elect to value your gas under paragraph (c) of this section, you must use this paragraph (b) to value gas when:

(1) You sell under an arm’s-length contract;

(2) You sell or transfer unprocessed gas to your affiliate or another person under a non-arm’s-length contract and that affiliate or person, or an affiliate of either of them, then sells the gas under an arm’s-length contract;

(3) You, your affiliate, or another person sell(s) unprocessed gas produced from a lease under multiple arm’s-length contracts, and that gas is valued under this paragraph. The value of the gas is the volume-weighted average of the values, established under this paragraph, for each contract for the sale of gas produced from that lease; or

(4) You or your affiliate sell(s) under a pipeline cash-out program. In that case, for over-delivered volumes within the tolerance under a pipeline cash-out program, the value is the price that the pipeline must pay you or your affiliate under the transportation contract. You must use the same value for volumes that exceed the over-delivery tolerances, even if those volumes are subject to a
lower price under the transportation contract.

(c) Alternatively, you may elect to value your unprocessed gas under this paragraph (c), which allows you to use an index-based valuation method to calculate royalty value. You may not change your election more often than once every two years.

(1)(i) If you can only transport gas to one index pricing point published in an ONRR-approved publication available at www.onrr.gov, your value, for royalty purposes, is the published average bidweek price to which your gas may flow for that respective production month.

(ii) If you can transport gas to more than one index pricing point published in an ONRR-approved publication available at www.onrr.gov, your value, for royalty purposes, is the highest of the published average bidweek prices to which your gas may flow for that respective production month, whether or not there are constraints for that production month.

(iii) If there are sequential index pricing points on a pipeline, you must use the first index pricing point at or after your gas enters the pipeline.

(iv) You may adjust the number calculated under paragraphs (c)(1)(i) and (ii) of this section by reducing the value by 10 percent, but not less than 10 cents per MMBtu nor more than 40 cents per MMBtu for sales from the OCS Gulf of Mexico and by 15 percent, but not less than 10 cents per MMBtu nor more than 50 cents per MMBtu, for sales from all other areas.

(v) After you select an ONRR-approved publication available at www.onrr.gov, you may not select a different publication more often than once every two years.

(vi) ONRR may exclude an individual index pricing point found in an ONRR-approved publication if ONRR determines that the index pricing point does not accurately reflect the values of production. ONRR will publish criteria for index pricing points available at www.onrr.gov.

(2) You may not take any other deductions from the value calculated under this paragraph (c).

(d) If some of your gas is used, lost, unaccounted for, or retained as a fee under the terms of a sales or service agreement, that gas will be valued for royalty purposes using the same royalty valuation method for valuing the rest of the gas that you do sell.

(e) If you have no written contract for the sale of gas or no sale of gas subject to this section and:

- (1) There is an index pricing point for the gas, then you must value your gas under paragraph (c) of this section; or
- (2) There is not an index pricing point for the gas, then:
  - (i) You must propose to ONRR a method to determine the value using the procedures in §1206.148(a).
  - (ii) You may use that method to determine value, for royalty purposes, until ONRR issues its decision.
  - (iii) After ONRR issues its determination, you must make the adjustments under §1206.143(a)(2).
  - (f) Under no circumstances may your gas be valued for royalty purposes at or less than zero.
  - (g) If you elect to value your gas under paragraph (c) of this section, ONRR reserves the right to collect actual transaction data in the future to assess the validity of the index-based valuation option.

12. Revise §1206.142 to read as follows:

§1206.142 How do I calculate royalty value for processed gas that I or my affiliate sell(s) under an arm’s-length or non-arm’s-length contract?

(a) This section applies to the valuation of processed gas, including but not limited to:

- (1) Gas that you or your affiliate do not sell, or otherwise dispose of, under an arm’s-length contract prior to processing.
- (2) Gas where your or your affiliate’s arm’s-length contract for the sale of gas prior to processing provides for payment to be determined on the basis of the value of any products resulting from processing, including residue gas or natural gas liquids.
- (3) Gas that you or your affiliate process under an arm’s-length keepwhole contract.
- (4) Gas where your or your affiliate’s arm’s-length contract includes a reservation of the right to process the gas, and you or your affiliate exercise(s) that right.

(b) The value of gas subject to this section, for royalty purposes, is the combined value of the residue gas and all gas plant products that you determine under this section plus the value of any condensate recovered downstream of the point of royalty settlement without resorting to processing that you determine under subpart C of this part less applicable transportation and processing allowances that you determine under this subpart, unless you exercise the option provided in paragraph (d) of this section.

(c) The value of residue gas or any gas plant product under this section for royalty purposes is the gross proceeds accruing to you or your affiliate under the first arm’s-length contract. This value does not apply if you exercise the option provided in paragraph (d) of this section. Unless you exercise the option provided in paragraph (d) of this section, you must use this paragraph (c) to value residue gas or any gas plant product when:

(1) You sell under an arm’s-length contract;
(2) You sell or transfer to your affiliate or another person under a non-arm’s-length contract, and that affiliate or person, or another affiliate of either of them, then sells the residue gas or any gas plant product under an arm’s-length contract;
(3) Your affiliate, or another person sell(s), under multiple arm’s-length contracts, residue gas or any gas plant products recovered from gas produced from a lease that you value under this paragraph. In that case, because you sold non-arm’s-length to your affiliate or another person, the value of the residue gas or any gas plant product is the volume-weighted average of the gross proceeds established under this paragraph for each arm’s-length contract for the sale of residue gas or any gas plant products recovered from gas produced from that lease; or
(4) You or your affiliate sell(s) under a pipeline cash-out program. In that case, for over-delivered volumes within the tolerance under a pipeline cash-out program, the value is the price that the pipeline must pay to you or your affiliate under the transportation contract. You must use the same value for volumes that exceed the over-delivery tolerances, even if those volumes are subject to a lower price under the transportation contract.

(d) Alternatively, you may elect to value your residue gas and NGLs under this paragraph (d). You may not change your election more often than once every two years.

(1)(i) If you can only transport residue gas to one index pricing point published in an ONRR-approved publication available at www.onrr.gov, your value, for royalty purposes, is the published average bidweek price to which your gas may flow for that respective production month.

(ii) If you can transport residue gas to more than one index pricing point published in an ONRR-approved publication available at www.onrr.gov, your value, for royalty purposes, is the highest of the published average bidweek prices to which your gas may flow for that respective production month, whether or not there are constraints for that production month.
(iii) If there are sequential index pricing points on a pipeline, you must use the first index pricing point at or after your residue gas enters the pipeline.

(iv) You may adjust the number calculated under paragraphs (d)(1)(i) and (ii) of this section by reducing the value by 10 percent, but not less than 10 cents per MMBtu nor more than 40 cents per MMBtu for sales from the OCS Gulf of Mexico and by 15 percent, but not less than 10 cents per MMBtu nor more than 50 cents per MMBtu for sales from all other areas.

(v) After you select an ONRR-approved publication available at www.onrr.gov, you may not select a different publication more often than once every two years.

(vi) ONRR may exclude an individual index pricing point found in an ONRR-approved publication if ONRR determines that the index pricing point does not accurately reflect the values of production. ONRR will publish criteria for index pricing points on www.onrr.gov.

1. (1) If you sell NGLs in an area with one or more ONRR-approved commercial price bulletins available at www.onrr.gov, you must choose one bulletin, and your value, for royalty purposes, is the monthly average price for that bulletin for the production month.

(ii) You must reduce the number calculated under paragraph (d)(2)(i) of this section by the amounts that ONRR posts at www.onrr.gov for the geographic location of your lease. The method that ONRR will use to calculate the amounts is set forth in the preamble to this regulation. This method is binding on you and ONRR. ONRR will update the amounts periodically using this method.

(iii) After you select an ONRR-approved commercial price bulletin available at www.onrr.gov, you must not select a different commercial price bulletin more often than once every two years.

(2) You may not take any other deductions from the value calculated under this paragraph (d).

(4) ONRR will post changes to any of the rates in this paragraph (d) on its website.

(e) If some of your gas or gas plant products are used, lost, unaccounted for, or retained as a fee under the terms of a sales or service agreement, that gas will be valued for royalty purposes using the same royalty valuation method for valuing the rest of the gas or gas plant products that you do sell.

(f) If you have no written contract for the sale of gas or no sale of gas subject to this section and:

(1) There is an index pricing point or commercial price bulletin for the gas, then you must value your gas under paragraph (d) of this section.

(2) There is not an index pricing point or commercial price bulletin for the gas, then:

(i) You must propose to ONRR a method to determine the value using the procedures in §1206.148(a).

(ii) You may use that method to determine value, for royalty purposes, until ONRR issues our decision.

(iii) After ONRR issues our determination, you must make the adjustments under §1206.143(a)(2).

(g) Under no circumstances may your gas be valued for royalty purposes at or less than zero.

(h) If you elect to value your gas under paragraph (d) of this section, ONRR reserves the right to collect actual transaction data in the future to assess the validity of the index-based valuation option.

13. Revise §1206.143 to read as follows:

§1206.143 How will ONRR determine if my royalty payments are correct?

(a)(1) ONRR may monitor, review, and audit the royalties that you report. If ONRR determines that your reported value is inconsistent with the requirements of this subpart, ONRR will direct you to use a different measure of royalty value.

(2) If ONRR directs you to use a different royalty value, you must either pay any additional royalties due, plus late payment interest calculated under §§1218.54 and 1218.102 of this chapter, or report a credit for, or request a refund of, any overpaid royalties.

(b) ONRR may examine whether your or your affiliate’s contract reflects the total consideration transferred for Federal gas, either directly or indirectly, for the gas, residue gas, or gas plant products.

(c) ONRR may examine whether your or your affiliate’s contract is arm’s-length.

(d) You have the burden of demonstrating that your or your affiliate’s contract is arm’s-length.

(e) ONRR may require you to certify that the provisions in your or your affiliate’s contract include(s) all of the consideration that the buyer paid to you or your affiliate, either directly or indirectly, for the gas, residue gas, or gas plant products.

(f)(1) Absent contract revision or amendment, if you or your affiliate fail(s) to take proper or timely action to receive prices or benefits to which you or your affiliate are entitled, you must pay royalty based upon that obtainable price or benefit.

(2) If you or your affiliate make timely application for a price increase or benefit allowed under your or your affiliate’s contract, but the purchaser refuses, you or your affiliate may not construe this paragraph to permit you to avoid your royalty payment obligation in situations where a purchaser fails to pay, in whole or in part, or in a timely manner, for a quantity of gas, residue gas, or gas plant products.

(g)(1) You or your affiliate must make all contracts, contract revisions, or amendments in writing.

(2) If you or your affiliate fail(s) to comply with paragraph (g)(1) of this section, ONRR may direct you to use a different measure of royalty value.

(3) This provision applies notwithstanding any other provisions in this Title 30 to the contrary.

§1206.144 [Reserved]

14. Remove and reserve §1206.144.

15. Revise §1206.148 to read as follows:

§1206.148 How do I request a valuation determination?

(a) You may request a valuation determination from ONRR regarding any gas or gas plant products you sell.

(b) If you have no written contract for the sale of gas or no sale of gas subject to this section and:

(1) Be in writing.

(2) Identify specifically all leases involved, all interest owners of those leases, the designee(s), and the operator(s) for those leases.
(3) Completely explain all relevant facts. You must inform ONRR of any changes to relevant facts that occur before we respond to your request.

(4) Include copies of all relevant documents.

(5) Provide your analysis of the issue(s).

(6) Suggest your proposed valuation method.

(b) In response to your request, ONRR may:

(1) Request that the Assistant Secretary for Policy, Management and Budget issue a determination;

(2) Decide that ONRR will issue guidance; or

(3) Inform you in writing that ONRR will not provide a determination or guidance. Situations in which ONRR typically will not provide any determination or guidance include, but are not limited to:

(i) Requests for guidance on hypothetical situations; or

(ii) Matters that are the subject of pending litigation or administrative appeals.

(c)(1) A determination that the Assistant Secretary for Policy, Management and Budget signs is binding on both you and ONRR until the Assistant Secretary modifies or rescinds it.

(2) After the Assistant Secretary for Policy, Management and Budget issues a determination, you must make any adjustments to royalty payments that follow from the determination, and, if you owe additional royalties, you must pay the additional royalties, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter.

(3) A determination that the Assistant Secretary for Policy, Management and Budget signs is the final action of the Secretary for Policy, Management and Budget based on the values of the products transported. Your allocation must use the same proportion as the ratio of the volume of each product to the volume of all products in the gaseous phase (excluding waste products with no value). Your allocation must consistently and equitably to each of the products transported. If your or your affiliate’s cost of transporting each product through the same transportation system. If your or your affiliate’s transportation contract includes more than one product in a gaseous phase, you must allocate costs consistently and equitably to each of the products transported. Your allocation must use the same proportion as the ratio of the volume of each product (excluding waste products with no value) to the volume of all products in the gaseous phase (excluding waste products with no value).

(1) You may not take an allowance for transporting lease production that is not royalty-bearing.

(2) You may propose to ONRR a prospective cost allocation method based on the values of the products transported. ONRR will approve the method if it is consistent with the purposes of the regulations in this subpart.

(3) You may use your proposed procedure to calculate a transportation allowance beginning with the production month following the month when ONRR received your proposed procedure until ONRR accepts or rejects your cost allocation. If ONRR rejects your cost allocation, you must amend your Form ONRR–2014 for the months when you used the rejected method and pay any additional royalty due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter.

(4) You or your affiliate’s payments for transportation costs incurred in excess of the limitations prescribed in paragraph (e)(1) of this section were reasonable, actual, and necessary. An application for exception (using Form ONRR–4393, Request to Exceed Regulatory Allowance Limitation) must contain all relevant and supporting documentation necessary for ONRR to make a determination. Under no circumstances may the value for royalty purposes under any sales type code be reduced to zero.

(5) You must express transportation allowances for residue gas, gas plant products, or unprocessed gas as a dollar-value equivalent. If your or your affiliate’s payments for transportation under a contract are not on a dollar-per-unit basis, you may consider that you or your affiliate are paid to a dollar-value equivalent.
ONRR may direct you to modify your transportation allowance if:

1. There is misconduct by or between the contracting parties;
2. ONRR determines that the consideration that you or your affiliate paid under an arm’s-length transportation contract does not reflect the reasonable cost of the transportation because you breached your duty to market the gas, residue gas, or gas plant products for the mutual benefit of yourself and the lessor; or
3. ONRR cannot determine if you properly calculated a transportation allowance under § 1206.153 or § 1206.154 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents that ONRR requests under 30 CFR part 1212, subpart B.

You do not need ONRR’s approval before reporting a transportation allowance.

17. Revise § 1206.153 to read as follows:

§ 1206.153 How do I determine a transportation allowance if I have an arm’s-length transportation contract?

(a)(1) If you or your affiliate incur transportation costs under an arm’s-length transportation contract, you may claim a transportation allowance for the reasonable, actual costs incurred, as more fully explained in paragraph (b) of this section, except as provided in § 1206.152(g) and subject to the limitation in § 1206.152(e).

(2) You must be able to demonstrate that your or your affiliate’s contract is arm’s-length.

(b) Subject to the requirements of paragraph (c) of this section, you may include, but are not limited to, the following costs to determine your transportation allowance under paragraph (a) of this section; you may not use any cost as a deduction that duplicates all or part of any other cost that you use under this section:

1. Firm demand charges paid to pipelines. You may deduct firm demand charges or capacity reservation fees that you or your affiliate paid to a pipeline, including charges or fees for unused firm capacity that you or your affiliate have not sold before you report your allowance. If you or your affiliate receive(s) a payment from any party for release or sale of firm capacity after reporting a transportation allowance that included the cost of that unused firm capacity, or if you or your affiliate receive(s) a payment or credit from the pipeline for penalty refunds, rate case refunds, or other reasons, you must reduce the firm demand charge claimed on Form ONRR–2014 by the amount of that payment. You must modify Form ONRR–2014 by the amount received or credited for the affected reporting period and pay any resulting royalty due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter.
2. Gas Supply Realignment (GSR) costs. The GSR costs result from a pipeline reforming or terminating supply contracts with producers in order to implement the restructuring requirements of FERC Orders 18 CFR part 284.
3. Commodity charges. The commodity charge allows the pipeline to recover the costs of providing service.
4. Wheeling costs. Hub operators charge a wheeling cost for transporting gas from one pipeline to either the same or another pipeline through a market center or hub. A hub is a connected manifold of pipelines through which a series of incoming pipelines are interconnected to a series of outgoing pipelines.
5. Gas Research Institute (GRI) fees. The GRI conducts research, development, and commercialization programs on natural gas-related topics for the benefit of the U.S. gas industry and gas customers. GRI fees are allowable, provided that such fees are mandatory in FERC-approved tariffs.
6. Annual Charge Adjustment (ACA) fees. FERC charges these fees to pipelines to pay for its operating expenses.
7. Payments (either volumetric or in value) for actual or theoretical losses. Theoretical losses are not deductible in transportation arrangements unless the transportation allowance is based on arm’s-length transportation rates charged under a FERC or State regulatory-approved tariff. If you or your affiliate receive(s) volumes or credit for line gain, you must reduce your transportation allowance accordingly and pay any resulting royalties plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter.
8. Temporary storage services. This includes short-duration storage services that market centers or hubs (commonly referred to as “parking” or “banking”) offer or other temporary storage services that pipeline transporters provide, whether actual or provided as a matter of accounting. Temporary storage is limited to 30 days or fewer.
9. Supplemental costs for compression, dehydration, and treatment of gas. ONRR allows these costs only if such services are required for transportation and exceed the services necessary to place production into marketable condition required under § 1206.146.
10. Costs of surety. You may deduct the costs of securing a letter of credit, or other surety, that the pipeline requires you or your affiliate, as a shipper, to maintain under a transportation contract.
11. Hurricane surcharges. You may deduct hurricane surcharges that you or your affiliate actually pay(s).
12. Fees or costs incurred for storage. This includes storing production in a storage facility, whether on or off of the lease, for more than 30 days.
13. Aggregator/marketer fees. This includes fees that you or your affiliate pay(s) to another person (including your affiliates) to market your gas, including purchasing and reselling the gas or finding or maintaining a market for the gas production.
14. Penalties that you or your affiliate incur(s) as a shipper. These penalties include, but are not limited to:
15. Hurricane surcharges, hurricane surcharges that you or your affiliate actually pay(s).
16. Fees or costs incurred for storage. This includes storing production in a storage facility, whether on or off of the lease, for more than 30 days.
17. Aggregator/marketer fees. This includes fees that you or your affiliate pay(s) to another person (including your affiliates) to market your gas, including purchasing and reselling the gas or finding or maintaining a market for the gas production.
18. Penalties that you or your affiliate incur(s) as a shipper. These penalties include, but are not limited to:
19. Hurricane surcharges, hurricane surcharges that you or your affiliate actually pay(s).
20. Fees or costs incurred for storage. This includes storing production in a storage facility, whether on or off of the lease, for more than 30 days.
21. Aggregator/marketer fees. This includes fees that you or your affiliate pay(s) to another person (including your affiliates) to market your gas, including purchasing and reselling the gas or finding or maintaining a market for the gas production.
22. Penalties that you or your affiliate incur(s) as a shipper. These penalties include, but are not limited to:
provide scheduling services, if such fees are separately identified from aggregator/marketer fees.

(7) Internal costs. This includes salaries and related costs, rent/space costs, office equipment costs, legal fees, and other costs to schedule, nominate, and account for the sale or movement of production.

(8) Other non-allowable costs. Any cost you or your affiliate incur(s) for services that you are required to provide at no cost to the lessor, including, but not limited to, costs to place your gas, residue gas, or gas plant products into marketable condition disallowed under § 1206.146 and costs of boosting residue gas disallowed under § 1202.151(b) of this chapter.

(d) If you have no written contract for the arm’s-length transportation of gas, and neither you nor your affiliate perform your own transportation, you must propose to ONRR a method to determine the transportation allowance using the procedures in § 1206.148(a).

(1) You may use that method to determine your allowance until ONRR issues its determination.

(2) [RESERVED]

§ 1206.157 What interest and penalties apply if I improperly report a transportation allowance?

(a)(1) If ONRR determines that you took an unauthorized transportation allowance, then you must pay any additional royalties due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter.

(2) If you understated your transportation allowance, you may be entitled to a credit, with interest.

(b) If you deduct a transportation allowance on Form ONRR–2014 that exceeds 50 percent of the value of the gas, residue gas, or gas plant products transported without obtaining ONRR’s prior approval under § 1206.152(e)(2), you must pay additional royalties due, plus late payment interest calculated under §§ 1218.54 and 1218.102 of this chapter, on the excess allowance amount taken from the date when that amount is taken to the date when you file an exception request that ONRR approves. If you do not file an exception request, or if ONRR does not approve your request, you must pay late payment interest on the excess allowance amount taken from the date that amount is taken until the date you pay the additional royalties owed.

(c) If you improperly net a transportation allowance against the sales value of the residue gas, gas plant products, or unprocessed gas instead of reporting the allowance as a separate entry on Form ONRR–2014, ONRR may assess a civil penalty under 30 CFR part 1241.

§ 1206.159 What general processing allowances requirements apply to me?

(a)(1) When you value any gas plant product under § 1206.142(c), you may deduct from the value the reasonable, actual costs of processing.

(2) You do not need ONRR’s approval before reporting a processing allowance.

(b) You must allocate processing costs among the gas plant products. You must determine a separate processing allowance for each gas plant product and processing plant relationship. ONRR considers NGLs to be one product.

(c)(1) You may not apply the processing allowance against the value of the residue gas, except as provided in paragraph (c)(4) of this section.

(2) The processing allowance deduction on the basis of an individual product may not exceed 66⅔ percent of the value of each gas plant product determined under § 1206.142(c), except as provided under paragraphs (c)(3) or (4) of this section. Before you calculate the 66⅔- percent limit, you must first reduce the value for any transportation allowances related to post-processing transportation authorized under § 1206.152.

(3) You may ask ONRR to approve a processing allowance in excess of the limitation prescribed by paragraph (c)(2) of this section. You must demonstrate that the processing costs incurred in excess of the limitation prescribed in paragraph (c)(2) of this section were reasonable, actual, and necessary. An application for exception (using Form ONRR–4393, Request to Exceed Regulatory Allowance Limitation) must contain all relevant and supporting documentation for ONRR to make a determination. Under no circumstances may the value for royalty purposes of any gas plant product be reduced to zero.

(4) If you incur extraordinary costs for processing gas, you may apply to ONRR for an allowance for those costs which must be in addition to any other processing allowance to which the lessee is entitled pursuant to this section. You must demonstrate that the costs are, by reference to standard industry conditions and practice, extraordinary, unusual, or unconventional. You are not required to receive ONRR’s approval to continue an extraordinary processing allowance. However, you must report the deduction to ONRR in a form and manner prescribed by ONRR in order to retain the ability to deduct the allowance.

(d)(1) ONRR will not allow a processing cost deduction for the costs of placing lease products in marketable condition, including dehydration, separation, compression, or storage, even if those functions are performed off the lease or at a processing plant.

(2) Where gas is processed for the removal of acid gases, commonly referred to as “sweetening,” ONRR will not allow processing cost deductions for such costs unless the acid gases removed are further processed into a gas plant product.

(i) In such event, you are eligible for a processing allowance determined under this subpart.

(ii) ONRR will not grant any processing allowance for processing lease production that is not royalty bearing.

(e) ONRR may direct you to modify your processing allowance if:

(1) There is misconduct by or between the contracting parties;

(2) ONRR determines that the consideration that you or your affiliate paid under an arm’s-length processing contract does not reflect the reasonable cost of the processing because you breached your duty to market the gas, residue gas, or gas plant products for the mutual benefit of yourself and the lessor; or

(3) ONRR cannot determine if you properly calculated a processing allowance under § 1206.160 or § 1206.161 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents that ONRR requests under 30 CFR part 1212, subpart B.

§ 1206.160 How do I determine a processing allowance if I have an arm’s-length processing contract?

(a)(1) If you or your affiliate incur processing costs under an arm’s-length processing contract, you may claim a processing allowance for the reasonable, actual costs incurred, as more fully explained in paragraph (b) of this section, except as provided in § 1206.159(e) and subject to the limitation in § 1206.159(c)(2).

(2) You must be able to demonstrate that your or your affiliate’s contract is arm’s-length.

(b)(1) If your or your affiliate’s arm’s-length processing contract includes more than one gas plant product, and you can determine the processing costs for each contract based on the contract, then you must determine the processing
costs for each gas plant product under the contract.

(2) If your or your affiliate’s arm’s-length processing contract includes more than one gas plant product, and you cannot determine the processing costs attributable to each product from the contract, you must propose an allocation procedure to ONRR.

(i) You may use your proposed allocation procedure until ONRR issues its determination.

(ii) You must submit all relevant data to support your proposal.

(iii) ONRR will determine the processing allowance based upon your proposal and any additional information that ONRR deems necessary.

(iv) You must submit the allocation proposal within three months of claiming the allocated deduction on Form ONRR–2014.

(3) You may not take an allowance for the costs of processing lease production that is not royalty-bearing.

(4) If your or your affiliate’s payments for processing under an arm’s-length contract are not based on a dollar-per-unit basis, you must convert whatever consideration that you or your affiliate paid to a dollar-value equivalent.

(c) If you have no written contract for the arm’s-length processing of gas, and neither you nor your affiliate perform your own processing, you must propose to ONRR a method to determine the processing allowance using the procedures in §1206.148(a).

(1) You may use that method to determine your allowance until ONRR issues a determination.

(2) [RESERVED]

§ 1206.164 What interest and penalties apply if I improperly report a processing allowance?

(a)(1) If ONRR determines that you took an unauthorized processing allowance, then you must pay any additional royalties due, plus late payment interest calculated under §§1218.54 and 1218.102 of this chapter.

(2) If you understated your processing allowance, you may be entitled to a credit, with interest.

(b) If you deduct a processing allowance on Form ONRR–2014 that exceeds 66⅔ percent of the value of a gas plant product without obtaining ONRR’s prior approval under §1206.159(c)(3), you must pay additional royalties due, plus late payment interest calculated under §§1218.54 and 1218.102 of this chapter, on the excess allowance amount taken from the date when that amount is taken to the date when you file an exception request that ONRR approves. If you do not file an exception request, or if ONRR does not approve your request, you must pay late payment interest on the excess allowance amount taken from the date that amount is taken until the date you pay the additional royalties owed.

(c) If you improperly net a processing allowance against the sales value of a gas plant product instead of reporting the allowance as a separate entry on Form ONRR–2014, ONRR may assess a civil penalty under 30 CFR part 1241.

Subpart F—Federal Coal

22. Revise §1206.252 to read as follows:

§1206.252 How do I calculate royalty value for coal that I or my affiliate sells under an arm’s-length or non-arm’s-length contract?

(a) The value of coal under this section for royalty purposes is the gross proceeds accruing to you or your affiliate under the first arm’s-length contract, less an applicable transportation allowance determined under §§1206.260 through 1206.262 and washing allowance determined under §§1206.267 through 1206.269. You must use this paragraph (a) to value coal when:

(1) You sell under an arm’s-length contract;

(2) You sell or transfer to your affiliate or another person under a non-arm’s-length contract, and that affiliate or person, or another affiliate of either of them, then sells the coal under an arm’s-length contract.

(b) If you have no contract for the sale of coal subject to this section because you or your affiliate used the coal in a power plant that you or your affiliate owned(s) for the generation and sale of electricity:

(i) You must propose to ONRR a method to determine the value using the procedures in §1206.258(a).

(ii) You must use that method to determine value, for royalty purposes, until ONRR issues a determination.

(iii) After ONRR issues a determination, you must make the adjustments, if any, under §1206.253(a)(2).

(c) If you are entitled to take a washing allowance and transportation allowance for royalty purposes under this section, under no circumstances may the washing allowance plus the transportation allowance reduce the royalty value of the coal to zero.

23. Revise §1206.253 to read as follows:

§1206.253 How will ONRR determine if my royalty payments are correct?

(a)(1) ONRR may monitor, review, and audit the royalties that you report, and, if ONRR determines that your reported value is inconsistent with the requirements of this subpart, ONRR may establish a reasonable royalty value based on other relevant matters.

(2) If ONRR directs you to use a different royalty value, you must either pay any underpaid royalties due, plus late payment interest calculated under §1218.202 of this chapter, or report a credit for—or request a refund of—any overpaid royalties.

(b) ONRR may examine whether your or your affiliate’s contract reflects the total consideration transferred for Federal coal, either directly or indirectly, from the buyer to you or your affiliate. If ONRR determines that additional consideration beyond that reflected in the contract was transferred, or that any portion of the consideration was not included in gross proceeds reported, ONRR may establish a reasonable royalty value based on other relevant matters.

(c) ONRR may establish a reasonable royalty value based on other relevant matters if ONRR determines that the gross proceeds accruing to you or your affiliate under a contract do not reflect reasonable consideration because:

(1) There is misconduct by or between the contracting parties;

(2) You breached your duty to market the coal for the mutual benefit of yourself and the lessor; or

(3) ONRR cannot determine if you properly valued your coal under §1206.252 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents to ONRR under 30 CFR part 1212, subpart E.

(d) You have the burden of demonstrating that your or your affiliate’s contract is arm’s-length.

(e) ONRR may require you to certify that the provisions in your or your affiliate’s contract include(s) all of the consideration that the buyer paid to you or your affiliate, either directly or indirectly, for the coal.

(f)(1) Absent any contract revisions or amendments, if you or your affiliate fail(s) to take proper or timely action to receive prices or benefits to which you or your affiliate are entitled, you must pay royalty based upon that obtainable price or benefit.

(2) If you or your affiliate apply in a timely manner for a price increase or benefit allowed under your or your affiliate’s contract, but the purchaser refuses, and you or your affiliate take reasonable, documented measures to force purchaser compliance, you will not owe additional royalties unless or until you or your affiliate receive additional monies or consideration.
resulting from the price increase. You may not construe this paragraph to permit you to avoid your royalty payment obligation in situations where a purchaser fails to pay in whole or in part, or in a timely manner, for a quantity of coal.

(5) You or your affiliate must make all contracts, contract revisions, or amendments in writing.

(2) If you or your affiliate fail(s) to comply with paragraph (g)(1) of this section, ONRR may establish a reasonable royalty value based on other relevant matters.

(3) This provision applies notwithstanding any other provisions in this title 30 to the contrary.

§ 1206.254 [Reserved]
■ 25. Revise § 1206.258 to read as follows:

§ 1206.258 How do I request a valuation determination?

(a) You may request a valuation determination from ONRR regarding any coal produced. Your request must comply with all of the following:

(1) Be in writing.

(2) Identify specifically all leases involved, all interest owners of those leases, and the operator(s) for those leases.

(3) Completely explain all relevant facts. You must inform ONRR of any changes to relevant facts that occur before we respond to your request.

(b) In response to your request, ONRR may:

(1) Be in writing.

(2) Identify specifically all leases involved, all interest owners of those leases, and the operator(s) for those leases.

(3) Completely explain all relevant facts.

(c) Provide your analysis of the issue(s).

(d) Suggest a proposed valuation method.

(e) In response to your request, ONRR may:

(1) Request that the Assistant Secretary for Policy, Management and Budget issue a determination;

(2) Decide that ONRR will issue guidance; or

(3) Inform you in writing that ONRR will not provide a determination or guidance. Situations in which ONRR typically will not provide any determination or guidance include, but are not limited to:

(i) Requests for guidance on hypothetical situations; or

(ii) Matters that are the subject of pending litigation or administrative appeals.

(c)(1) A determination that the Assistant Secretary for Policy, Management and Budget issues a determination, you must make any adjustments in royalty payments that follow from the determination and, if you owe additional royalties, you must pay any additional royalties due, plus late payment interest calculated under § 1218.202 of this chapter.

(2) A determination that the Assistant Secretary for Policy, Management and Budget signs is the final action of the Department and is subject to judicial review under 5 U.S.C. 701–706.

(d) Guidance that ONRR issues is not binding on ONRR, delegated States, or you with respect to the specific situation addressed in the guidance.

(1) Guidance and ONRR’s decision whether or not to issue guidance or to request an Assistant Secretary for Policy, Management and Budget determination, or neither, under paragraph (b) of this section, are not appealable decisions or orders under 30 CFR part 1290.

(2) If you receive an order requiring you to pay royalty on the same basis as the guidance, you may appeal that order under 30 CFR part 1290.

(3) Costs to move a particular tonnage of production for which you did not incur those costs.

(4) You may only claim a transportation allowance when you sell the coal and pay royalties.

(e) You must allocate transportation allowances to the coal attributed to the lease from which it was extracted.

(1) If you commingle coal produced from Federal and non-Federal leases, you may not disproportionately allocate transportation costs to Federal lease production. Your allocation must use the same proportion as the ratio of the tonnage from the Federal lease production to the tonnage from all production.

(2) If you commingle coal produced from more than one Federal lease, you must allocate transportation costs to each lease, as appropriate. Your allocation must use the same proportion as the ratio of the tonnage from each Federal lease production to the tonnage of all production.

(3) For unwashed coal, you may take a transportation allowance for the total coal transported.

(4) For unwashed coal, you may take a transportation allowance for the total coal transported.

(5) If you must report your transportation costs on Form ONRR–4430 as clean coal short tons sold during the reporting period multiplied by the sum of the per-short-ton cost of transporting the raw tonnage to the wash plant and, if applicable, the per-short-ton cost of transporting the clean coal tons from the wash plant to a remote sales point.

(6) You must determine the cost per short ton of clean coal transported by dividing the total applicable transportation cost by the number of clean coal tons resulting from washing the raw coal transported.

(7) You must express transportation allowances for coal as a dollar-value.
(2) You do not need ONRR’s approval before reporting a washing allowance.
(b) You may not:
(1) Take an allowance for the costs of washing lease production that is not royalty bearing.
(2) Disproportionately allocate washing costs to Federal leases. You must allocate washing costs to washed coal attributable to each Federal lease by multiplying the input ratio determined under §1206.251(e)(2)(i) by the total allowable costs.
(c)(1) You must express washing allowances for coal as a dollar-value equivalent per short ton of coal washed.
(2) If you do not base your or your affiliate’s payments for washing under an arm’s-length contract on a dollar-per-unit basis, you must convert whatever consideration that you or your affiliate paid to a dollar-value equivalent.
(d) ONRR may direct you to modify your washing allowance if:
(1) There is misconduct by or between the contracting parties;
(2) ONRR determines that the consideration that you or your affiliate paid under an arm’s-length transportation contract does not reflect the reasonable cost of the transportation because you breached your duty to market the coal for the mutual benefit of yourself and the lessor by transporting your coal at a cost that is unreasonably high; or
(3) ONRR cannot determine if you properly calculated a transportation allowance under §1206.261 or §1206.262 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents that ONRR requests under 30 CFR part 1212, subpart E.
27. Revise §1206.261 to read as follows:

§1206.261 How do I determine a transportation allowance if I have an arm’s-length transportation contract?

(a) If you or your affiliate incur(s) transportation costs under an arm’s-length transportation contract, you may claim a transportation allowance for the reasonable, actual costs incurred for transporting the coal under that contract.

(b) You must be able to demonstrate that your or your affiliate’s contract is at arm’s-length.

(c) If you have no written contract for the arm’s-length transportation of coal, and neither you nor your affiliate perform your own transportation, you must propose to ONRR a method to determine the transportation allowance using the procedures in §1206.258(a).

(1) You must use that method to determine your allowance until ONRR issues a determination.
(2) [RESERVED]
28. Revise §1206.267 to read as follows:

§1206.267 What general washing allowance requirements apply to me?

(a)(1) If you determine the value of your coal under §1206.252, you may take a washing allowance for the reasonable, actual costs to wash the coal. The allowance is a deduction when determining coal royalty value for the costs that you incur to wash coal.
(2) If you do not need ONRR’s approval before reporting a washing allowance.
(b) You may not:
(1) Take an allowance for the costs of washing lease production that is not royalty bearing.
(2) Disproportionately allocate washing costs to Federal leases. You must allocate washing costs to washed coal attributable to each Federal lease by multiplying the input ratio determined under §1206.251(e)(2)(i) by the total allowable costs.
(c)(1) You must express washing allowances for coal as a dollar-value equivalent per short ton of coal washed.
(2) If you do not base your or your affiliate’s payments for washing under an arm’s-length contract on a dollar-per-unit basis, you must convert whatever consideration that you or your affiliate paid to a dollar-value equivalent.
(d) ONRR may direct you to modify your washing allowance if:
(1) There is misconduct by or between the contracting parties;
(2) ONRR determines that the consideration that you or your affiliate paid under an arm’s-length washing contract does not reflect the reasonable cost of the washing because you breached your duty to market the coal for the mutual benefit of yourself and the lessor by washing your coal at a cost that is unreasonably high; or
(3) ONRR cannot determine if you properly calculated a transportation allowance under §§1206.261 and 1206.262 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents that ONRR requests under 30 CFR part 1212, subpart E.

(e) You may only claim a washing allowance when you sell the washed coal and report and pay royalties.
29. Revise §1206.268 to read as follows:

§1206.268 How do I determine washing allowances if I have an arm’s-length washing contract or no written arm’s-length contract?

(a) If you or your affiliate incur(s) washing costs under an arm’s-length washing contract, you may claim a washing allowance for the reasonable, actual costs incurred.

(b) You must be able to demonstrate that your or your affiliate’s washing contract is arm’s-length.

(c) If you have no written contract for the arm’s-length washing of coal, and neither you nor your affiliate perform your own washing, you must propose to ONRR a method to determine the washing allowance using the procedures in §1206.258(a).

(1) You must use that method to determine your allowance until ONRR issues a determination.
(2) [RESERVED]

Subpart J—Indian Coal

30. Revise §1206.452 to read as follows:

§1206.452 How do I calculate royalty value for coal that I or my affiliate sell(s) under an arm’s-length or non-arm’s-length contract?

(a) The value of coal under this section for royalty purposes is the gross proceeds accruing to you or your affiliate under the first arm’s-length contract, less an applicable transportation allowance determined under §§1206.460 through 1206.462 and washing allowance under §§1206.467 through 1206.469. You must use this paragraph (a) to value coal when:

(1) You sell under an arm’s-length contract; or
(2) You sell or transfer to your affiliate or another person under a non-arm’s-length contract, and that affiliate or person, or another affiliate of either of them, then sells the coal under an arm’s-length contract.

(b) If you have no contract for the sale of coal subject to this section because you or your affiliate used the coal in a power plant that you or your affiliate own(s) for the generation and sale of electricity:

(i) You must propose to ONRR a method to determine the value using the procedures in §1206.458(a).
(ii) You must use that method to determine value, for royalty purposes, until ONRR issues a determination.
(iii) After ONRR issues a determination, you must make the adjustments under §1206.453(a)(2).

(c) If you are entitled to take a washing allowance and transportation allowance for royalty purposes under this section, under no circumstances may the washing allowance plus the transportation allowance reduce the royalty value of the coal to zero.
31. Revise §1206.453 to read as follows:

§1206.453 How will ONRR determine if my royalty payments are correct?

(a)(1) ONRR may monitor, review, and audit the royalties that you report, and, if ONRR determines that your reported value is inconsistent with the requirements of this subpart, ONRR may establish a reasonable royalty value based on other relevant matters.
(2) If ONRR directs you to use a different royalty value, you must either pay any underpaid royalties due, plus
late payment interest calculated under § 1218.202 of this chapter, or report a credit for—or request a refund of—any overpaid royalties.

(b) ONRR may examine whether your or your affiliate’s contract reflects the total consideration transferred for Indian coal, either directly or indirectly, from the buyer to you or your affiliate. If ONRR determines that additional consideration beyond that reflected in the contract was transferred, or that any portion of the consideration was not included in gross proceeds reported, ONRR may establish a reasonable royalty value based on other relevant matters.

(c) ONRR may establish a reasonable royalty value based on other relevant matters if ONRR determines that the gross proceeds accruing to you or your affiliate under a contract do not reflect reasonable consideration because:
   (1) There is misconduct by or between the contracting parties;
   (2) You breached your duty to market the coal for the mutual benefit of yourself and the lessor; or
   (3) ONRR cannot determine if you properly valued your coal under § 1206.452 for any reason, including, but not limited to, your or your affiliate’s failure to provide documents to ONRR under 30 CFR part 1212, subpart E.

(d) You have the burden of demonstrating that your or your affiliate’s contract is arm’s-length.

(e) ONRR may require you to certify that the provisions in your or your affiliate’s contract include(s) all of the consideration that the buyer paid to you or your affiliate, either directly or indirectly, for the coal.

(f)(1) Absent any contract revisions or amendments, if you or your affiliate fail(s) to take proper or timely action to receive prices or benefits to which you or your affiliate are entitled, you must pay royalty based upon that obtainable price or benefit.

(2) If you or your affiliate apply in a timely manner for a price increase or benefit allowed under your or your affiliate’s contract, but the purchaser refuses, and you or your affiliate take reasonable, documented measures to enforce purchaser compliance, you will not owe additional royalties unless or until you or your affiliate receive additional monies or consideration resulting from the price increase. You may not construe this paragraph to permit you to avoid your royalty payment obligation in situations where a purchaser fails to pay in whole or in part, or in a timely manner, for a quantity of coal.

(g)(1) You or your affiliate must make all contracts, contract revisions, or amendments in writing.

(2) If you or your affiliate fail(s) to comply with paragraph (g)(1) of this section, ONRR may establish a reasonable royalty value based on other relevant matters.

(3) This provision applies notwithstanding any other provisions in this title 30 to the contrary.

§ 1206.454 [Removed and reserved]

■ 32. Remove and reserve § 1206.454.
■ 33. Revise § 1206.458 to read as follows:

§ 1206.458 How do I request a valuation determination?

(a) You may request a valuation determination from ONRR regarding any coal produced. Your request must comply with all of the:
   (1) Be in writing.
   (2) Identify specifically all leases involved, all interest owners of those leases, and the operator(s) for those leases.
   (3) Completely explain all relevant facts. You must inform ONRR of any changes to relevant facts that occur before we respond to your request.
   (4) Include copies of all relevant documents.
   (5) Provide your analysis of the issue(s).
   (6) Suggest a proposed valuation method.

(b) In response to your request, ONRR may:
   (1) Request that the Assistant Secretary for Policy, Management and Budget issue a determination;
   (2) Decide that ONRR will issue guidance; or
   (3) Inform you in writing that ONRR will not provide a determination or guidance. Situations in which ONRR typically will not provide any determination or guidance include, but are not limited to:
   (i) Requests for guidance on hypothetical situations; or
   (ii) Matters that are the subject of pending litigation or administrative appeals.

(c)(1) A determination that the Assistant Secretary for Policy, Management and Budget signs is binding on both you and ONRR until the Assistant Secretary modifies or rescinds it.

(2) After the Assistant Secretary for Policy, Management and Budget issues a determination, you must make any adjustments in royalty payments that follow from the determination and, if you owe additional royalties, you must pay any additional royalties due, plus late payment interest calculated under § 1218.202 of this chapter.

(3) A determination that the Assistant Secretary for Policy, Management and Budget signs is the final action of the Department and is subject to judicial review under 5 U.S.C. 701–706.

(d) Guidance that ONRR issues is not binding on ONRR, delegated States, or you with respect to the specific situation addressed in the guidance.

(1) Guidance and ONRR’s decision whether or not to issue guidance or to request an Assistant Secretary for Policy, Management and Budget determination, or neither, under paragraph (b) of this section, are not appealable decisions or orders under 30 CFR part 1290.

(2) If you receive an order requiring you to pay royalty on the same basis as the guidance, you may appeal that order under 30 CFR part 1290.

(e) ONRR or the Assistant Secretary for Policy, Management and Budget may use any of the applicable criteria in this subpart to provide guidance or to make a determination.

(f) A change in an applicable statute or regulation on which ONRR based any guidance, or the Assistant Secretary for Policy, Management and Budget based any determination, takes precedence over the determination or guidance after the effective date of the statute or regulation, regardless of whether ONRR or the Assistant Secretary modifies or rescinds the guidance or determination.

(g) ONRR or the Assistant Secretary for Policy, Management and Budget generally will not retroactively modify or rescind a valuation determination issued under paragraph (d) of this section, unless:
   (1) There was a misstatement or omission of material facts; or
   (2) The facts subsequently developed are materially different from the facts on which the guidance was based.

(h) ONRR may make requests and replies under this section available to the public, subject to the confidentiality requirements under § 1206.259.

■ 34. Revise § 1206.460 to read as follows:

§ 1206.460 What general transportation allowance requirements apply to me?

(a)(1) ONRR will allow a deduction for the reasonable, actual costs to transport coal from the lease to the point off of the lease or mine as determined under § 1206.461 or 1206.462, as applicable.

(2) You do not need ONRR’s approval before reporting a transportation allowance for costs incurred.

(b) You may take a transportation allowance when:
must convert whatever consideration your affiliate's payments for transported. If you do not base your or equivalent per short ton of coal
allowances for coal as a dollar-value the raw coal transported.

dividing the total applicable
costs that you incur to wash the
costs that you incur
reasonable cost of the transportation
be breached your duty to
the reasonable cost of the transit
pay to a dollar-value equivalent.

d ONRR may direct you to modify
your allowance if:
(1) There is misconduct by or between
the contracting parties;
(2) ONRR determines that the
consideration that you or your affiliate
paid under an arm's-length
transportation contract does not reflect the
reasonable cost of the transportation
because you breached your duty to
market the coal for the mutual benefit of
yourself and the lessor by transporting
your coal at a cost that is unreasonably
high; or
(3) ONRR cannot determine if you
properly calculated a transportation
allowance under § 1206.461 or 1206.462
for any reason, including, but not
limited to, your or your affiliate's failure
to provide documents that ONRR
requests under 30 CFR part 1212,
subpart E.

§ 1206.452 How do I determine washing allowance if I have an arm’s-length transportation contract?

(a) If you or your affiliate incur(s)
transportation costs under an arm’s-length
transportation contract, you may claim a
transportation allowance for the
reasonable, actual costs incurred for
transporting the coal under that
contract.
(b) You must be able to demonstrate
that your or your affiliate’s contract is at
arm’s-length.
(c) If you have no written contract for
the arm’s-length transportation of coal,
then you must propose to ONRR a
method to determine the allowance
using the procedures in § 1206.458(a).
You may use that method to determine
your allowance until ONRR issues a
determination.
(1) You must use that method to
determine your allowance until ONRR
issues a determination.
(2) [RESERVED]

§ 1206.468 How do I determine washing allowances if I have an arm’s-length washing contract or no written arm’s-length contract?

(a) If you or your affiliate incur(s)
washing costs under an arm’s-length
washing contract, you may claim a
washing allowance for the reasonable,
actual costs incurred.
(b) You must be able to demonstrate
that your or your affiliate’s contract is
arm’s-length.
(c) If you have no written contract for
the arm’s-length washing of coal,
and neither you nor your affiliate perform
your own washing, you must propose to
ONRR a method to determine the
washing allowance using the procedures
in § 1206.458(a).
(1) You may use that method to
determine your allowance until ONRR
issues a determination.
(2) [RESERVED]
PART 1241—PENALTIES

38. The authority citation for part 1241 continues to read as follows:


Subpart A—General Provisions

39. Revise §1241.11 to read as follows:

§1241.11 Does my hearing request affect a penalty?

(a) If you do not correct the violation identified in a Notice, any penalty will continue to accrue, even if you request a hearing, except as provided in paragraph (b) of this section.

(b) Standards and procedures for obtaining a stay. If you request in a timely manner a hearing on a Notice, you may petition the DCHD to stay the assessment or accrual of penalties pending the hearing on the record and a decision by the ALJ under §1241.8.

(1) You must file your petition for stay within 45 calendar days after you receive a Notice.

(2) You must file your petition for stay under 43 CFR 4.21(b), in which event:

(i) We may file a response to your petition within 30 days after service.

(ii) The 45-day requirement set out in 43 CFR 4.21(b)(4) for the ALJ to grant or deny the petition does not apply.

(3) If the ALJ determines that a stay is warranted, the ALJ will issue an order granting your petition, subject to your satisfaction of the following condition: Within 10 days of your receipt of the order, you must post a bond or other surety instrument using the same standards and requirements as prescribed in 30 CFR part 1243, subpart B; or demonstrate financial solvency using the same standards and requirements as prescribed in 30 CFR part 1243, subpart C, for any specified, unpaid principal amount that is the subject of the Notice, any interest accrued on the principal, and the amount of any penalty set out in a Notice accrued up to the date of the ALJ order conditionally granting your petition.

(4)(i) If you satisfy the condition to post a bond or surety instrument or demonstrate financial solvency under paragraph (b)(3) of this section, the accrual of penalties will be stayed effective on the date of the ALJ’s order conditionally granting your petition.

(ii) If you fail to satisfy the condition to post a bond or surety instrument or demonstrate financial solvency under paragraph (b)(3) of this section, penalties will continue to accrue.

Subpart C—Penalty Amount, Interest, and Collections

40. Revise §1241.70 to read as follows:

§1241.70 How does ONRR decide the amount of the penalty to assess?

(a) ONRR will determine the amount of the penalty to assess by considering:

(1) The severity of the violation.

(2) Your history of noncompliance.

(3) The size of your business. To determine the size of your business, we may consider the number of employees in your company, parent company or companies, and any subsidiaries and contractors.

(b) For payment violations only, we will consider the unpaid, underpaid, or late payment amount in our analysis of the severity of the violation.

(c) We will post the FCCP and ILCP assessment matrices and any adjustments to the matrices on our website.

(d) After we provisionally determine the civil penalty amount using the criteria and matrices described in paragraphs (a), (b), and (c) of this section, we may adjust the penalty amount in the FCCP or ILCP upward or downward if we find aggravating or mitigating circumstances.

(1) Aggravating circumstances may include, but are not limited to:

(i) Committing a violation because you determined that the cost of a potential penalty is less than the cost of compliance; and

(ii) Committing a violation where you have no recent history of noncompliance of the same type, but you have a history of noncompliance of other violation types.

(iii) Committing a violation that is also a criminal act.

(2) Mitigating circumstances may include, but are not limited to:

(i) Operational impacts resulting from the unexpected illness or death of an employee, natural disasters, pandemics, acts of terrorism, civil unrest, or armed conflict;

(ii) Delays caused by government action or inaction, including as a result of a government shutdown and ONRR-system downtime; and

(iii) Good faith efforts to comply with formal or informal agency guidance.
Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1 and 251

Importation of Prescription Drugs; Final Rule
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 251

[Docket No. FDA–2019–N–5711]

RIN 0910–AI45

Importation of Prescription Drugs

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

ACTION: Final rule.

SUMMARY: The Secretary of Health and Human Services (Secretary) is issuing a final rule to implement a provision of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to allow importation of certain prescription drugs from Canada. Under this final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the Food and Drug Administration (FDA, the Agency, or we) for review and authorization. An importation program may be cosponsored by a State, Indian Tribe, pharmacist, or wholesaler. The final rule contains all requirements necessary for a sponsor to demonstrate that their importation program will pose no additional risk to the public’s health and safety. In addition, the final rule requires that the sponsor explain how they will ensure their program will result in a significant reduction in the cost of covered products to the American consumer.

DATES: This final rule is effective November 30, 2020.

ADDRESSES: For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number found in brackets in the "Search" box and follow the prompts, or imprinted on a package and homogenous case of eligible prescription drugs. The Importer has to ensure that the lot number that is included as part of the product identifier is the unique to each package or homogenous case, is affixed to or imprinted on each package and homogenous case of eligible prescription drugs shipped from Canada. The purpose of the final rule is to achieve a significant reduction in the cost of covered products to the American consumer while posing no additional risk to the public’s health and safety.

B. Summary of the Major Provisions of the Final Rule

Under the final rule, section 804 of the FD&C Act (21 U.S.C. 384(b) through (h)) to allow importation of certain prescription drugs shipped from Canada. The purpose of the final rule is to achieve a significant reduction in the cost of covered products to the American consumer while posing no additional risk to the public’s health and safety.

A. Purpose of the Final Rule

The Secretary is issuing this rule to implement section 804(b) through (h) of the FD&C Act (21 U.S.C. 384(b) through (h)) to allow importation of certain prescription drugs shipped from Canada. The purpose of the final rule is to achieve a significant reduction in the cost of covered products to the American consumer while posing no additional risk to the public’s health and safety.

B. Summary of the Major Provisions of the Final Rule

Under the final rule, section 804 of the FD&C Act will be implemented through time-limited Section 804 Importation Programs (SIPs), which will be authorized by FDA and managed by States or Indian Tribes, or in certain circumstances by pharmacists or wholesale distributors (SIP Sponsors). A SIP can be cosponsored by a State, Indian Tribe, pharmacist, or wholesale distributor.

The final rule requires that a SIP Sponsor specify the eligible prescription drugs that will be included in the SIP. To be eligible under the final rule, a drug needs to be approved by the Government of Canada’s Health Canada or an Health Products and Food Branch (HPFB) and, but for the fact it bears the HPFB-approved labeling when marketed in Canada, needs to otherwise meet the conditions in an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA). Essentially, eligible prescription drugs are those that could be sold legally on either the Canadian market or the American market with appropriate labeling.

The final rule also requires that the SIP Proposal identify the Foreign Seller in Canada that will purchase the eligible prescription drug directly from its manufacturer, and the Importer in the United States that will buy the drug directly from the Foreign Seller. Although the initial SIP Proposal will identify just one Foreign Seller and one Importer, if a SIP can show that it has consistently imported eligible prescription drug(s) in accordance with section 804 of the FD&C Act and the rule, the SIP Sponsor will be able to submit a supplemental proposal to add Foreign Sellers or Importers. Each supply chain under a SIP must be limited to three entities, i.e., one manufacturer, one Foreign Seller, and one Importer.

The final rule requires that the Foreign Seller be licensed to wholesale drugs by Health Canada and registered with FDA as a Foreign Seller, and that the Importer be a wholesale distributor or pharmacist licensed to operate in the United States. Both the Foreign Seller and the Importer will be subject to the supply chain security requirements set forth in this rulemaking and under the FD&C Act. Among other things, the Foreign Seller has to ensure that a section 804 serial identifier (SSI), which is an alphanumeric serial number unique to each package or homogenous case, is affixed to or imprinted on each package and homogenous case of the drugs. The Importer has to ensure that a product identifier meeting the requirements of section 582 of the FD&C Act (21 U.S.C. 360ee–1) (i.e., a product identifier that includes a National Drug Code, unique alphanumeric serial number of up to 20 characters, lot number, and expiration date, in both human- and machine-readable format) is affixed to or imprinted on each package and homogenous case of eligible prescription drugs received from the Foreign Seller. The final rule clarifies that the lot number that is included as part of the product identifier is the number that was assigned by the manufacturer of the eligible prescription drug; separately, section 804(d)(1)(H) of the FD&C Act requires that the Importer shall submit it to the Secretary. The Importer also has to maintain records linking the product identifier affixed to or imprinted on a package and
homogenous case to the SSI that the Foreign Seller assigned. The Foreign Seller must maintain records associating the SSI with the drug identification number (DIN) from the HPFB and all the records the Foreign Seller received from the manufacturer upon receipt of the original shipment intended for the Canadian market.

After FDA has authorized a SIP Proposal, the Importer must submit a Pre-Import Request to FDA at least 30 calendar days before the scheduled date of arrival or entry for consumption of a shipment containing an eligible prescription drug covered by the SIP, whichever is earlier. “Entered for consumption,” as defined in 19 CFR 141.0a(f), is the most common entry type for FDA-regulated products and is used when products are imported for use in the United States and go directly into United States commerce without any restrictions of time or use placed on them. Once the shipment arrives or is entered at a port of entry, it may be examined by a government agency. Entry of a shipment containing an eligible prescription drug is limited under the final rule to the U.S. Customs and Border Protection (CBP) port of entry authorized by FDA. The Importer or its authorized customs broker is required to electronically file an entry for consumption in the Automated Commercial Environment (ACE) or other electronic data interchange system authorized by CBP for each eligible prescription drug imported or offered for import into the United States. These entries must be filed as formal entries. If an eligible prescription drug that is imported or offered for import does not comply with section 804 of the FD&C Act and the provisions of this final rule, that drug will be subject to refusal under section 801 of the FD&C Act (21 U.S.C. 381).

In accordance with section 804(e)(1) of the FD&C Act, the final rule requires the manufacturer or the Importer to conduct testing of the eligible prescription drugs for authenticity, degradation, and to ensure that the eligible prescription drugs are in compliance with established specifications and standards (Statutory Testing). If the manufacturer does not perform the Statutory Testing required under section 804 of the FD&C Act, the Importer must arrange for Statutory Testing by a qualifying laboratory in the United States and must also ensure that the drug complies with all labeling requirements under the FD&C Act. If such testing is performed by the Importer, section 804(e)(2) requires that the manufacturer of the eligible prescription drug supply the information the Importer needs to authenticate the drug and to confirm that its labeling complies with all labeling requirements under the FD&C Act. In the final rule, FDA requires that the manufacturer provide the Importer with, among other things, protocols to support required testing, including a validated stability-indicating assay so the drug can be tested for degradation.

Under the final rule, the Importer can choose to admit the drug or drugs specified in the section 804 Pre-Import Request to an authorized foreign trade zone and then conduct the required Statutory Testing and relabeling; or alternatively, the Importer can file an entry for consumption and request to recondition the drug or drugs, which would include the required testing and relabeling. Under the final rule, the results of this testing will be subject to review and acceptance by FDA, and subsequently, the drug has to be relabeled to be consistent with the FDA-approved labeling before the drug can be distributed in the United States. Pursuant to section 804(c)(3) of the FD&C Act, the final rule also sets forth post-importation requirements. Each SIP Sponsor is required to provide FDA with data and information about its SIP, including the SIP’s cost savings to the American consumer. An Importer is required to submit adverse event, field alert, and other reports to a drug’s manufacturer and to FDA. If FDA or any participant in a SIP determines that a recall is warranted, the SIP Sponsor is responsible for effectuating the recall. The final rule requires that each SIP have a written recall plan that describes the procedures to perform a recall of the product and specifies who will be responsible for performing those procedures.

A SIP is eligible for extension by FDA before the end of its authorization period. A SIP may also be terminated by FDA at any time for the reasons outlined in this final rule.

C. Legal Authority

Section 804(f)(1) of the FD&C Act provides that section 804 becomes effective only if the Secretary certifies to Congress that the implementation of this section will pose no additional risk to the public’s health and safety, and will result in a significant reduction in the cost of covered products to the American consumer. The Secretary is making this certification with regard to section 804(b) through (h) to Congress concurrent with the issuance of this final rule. The Secretary is issuing this final rule regarding importation of prescription drugs under section 804(b) through (h) of the FD&C Act. The final rule is also being issued pursuant to the Secretary’s authorities related to adulterated and misbranded drugs under sections 501 and 502 of the FD&C Act (21 U.S.C. 351 and 352); the Secretary’s authorities with regard to wholesale distribution under section 503(e) of the FD&C Act (21 U.S.C. 353(e)); the Secretary’s authority related to new drugs under section 505 of the FD&C Act (21 U.S.C. 355); the Secretary’s authorities related to pharmaceutical supply chain security in sections 581 and 582 of the FD&C Act (21 U.S.C. 360eee and 360eee–1); the Secretary’s authority related to inspection under section 704 of the FD&C Act (21 U.S.C. 374); and the Secretary’s authority related to rulemaking under section 701(a) of the FD&C Act (21 U.S.C. 371(a)).

D. Costs and Benefits

The final rule allows commercial importation of certain prescription drugs from Canada through time-limited programs sponsored by State, Indian Tribe, or in certain future circumstances by a pharmacist or wholesale distributor, with possible cosponsorship by a State, Indian Tribe, pharmacist, or wholesale distributor. If such programs are authorized and implemented, allowing Importers to leverage drug price differences between the United States and Canada for the eligible prescription drugs identified in the SIP, these programs will result in cost savings for the American consumer.

Costs of the final rule may accrue to the Federal Government, SIP Sponsors, Importers, and manufacturers of imported drugs. The Federal Government will incur costs to implement the final rule and conduct oversight of authorized programs. SIP Sponsors will face costs to prepare proposals, implement authorized programs, and produce records and program reports. Drug manufacturers will have to provide certain information to Importers if their drugs are imported into the United States from Canada by a SIP. SIPs may offer cost savings to patients, as well as participating States, Indian Tribes, wholesale distributors, pharmacies, hospitals, and third-party payers. As SIP Sponsors and Importers realize savings in acquiring eligible prescription drugs and pass some of these savings on to consumers, it is possible that U.S.-based drug manufacturers may experience a transfer in U.S. sales revenues to these parties.

We are unable to estimate the cost savings from this final rule because we lack information about the likely size and scope of SIPs, the specific eligible prescription drugs that may be...
imported, the degree to which these imported drugs will be less expensive than non-imported drugs available in the United States, and which eligible prescription drugs are produced by U.S.-based drug manufacturers.

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

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<thead>
<tr>
<th>Abbreviation</th>
<th>What it means</th>
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<tr>
<td>ACE</td>
<td>Automated Commercial Environment or any Other Electronic Data Interchange System authorized by U.S. Customs and Border Protection.</td>
</tr>
<tr>
<td>ANDA</td>
<td>Abbreviated New Drug Application.</td>
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<tr>
<td>ANSI</td>
<td>American National Standards Institute.</td>
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<td>APA</td>
<td>Administrative Procedure Act.</td>
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<td>API</td>
<td>Active Pharmaceutical Ingredient.</td>
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<tr>
<td>BLA</td>
<td>Biologics License Application.</td>
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<tr>
<td>CBP</td>
<td>U.S. Customs and Border Protection.</td>
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<td>CDER</td>
<td>Center for Drug Evaluation and Research.</td>
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<tr>
<td>CGMP</td>
<td>Current Good Manufacturing Practice.</td>
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<tr>
<td>DIN</td>
<td>Drug Identification Number.</td>
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<td>DSCSA</td>
<td>Drug Supply Chain Security Act.</td>
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<tr>
<td>ESG</td>
<td>Electronic Submissions Gateway.</td>
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<td>FDA</td>
<td>Food and Drug Administration.</td>
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<td>HHS</td>
<td>Health and Human Services.</td>
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<td>HPFB</td>
<td>Health Canada Health Products and Food Branch.</td>
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<td>Individual Case Safety Reports.</td>
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<td>NDA</td>
<td>New Drug Application.</td>
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<td>National Drug Code.</td>
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<td>NPRM</td>
<td>Notice of Proposed Rulemaking.</td>
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<td>OMB</td>
<td>Office of Management and Budget.</td>
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<td>PHS Act</td>
<td>Public Health Service Act.</td>
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<td>REMS</td>
<td>Risk Evaluation and Mitigation Strategies.</td>
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<td>RWD</td>
<td>Real-World Data.</td>
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<td>RWE</td>
<td>Real-World Evidence.</td>
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<td>SIP</td>
<td>Section 804 Importation Program.</td>
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<td>SSI</td>
<td>Section 804 Serial Identifier.</td>
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<td>USP</td>
<td>United States Pharmacopoeia.</td>
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III. Background

A. Need for the Regulation/History of the Rulemaking

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was signed into law on December 8, 2003. Section 1121 of the MMA amended section 804 of the FD&C Act to its current version, which, among other things, authorizes the Secretary, after consultation with the U.S. Trade Representative and the Commissioner of Customs, to issue regulations permitting pharmacists and wholesalers to import certain prescription drugs from Canada under certain conditions and limitations. Since the passage of the MMA, the Commissioner of Customs is now known as the Commissioner of CBP. For section 804 of the FD&C Act to become effective, the Secretary must certify that its implementation will pose no additional risk to the public’s health and safety, and that it will result in a significant reduction in the cost of covered products to the American consumer.

As described in the notice of proposed rulemaking (NPRM), there has been interest for many years in allowing the importation of less expensive drugs from Canada to help American consumers benefit from these lower prices. However, no prior Health and Human Services (HHS) Secretary has made the certification required under section 804(j)(1) to begin implementing any part of section 804 of the FD&C Act. In the Federal Register of December 23, 2019 (84 FR 70796), FDA published a proposed rule to implement section 804(b) through (h) of the FD&C Act to allow importation of certain prescription drugs from Canada.

Executive Order 13938 of July 24, 2020 (85 FR 45757), directs the Secretary, as appropriate and consistent with applicable law, to take action to expand safe access to lower-cost imported prescription drugs by, among other things, completing the rulemaking process regarding the proposed rule to implement section 804(b) through (h) of the FD&C Act to allow importation of certain prescription drugs from Canada.

B. Summary of Comments to the Proposed Rule

We received over 1,200 comment letters on the proposed rule by the close of the comment period. We received comments from consumers, consumer groups, trade organizations, industry, public health organizations, public advocacy groups, States, Canadian entities (including governmental agencies), and others. These comments addressed nearly every aspect of the proposed rule and a number responded to specific FDA requests for comment.

IV. Legal Authority

Section 804(j)(1) of the FD&C Act provides that section 804 becomes effective only if the Secretary certifies to Congress that the implementation of this section will pose no additional risk to the public’s health and safety and will result in a significant reduction in the cost of covered products to the American consumer. The Secretary is making this certification with regard to section 804(b) through (h) to Congress concurrent with the issuance of this final rule. The Secretary is issuing this final rule under the Secretary’s rulemaking authority regarding importation of prescription drugs under section 804(b) through (h) of the FD&C Act. The final rule is also being issued pursuant to the Secretary’s authorities related to adulterated and misbranded...
drugs under sections 501 and 502 of the FD&C Act; the Secretary’s authorities with regard to wholesale distribution under section 503(e) of the FD&C Act; the Secretary’s authority related to new drugs under section 505 of the FD&C Act; the Secretary’s authorities related to pharmaceutical supply chain security in sections 581 and 582 of the FD&C Act; the Secretary’s authority related to inspection under section 704 of the FD&C Act; and the Secretary’s authority related to rulemaking under section 701(a) of the FD&C Act (21 U.S.C. 371(a)).

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We describe and respond to comments on the proposed rule in sections V.B through L. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment’s value or importance or the order in which comments were received. The Agency also received a number of comments that were outside the scope of the proposed rule and therefore were not considered in its final development and are not discussed here.

B. Description of General Comments and FDA Response

Many comments made general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) Several comments assert that limitations on the volume of eligible prescription drugs that could be imported, due to the geographic restriction to Canada and supply of prescription drug products in Canada, could limit the overall program’s effectiveness in reducing U.S. prescription drug costs.

(Response 1) The final rule affords significant flexibility to SIPs to choose which eligible prescription drugs to import and in what quantities. This flexibility could allow SIPs to make adjustments in response to the supply of eligible prescription drugs available for importation. In addition, several potential SIP Sponsors have indicated in comments that they believe they can implement a SIP that, if authorized by FDA, will achieve a significant reduction in the cost of covered products to the American consumer with no additional risk to the public’s health and safety.

(Comment 2) Several comments ask FDA to expand the proposed rule to implement section 804(j) of the FD&C Act to allow personal importation of certain prescription drugs. Several comments support FDA’s decision not to address in this rulemaking personal importation under section 804(j).

(Response 2) We are not implementing the personal importation provisions in section 804(j) of the FD&C Act through this rulemaking. We note that Executive Order 13938 of July 24, 2020, directs the Secretary, as appropriate and consistent with applicable law, to take action to expand safe access to lower-cost imported prescription drugs by, among other things, facilitating grants to individuals of waivers of the prohibition of importation of prescription drugs provided such importation poses no additional risk to public safety and results in lower costs to American patients, pursuant to section 804(j)(2) of the FD&C Act.

C. Comments on General Provisions

(Comment 3) Several comments recommend expanding the definition of “eligible prescription drug” in particular to include biological products.

(Response 3) Section 804(a)(3) of the FD&C Act excludes several categories of drug products from the definition of “prescription drug” that can potentially be imported from Canada pursuant to section 804 of the FD&C Act, including controlled substances, biological products (as defined in section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262)), infused drugs (including a peritoneal dialysis solution), intravenously injected drugs, and drugs that are infused during surgery.

(Comment 4) Several comments suggest that some risk evaluation and mitigation strategies (REMS) could be implemented effectively under a SIP with no additional risk, so drugs that are subject to REMS should not be excluded from the definition of “eligible prescription drug.”

(Response 4) As discussed in the NPRM (84 FR 70796 at 70804), REMS drugs are high-risk products with known safety issues. REMS programs are mandated by FDA but implemented by manufacturers. In order to implement and assess a REMS, a manufacturer needs to have control over the drug that is the subject of the REMS. For example, for REMS that require tight controls on distribution of a drug in order to mitigate risks, use of Foreign Sellers will make it much more difficult to maintain those controls and could introduce gaps that have a significant impact on the safety of the drug.

(Comment 5) Several comments recommend excluding certain other types of drug products from the definition of “eligible prescription drug.” One comment suggests that the definition of “eligible prescription drug” should be limited to sole-source drugs and exclude drugs with remaining patents or exclusivities, drugs subject to post-marketing commitments or requirements, and drugs considered biologics in Canada. In addition, several comments request clarification regarding criteria FDA may use in determining whether a particular drug product can be imported safely in the context of a specific SIP Proposal.

(Response 5) At this time, FDA is not excluding additional categories from the final rule. For products not excluded by the final rule, FDA will determine whether the product can be imported safely in the context of a specific SIP Proposal on a product-by-product basis, including, for example, sterile drugs; drugs requiring special storage conditions such as temperature controls; or drugs intended to be used solely with a specific, separately distributed delivery system (such as may be the case for drug constituent parts of cross-labeled combination products, see 21 CFR 3.2(e)(3), (4)). A SIP Sponsor would need to explain in its SIP Proposal how it will address any concerns arising from the manufacture, storage, and transport of each eligible prescription drug, including concerns related to controlling contamination, preserving sterility, and ensuring stability.

(Comment 6) Several comments raise concerns about SIPs potentially turning to online pharmacies as Foreign Sellers.

(Response 6) We are not changing the rule based on these comments, as the final rule includes provisions to safeguard against a SIP turning to rogue online pharmacies as Foreign Sellers. As discussed in the NPRM, while there are pharmacy websites that operate legally and offer convenience, privacy, and safeguards for purchasing medicines, we agree that there are many rogue online pharmacies that sell medicines at deeply discounted prices, often without requiring a prescription or adhering to other safeguards followed by FDA and State in the United States (Refs. 1 and 2). The final rule defines “Foreign Seller” to mean an...
establishment within Canada engaged in the distribution of an eligible prescription drug that is imported or offered for importation into the United States. The final rule further provides that a Foreign Seller must have an active drug establishment license to wholesale drugs by Health Canada and must be registered with provincial regulatory authorities to distribute HPFB-approved drugs. The final rule also requires that a Foreign Seller cannot be licensed by a provincial regulatory authority with an international pharmacy license that allows it to distribute drugs that are approved by countries other than Canada and that are not HPFB-approved for distribution in Canada. A Foreign Seller must also be registered with FDA under section 804 of the FD&C Act. The final rule also includes a number of supply chain requirements for Foreign Sellers. Moreover, FDA retains the authority not to approve a SIP, or to discontinue a SIP, absent a continued demonstration that the Foreign Seller meets all the relevant safety criteria.

(Comment 7) One comment proposes that FDA revise the definition of the term “manufacturer” to include only an applicant, as defined in § 314.3 (21 CFR 314.3), who owns an approved NDA or ANDA for an eligible prescription drug.

(Response 7) As described in the NPRM, under the rule the term “manufacturer” includes an applicant, as defined in § 314.3, who owns an approved NDA or ANDA for an eligible prescription drug, or a person who owns or operates an establishment that manufactures an eligible prescription drug. “Manufacturer” also means a holder of a drug master file containing information necessary to conduct the Statutory Testing, prepare the manufacturer’s attestation and information statement, or otherwise comply with section 804 of the FD&C Act or this part. We decline to change this definition because we continue to believe that a person that owns or operates an establishment that manufactures an eligible prescription drug or a holder of a drug master file containing information necessary to conduct the Statutory Testing or prepare the manufacturer’s attestation and information statement may have information about eligible prescription drugs that will be needed to ensure that the drugs comply with the FD&C Act and the requirements in this final rule. An Importer may send a request for batch and stability testing records to the facility that manufactured the eligible prescription drug and that entity would be required to provide those records if the records are in the facility’s possession or control.

(Comment 8) Several comments request that the definition of “SIP Sponsor” include a State agency that has authorized to submit a SIP Proposal even if the State agency does not otherwise oversee pharmacies and wholesaler distributors.

(Response 8) FDA has revised the definition of the term “SIP Sponsor” to clarify that the term means a State or Indian Tribe that regulates wholesale drug distribution or the practice of pharmacy, submits a proposal to FDA that describes a program to facilitate the importation of prescription drugs from Canada under section 804 of the FD&C Act, and is responsible for oversight of the implementation of the program. Under section 201 of the FD&C Act (21 U.S.C. 321), “State” generally means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico. In certain circumstances, a pharmacist or wholesale distributor may be a SIP Sponsor. FDA has also added a separate definition for the term “SIP Co-Sponsor,” which means any other State, Indian Tribe, pharmacist, or wholesale distributor that, with the SIP Sponsor, signs a SIP Proposal. A State agency that has authorized to submit a SIP Proposal may submit a SIP Proposal on behalf of the State, even if the State agency does not otherwise oversee pharmacists and wholesalers.

(Comment 9) Several comments suggest that the rule be changed to allow pharmacists or wholesalers to be SIP Sponsors without a State or Indian Tribe as a cosponsor. Some of these comments assert, for example, that pharmacists and wholesalers operate under robust regulatory requirements and that (Response 9) In the NPRM, FDA sought comment on whether it could be possible for a pharmacist or wholesaler to be a SIP Sponsor without a State or Indian Tribe as a sponsor, while posing no additional risk to the public’s health and safety. We believe oversight by a State or Indian Tribe is an important safeguard because these entities, which oversee pharmacies and wholesale distribution and have tools to protect public health, are uniquely positioned to provide independent oversight of importation activities. Although we could not foresee how this approach could be adopted without posing additional risk to the public’s health and safety, we stated that if we received information that demonstrates how a proposal does not include a State or Indian Tribe as a sponsor would provide the same level of assurance of safety as a proposal with such a sponsor, we would consider having the final rule allow for this possibility. We provided an alternative codified provision that appeared under “Option 2” in proposed § 251.2 (21 CFR 251.2). FDA declines to adopt the alternative codified provision. However, as open to the possibility that a pharmacist or wholesaler, after actively participating in a SIP, may be able to demonstrate that their proposal that does not include a State or Indian Tribe as the SIP sponsor could provide the same level of assurance of safety. Further, we recognize that Agency experience with this novel program is necessary to determine how to appropriately evaluate whether a pharmacist or wholesaler has adequately supported such a demonstration. Accordingly, we have revised the rule to provide that, after an initial 2-year period beginning on the date of the first import entry under any SIP authorized under this rule, the Secretary may determine, based on experience under the program, that there is a sufficient likelihood that a proposal that does not include a State or Indian Tribe as the SIP sponsor could provide the same level of assurance of safety as a proposal that does include...
such a sponsor, such that FDA may begin receiving, reviewing, and potentially authorizing applications for SIPs without such a sponsor. After the Secretary makes such a determination, a pharmacist or wholesaler may propose a SIP that does not include a State or Indian Tribe as a sponsor, and FDA may authorize such a SIP if the sponsor demonstrates that the SIP meets the criteria for authorization with the same level of assurance of safety as a proposal that includes a State or Indian Tribe as the SIP sponsor, which FDA shall evaluate consistent with any considerations described in the Secretary’s determination, including by evaluating whether the application demonstrates that the proposed sponsor has sufficient relevant experience, such as participating in a SIP and demonstrating compliance with the requirements of the FD&C Act and the rule.

(Comment 10) Several comments suggest that a pharmacist or wholesaler should not be allowed to be both a SIP cosponsor and an Importer in the same SIP, because it could remove a key layer of oversight and result in conflicts of interest. One comment suggests that entities and individuals receiving imported drugs should fall within the jurisdiction of the State sponsoring each SIP.

(Response 10) We are not changing the final rule in response to these comments. We continue to believe, as discussed in the NPRM (84 FR 70796 at 70801), that cosponsorship could introduce valuable flexibility that a non-governmental entity. If a non-governmental entity is a licensed pharmacist or wholesaler and meets the requirements of this rule, the entity can cosponsor a SIP.

D. Comments on SIP Proposals and Pre-Approval Requests

(Comment 12) Several comments request that FDA amend the proposed rule to allow submission of SIP Proposals without identifying or providing certain information about participating entities or persons and provide for “conditional approval” of SIPs before those specific participating entities or persons are identified, followed by “final approval” when participation agreements are in place. According to these comments, entities or persons such as a potential Foreign Seller or Importer may be unwilling to commit to participating in a SIP until they are assured that a prospective SIP Sponsor has received FDA authorization. The comments also assert that a SIP Sponsor would need sufficient time to determine and finalize contracts or other arrangements with the entities or persons that will be participating in a SIP.

(Response 12) In response to these comments and related concerns, in particular about finding a Foreign Seller to obtain the eligible prescriptions drugs identified in the SIP Proposal, we are retaining the final rule to provide that FDA may use a phased review process to review a SIP Proposal that does not identify a Foreign Seller in an initial submission but otherwise meets the requirements of this part. Importers, relabelers, and repackagers still need to be identified and the required information regarding these participating persons must be included in the initial submission of the SIP Proposal. A Foreign Seller must be identified within 6 months of the initial submission date of the SIP Proposal. This change to allow for phased review reflects the importance of finding a well-qualified Foreign Seller for a short supply chain. The 6-month period helps ensure that the information provided in the SIP Proposal to FDA for consideration is current and FDA is able to better handle the workload of reviewing SIP proposals. A Foreign Seller will still need to be identified and registered with FDA, and FDA will still review information about the Foreign Seller, before FDA will authorize a SIP.

(Comment 13) Several comments recommend that the proposed rule be changed to allow an initial SIP Proposal to identify more than one Foreign Seller and more than one Importer. Several comments also support allowing a longer supply chain, to include multiple Foreign Sellers. These comments assert, for example, that a short supply chain would allow drug manufacturers to discriminate against a Foreign Seller specified in a SIP, preventing the SIP from demonstrating to FDA that the SIP can consistently and successfully import eligible prescription drugs. Other comments express support for the rule as proposed, noting among other things that more complex supply chains may be less secure.

(Response 13) As described in the NPRM (84 FR 70796 at 70797), the rule provides that a SIP Proposal needs to identify the Foreign Seller in Canada that will purchase the eligible prescription drug directly from its manufacturer, and identify the Importer in the United States that will buy the drug directly from the Foreign Seller before FDA will authorize the SIP. We have revised the rule to require that each supply chain under a SIP must still be limited to one manufacturer, one Foreign Seller, and one Importer. Although the initial SIP Proposal would be authorized to allow just one Foreign Seller and one Importer, if the SIP can show that it has consistently imported eligible prescription drugs in accordance with section 804 of the FD&C Act and the rule, the SIP Sponsor can submit a supplemental proposal to add supply chains, which would each consist of one or more eligible prescription drugs, one Foreign Seller, and one Importer. We believe that
because SIPs are new and unique programs which may be challenging to implement at first, they should begin with a single importer and single foreign seller. Based on FDA’s experience with drug importation and implementation of new programs, we believe that an increase in the number of entities a SIP must oversee and, potentially, a corresponding increase in the volume of product, could multiply the opportunity for supply chain security problems. Absent a demonstrated track record of oversight capability and compliance, initially limiting a SIP to one Foreign Seller and one Importer is an important safeguard. With regard to the concern raised in some comments that a manufacturer could refuse to deal with participating Foreign Sellers, we do not intend to publicly disclose information from the SIP Proposal or authorization that is confidential business information unless that information is made public by the information owner. However, this information might become public in other ways, such as through state open records laws. Even under such circumstances, the relationship between a manufacturer and a Foreign Seller will be subject to complex market dynamics, with many variables including relative market power, and it is difficult to predict what transactions might or might not occur.

(Comment 14) One comment recommends that SIP Proposals describe a plan for ensuring that FDA-approved patient labeling is dispensed to patients. One comment asks that the FDA-approved patient labeling include additional information pertaining to importation under a SIP generally or under a particular SIP. For those eligible prescription drugs that do not have FDA-approved patient labeling, the comment asks that FDA require that they have patient labeling that is not specific to a particular product that includes information pertaining to importation under a SIP generally or under a particular SIP. The comment asks that this patient labeling include the labeling statement described in §251.13.

(Response 14) We are not making changes to the final rule with regard to this comment. The final rule provides that Importers are responsible for, among other things, ensuring that eligible prescription drugs are relabeled with the required U.S. labeling, including patient labeling such as Medication Guides, Instruction for Use documents, and patient package inserts. As described in the NPRM, a SIP Proposal must identify the FDA-registered repackager or relabeler in the United States that will relabel the imported drugs with the required U.S. labeling, including the carton and container labeling, Prescribing Information, and any patient labeling, such as Medication Guides, Instruction for Use documents, and patient package inserts. The final rule requires that the SIP Proposal explain how the SIP Sponsor will educate pharmacists, healthcare providers, pharmacy benefit managers, health insurance issuers and plans, as appropriate, and patients about the eligible prescription drugs imported under its SIP. We do not believe it is necessary to add a requirement to provide patient labeling that is not specific to a particular product and that includes information pertaining to importation under a SIP generally or under a particular SIP.

(Comment 15) Several comments address issues related to identification in a SIP Proposal of drugs that may meet program requirements, if some information about potentially eligible prescription drugs is not available to the SIP Sponsor at the time it submits a SIP Proposal. One comment suggests that manufacturers should not be required to disclose manufacturing information before SIP authorization.

(Response 15) We decline to make changes in response to these comments. As noted in the NPRM (84 FR 70796 at 70807), we recognize that at the time of submission of a SIP Proposal the SIP Sponsor may not know whether a drug meets the conditions in an FDA-approved NDA or ANDA. FDA intends to review, among other things, the information that the SIP Sponsor is able to provide about each of the drugs that the SIP Sponsor seeks to import to confirm that each is approved by both HPFB and FDA, that each FDA-approved drug is currently marketed in the United States, and that none of the drugs falls into any of the exclusions from the definition of eligible prescription drug. Under the final rule, §251.3(d)(5)–(6), (e)(5) and (7), manufacturers are not required to disclose information before a SIP is authorized.

(Comment 16) One comment claims that the rule would, if finalized as proposed, increase risks to the public health by assigning pharmacovigilance and recall responsibilities to States and to other chain participants the States license, and to take disciplinary action if warranted. States also have tools that they can use to respond rapidly should activities under their SIP adversely affect the public health. In addition, under the final rule, Importers will submit adverse event, field alert, and other reports to both FDA and the manufacturer. The reports will aid the manufacturer in its pharmacovigilance efforts and will provide FDA with information that may be relevant to its review of SIP Proposals and Pre-Import Requests, as well as to its oversight of drugs imported under section 804 of the FD&C Act and of section 804 in general. The SIP Proposal must include a written recall plan that will be reviewed for completeness and effectiveness by the Agency before the SIP is authorized. In addition, FDA assists firms with carrying out their recall responsibilities to protect the public from distributed products in violation of the FD&C Act and other laws administered by FDA.

(Comment 17) Several comments suggest that before FDA authorizes a SIP Proposal submitted by a State agency, a potential SIP Sponsor should need to show that the SIP and any necessary funding have been approved by the State’s legislature and executive.

(Response 17) We decline to make changes in the final rule because it may not be feasible for a State to make a final funding determination for a SIP before FDA evaluates the SIP Proposal. Instead, the final rule requires that a SIP Proposal include, among other things, an explanation of how the SIP Sponsor will ensure that all the participants in the SIP comply with the requirements of section 804 of the FD&C Act and the rule, as well as a description of the procedures the SIP Sponsor will use to ensure that these requirements are met. In addition, the final rule provides that, among other reasons, FDA may decline to authorize a SIP Proposal because
of potential safety concerns with the SIP, because there exists a degree of uncertainty that the SIP Proposal would adequately ensure the protection of public health, because of the relative likelihood that the SIP Proposal would not result in significant cost savings, or in order to limit the number of authorized SIPs so FDA can effectively and efficiently carry out its responsibilities under section 804 of the FD&C Act in light of the amount of resources allocated to carrying out such responsibilities.

(Comment 18) Several comments suggest that various entities or persons participating in a SIP, including Foreign Sellers, Importers, repackagers, relabelers, and laboratories, should be inspected by FDA before the SIP could be authorized. One comment suggests that FDA should conduct periodic audits of shipments of eligible prescription drugs being imported. (Response 18) FDA is not making these changes because we believe the Agency’s existing mechanisms for oversight are sufficient. Although we decline to add a pre-authorization inspection requirement, we note, as discussed in the NPRM, that we retain our right to conduct inspections under section 704 of the FD&C Act. Inspections may occur before authorization or as part of FDA’s risk-based inspection program. In addition, the final rule requires SIP Sponsors and other SIP participants to agree to submit to audits of their books and records and inspections of their facilities as a condition of participation in a SIP. If a SIP Sponsor, manufacturer, Foreign Seller, Importer, qualifying laboratory, or other participant in the supply chain that is subject to inspection, delays, denies, or limits that inspection, or refuses to permit entry or inspection of its facility or its records, any drug held by that entity would be deemed to be adulterated (see section 501(j) of the FD&C Act). In those circumstances, FDA could also suspend the SIP, in whole or in part, immediately. We also decline to add a provision for periodic audits of shipments of eligible prescription drugs. All shipments are subject to Statutory Testing and, under this rule, FDA will be provided with three sets of the samples of each imported drug to enable FDA to also conduct the Statutory Testing as FDA deems warranted. In addition, FDA already has the authority to collect samples of shipments under 21 CFR 1.90.

(Comment 19) One comment proposes that SIP Proposals should be required to include background information for all entities or persons that are downstream of the SIP, in addition to the entities or persons in the SIP, if the SIP does not distribute drugs directly to patients. (Response 19) FDA declines to make this change. The final rule requires that SIP Proposals include, among other things, certain background information about Importers and Foreign Sellers. In the NPRM, we requested comment on whether the rule should require additional or alternative background information and on whether the background information requirement should cover additional or alternative individuals or entities. At this time, we do not believe that additional background information about downstream supply chain entities or persons is necessary to assure the security of the SIP supply chain or to assure that the requirements of the FD&C Act and this rule will be met because these entities and persons need to be in compliance with licensure and other Federal and State requirements.

(Comment 20) Several comments discuss the important role a Foreign Seller or Importer would play in a SIP. One comment recommends that FDA take additional steps to ensure Foreign Sellers maintain robust controls and that FDA obtain additional information regarding compliance and business history, including through inspections. The comment also recommends that the Foreign Seller or the Importer be required to disclose any civil judgments against or settlements entered into by the Foreign Seller or Importer related to liability for violations of State, Federal, or Canadian laws regarding drugs or devices or the sale or distribution of drugs or devices. One comment suggests that FDA require SIP Proposals to include disciplinary actions imposed against the Foreign Seller or the Importer beyond just United States and Canadian borders. Several comments reference potential difficulties in vetting and regulating Foreign Sellers. (Response 20) FDA declines to make changes in response to these comments because we believe the final rule includes sufficient controls without these requirements. Under the final rule, Foreign Sellers must, among other things, be licensed by Health Canada as drug wholesalers and be registered with a provincial regulatory authority to distribute HPFB-approved drugs. The final rule also requires that the SIP Sponsor’s importation plan include, among other things, a list of all disciplinary actions imposed against the Foreign Seller or the Importer by State, Federal, or Canadian regulatory bodies, including any such actions against the principals of the SIP’s facilities, or any facility manager or designated representative of such manager for the previous 7 years before submission of the SIP Proposal.

(Comment 21) Several comments suggest ways a SIP Proposal might account for costs and benefits associated with the SIP and determine whether the SIP would significantly reduce costs for American consumers. Several comments suggest that FDA should limit the ways in which a SIP Proposal should be able to meet this requirement. Several comments asked about how section 804 drugs will be treated under government programs, including Medicaid and the 340B Drug Pricing Program. One comment suggests that FDA should identify a threshold for whether a reduction in cost is significant. (Response 21) We decline to make any changes to the rule in response to these comments. As discussed in the NPRM, FDA intends to determine whether a reduction in cost is significant in the context of considering a specific proposal. The information needed to demonstrate anticipated cost savings to the American consumer is dependent on the specific mechanisms which the SIP Proposal is using to reduce costs for American consumers. The SIP proposal should clearly articulate the mechanism by which the proposal will reduce costs to consumers and provide relevant information given that context. To demonstrate expected cost savings, a SIP Sponsor could compare anticipated acquisition costs or consumer prices per unit of each eligible prescription drug that the SIP Sponsor is seeking to import. A SIP Sponsor could also compare the current retail cash price of the drugs. If the cost savings do not go to consumers directly, because, for example, they accrue to a healthcare provider or payor, the SIP Proposal would need to show that the SIP will result in a significant reduction in the cost of covered products to the American consumer. We anticipate that some SIP Sponsors may seek to import drugs to be used by patients in State-run programs in which consumers do not directly pay the cost of drugs. In such cases, a SIP Sponsor could submit information about whether cost-sharing expenses are reduced for the participants, or whether the program will result in cost savings that are passed on to consumers in other ways, such as increasing the number of people covered by a State program, or increasing the availability of drugs covered by the program. A SIP proposal cannot demonstrate cost savings in connection with a government program if the eligible prescription drugs to be purchased under the SIP do not meet the program’s requirements. This rule is not intended to address how agencies other
than FDA, such as those that administer Medicaid or other government programs, may apply their authorities to drugs imported under a SIP. HHS may issue further guidance or rulemaking as appropriate. HHS guidance, including the relevant Medicaid guidance for drugs imported under a SIP, can be found at https://www.hhs.gov/guidance/.

(Comment 22) One comment recommends that SIP Sponsors be required to demonstrate to FDA that participants in the SIP, including Importers and Foreign Sellers, are capable of meeting program requirements, such as for serialization and monitoring for counterfeit drugs. Several comments express concern that entities or persons involved in the SIP might lack capacity, experience, and resources to demonstrate that they could meet all the requirements under the proposed rule.

(Response 22) We are not making changes based on these comments because we believe the final rule includes sufficient mechanisms for FDA to evaluate participants in a SIP. The final rule requires a SIP Sponsor, in its proposal, to explain how the SIP Sponsor will ensure that all the participants in the SIP comply with the requirements of section 804 of the FD&C Act and the rule. Under section 804 of the FD&C Act and the rule, and describe the procedures the SIP Sponsor will use to ensure requirements are met, including steps regarding storage, handling, and distribution practices; supply chain security; and screening eligible prescription drugs. In addition, the Foreign Seller must maintain records regarding the identity or origin of the original shipment intended for the United States. The Importer is also responsible for ensuring compliance with certain requirements and does not affect the quality or impinge on the security of the eligible prescription drug(s). In addition, the Foreign Seller must maintain records associating the SSI with the DIN from the HPFB and all the records it received from the manufacturer upon receipt of the original shipment intended for the Canadian market. The Importer is also responsible for ensuring compliance with requirements for serialization and identifying suspect or illegitimate product when the drugs arrive in the United States.

(Comment 23) Several comments asked whether eligible prescription drugs imported under a SIP could be returned, and how those returns would be handled.

(Response 23) We have revised the rule to provide that a SIP Sponsor’s importation plan must include the SIP’s return plan, including an explanation of how the SIP Sponsor will ensure that a product that is returned after being in U.S. distribution is properly dispositioned in the United States if it is a non-saleable return in order to protect U.S. patients from expired or unsafe drugs. We are requiring that returned products be dispositioned in the United States, as appropriate, to prevent these products, which have been in U.S. distribution with the FDA-approved labeling prior to their return, from possible distribution in Canada with the U.S. labeling or from being re-imported into the U.S. as a non-SIP drug. In addition, it is unclear whether such products, which will have been relabeled to comply with U.S. requirements, could be returned to the Foreign Seller under Canadian law. Therefore, as an additional safeguard under section 804(c)(3) of the FD&C Act and to reduce opportunities for diversion and other forms of fraud, the return plan must explain how the SIP Sponsor will ensure that returned eligible prescription drugs, which have been relabeled for the U.S. market, are not exported from the United States. If the SIP Sponsor anticipates that its program will have returned product that may be considered as saleable and therefore re-distributed in the United States, the return plan should address how returned eligible prescription drugs will be determined to be saleable and how those products will be handled.

(Comment 24) One comment proposes several additional elements to be included in a SIP compliance plan, which must be submitted as part of the SIP Proposal. The comment suggests that a SIP compliance plan should include: (1) A compliance committee; (2) a program for internal monitoring and auditing; and (3) well-established processes for disciplinary actions for noncompliance. The comment also suggests that SIP’s have promotion compliance programs that address interactions with healthcare professionals, patient advocacy organizations, and others. The comment further recommends that FDA adopt certain submission requirements for promotional materials.

(Response 24) As discussed in the NPRM (84 FR 70796 at 70811), SIP Sponsors need to develop a compliance plan and describe it in detail in their SIP Proposal for FDA’s review and authorization. We have revised the rule to provide that a SIP Sponsor’s importation plan must include the SIP’s compliance plan, including: (1) A description of the division of responsibilities among cosponsors, if any, which includes a plan for timely communication of any compliance issues to the SIP sponsor; (2) identification of responsible individual(s) and a description of the respective area(s) of compliance that will be monitored by each responsible individual; (3) the creation of written compliance policies, procedures, and protocols; (4) the provision of written and training to ensure that Foreign Sellers, Importers, qualifying laboratories, and their employees understand their compliance-related responsibilities; (5) the creation and maintenance of effective lines of communication, including a process to protect the anonymity of complainants and to protect whistleblowers; and (6) the adoption of processes and procedures for uncovering and addressing noncompliance or misconduct. At this time, we decline to require that every SIP compliance plan include each element proposed in the comment. In recognition of the SIP Sponsors’ and cosponsors’ responsibilities, we have also revised the SIP Proposal provisions to require the signature of the SIP Sponsor and cosponsors, if any, or an authorized representative. In addition to the compliance plan, a SIP sponsor’s importation plan must explain how the SIP Sponsor will ensure that all the participants in the SIP comply with the requirements of section 804 of the FD&C Act and the rule. In addition, the final rule requires the SIP Sponsor to describe the procedures it will use to ensure that, among other things: (1) The storage, handling, and distribution practices of supply chain participants, including transportation providers, meet certain requirements and do not affect the quality or impinge on the security of the eligible prescription drugs; (2) the supply chain is secure; (3) the Importer screens the eligible prescription drugs it imports for evidence that they are adulterated, counterfeit, damaged, tampered with, expired, suspect foreign product, or illegitimate foreign product; and (4) the Importer fulfills its responsibilities to submit adverse event, field alert, and other reports. The SIP Proposal must also explain how the SIP Sponsor will educate pharmacists, healthcare providers, pharmacy benefit managers, health insurance issuers and plans, as appropriate, and patients about the drugs imported under its SIP. With regard to requirements for promotional materials, under the FD&C Act and the final rule, imported eligible prescription drugs cannot be misbranded and must meet applicable labeling requirements. As with other aspects of compliance, the SIP Proposal and the compliance plan it
Import Request, including among other things, the established and proprietary name of the drug, API information, and manufacturer information. Additionally, the final rule provides that Importers would need to maintain records, for not less than 6 years, that allow the Importer to associate the product identifier it affixed or imprinted to each package and homogenous case of product it received from the Foreign Seller, with the SSI that had been assigned by the Foreign Seller, and the Canadian DIN that was on the package when the Foreign Seller received the product from the original manufacturer.

Response 25
Because this program is novel, we do not have sufficient information to estimate a timeframe for the review of a SIP Proposal. Review times may depend on factors such as the quality and complexity of proposals and Agency resource constraints. FDA plans to establish internal processes for its review of SIPs, rather than specifying details, such as the order of its review, in this regulation.

Comment 26
One comment proposes that each reauthorization of a SIP be accompanied by a new assessment of whether the SIP would “pose no additional risk to the public’s health and safety.”

Response 26
We decline to change the rule in response to this comment. The final rule provides that FDA may deny a request for authorization, modification, or extension of a SIP including if a proposed SIP does not meet the standard for authorizing a SIP. The final rule further provides that if a SIP Proposal meets the requirements of the rule, FDA may nonetheless decide not to authorize a SIP Proposal. The final rule also provides that FDA may decide not to authorize a SIP Proposal because of potential safety concerns with the SIP or because of the degree of uncertainty that the SIP Proposal would adequately ensure the protection of public health.

Comment 27
Several comments support requirements on Importers to provide certain manufacturing information, including the source of the imported product and active pharmaceutical ingredient (API) information, and to maintain records of transactions.

Response 27
The final rule provides that a prescription drug may not be imported or offered for import under this part unless the Importer has filed a Pre-Import Request for that drug that has been granted by FDA. The Pre-Import Request must identify and include a description of the eligible prescription drug(s) covered by the Pre-Import Request, including among other things, the established and proprietary name of the drug, API information, and manufacturer information. Additionally, the final rule provides that Importers would need to maintain records, for not less than 6 years, that allow the Importer to associate the product identifier it affixed or imprinted to each package and homogenous case of product it received from the Foreign Seller, with the SSI that had been assigned by the Foreign Seller, and the Canadian DIN that was on the package when the Foreign Seller received the product from the original manufacturer.

Comment 28
Several comments assert that the final rule should rely as little as possible on requiring manufacturers to take certain actions and make certain disclosures. The comments say that because manufacturers may oppose those requirements, the final rule should primarily rely on other measures where possible to achieve the same aims. The comments assert that FDA must also be prepared to provide any necessary information that a manufacturer refuses to provide and to take any other action against the manufacturer as appropriate.

Response 28
The obligations on manufacturers under section 804 and this rule are enforceable under section 301(aa) of the FD&C Act (21 U.S.C. 331(aa)), which provides that, among other things, a violation of the regulations implementing section 804 is a prohibited act. Furthermore, section 303(b)(6) of the FD&C Act (21 U.S.C. 333(b)(6)) provides for a prison term of up to 10 years for manufacturers or Importers that knowingly fail to comply with a requirement of section 804(e) of the FD&C Act, including that: (1) The manufacturer or Importer conduct the Statutory Testing at a qualifying laboratory; (2) if the Importer conducts the testing, the manufacturer supply the information needed to authenticate the drug being tested and to confirm that the labeling is in compliance with the FD&C Act; and (3) if the manufacturer supplies this information to the Importer, the Importer keep it in strict confidence and only use it for testing and complying with the FD&C Act. Violators are also subject to fines under 18 U.S.C. 3571. Because of these provisions, we have determined that it is not necessary to include proposed § 251.16(i) in the final rule. That provision stated that “FDA may transmit information that the manufacturer is required to provide to an Importer under this section on the manufacturer’s request if the manufacturer has not transmitted such information to the Importer in a timely fashion and if such information is available to FDA in the NDA or ANDA.”

Comment 29
One comment recommends that FDA shorten the pre-import notification period to give SIPs more flexibility to respond to emerging needs based on demand for certain products, and to avoid having to forecast demand far in advance of importation.

Response 29
The NPRM provided that after FDA has authorized a SIP Proposal, the Importer would submit a Pre-Import Request to FDA at least 30 calendar days before the scheduled date of arrival or entry for consumption for a shipment containing an eligible prescription drug covered by the SIP, whichever is earlier. FDA declines to change this provision because the Agency will need sufficient time to review the Pre-Import Request and determine if the Importer will meet all the requirements for importation. FDA may consider expediting reviews of Pre-Import Requests, if appropriate, and depending on resource availability.

Comment 30
Several comments recommend that the final rule require an Importer to file a separate Pre-Import Request for each shipment of eligible prescription drugs.

Response 30
FDA is not making changes in response to these comments. As discussed in the NPRM, when a Pre-Import Request is granted by FDA, that Pre-Import Request covers subsequent shipments of the eligible prescription drug(s) identified in the Agency’s grant of that Request, provided that all of the information contained in the Pre-Import Request, with the exception of the anticipated dates of shipment, is the same for each subsequent shipment covered by the Pre-Import Request when the shipment arrives in the United States. We believe that Importers should have the flexibility to decide how many shipments should be covered by a Pre-Import Request. An Importer could choose to send one eligible prescription drug covered by a Pre-Import Request in a separate shipment, for example. An Importer could also choose to send one eligible prescription drug covered by a Pre-Import Request in multiple shipments. Requiring an Importer to file a separate Pre-Import Request for each shipment would not facilitate the importation of eligible prescription drugs and would unnecessarily burden both the Importer and the Agency.

Comment 31
One comment recommends that FDA clarify that a manufacturer is not required to provide an attestation unless it has received formal notification from FDA that an applicable SIP has been authorized. The
comment further recommends that FDA clarify that a manufacturer may decline to provide an attestation if, in the manufacturer’s opinion, the Canadian version of the drug fails to meet any of the conditions in the FDA-approved NDA or ANDA, including process-related and manufacturing specifications. The comment also asks FDA to clarify that the refusal or failure to provide an attestation under such circumstances is not a violation of section 804 of the FD&C Act or the final rule. The comment requests that FDA clarify that a manufacturer has the initial option to conduct such testing and that the Importer may conduct it only if the manufacturer declines, because such testing requires the disclosure of sensitive information.

(Response 31) We decline to change the rule in the manner suggested. We intend to provide updates on SIP authorizations and do not believe it is necessary to provide additional, formal notification to manufacturers. We further believe that the rule is sufficiently clear that a manufacturer does not need to provide an attestation and information statement if the drug proposed for import does not, except for the fact that it bears the HPFB-approved labeling, meet the conditions in the FDA-approved NDA or ANDA, including any process-related or other requirements for which compliance cannot be established through laboratory testing. To facilitate importation, the final rule clarifies that the manufacturer must notify the Importer and FDA if it cannot provide the required attestation and information statement and articulate with specificity the reasons it cannot provide that attestation and information statement. We do not believe that it is necessary to revise the rule to clarify that a manufacturer has the initial option to conduct the Statutory Testing and that the Importer may conduct it only if the manufacturer declines to do so. Under the final rule, the manufacturer must notify the Importer and FDA of the manufacturer’s intent to perform the Statutory Testing within 30 calendar days of receipt of a request from the Importer.

(Comment 32) The proposed rule provided that unless an extension is granted, authorization for a SIP automatically terminates after 2 years, or a shorter period of time if a shorter period of time is specified in the authorization for the SIP. Several comments assert that this limitation could discourage participation.

(Response 32) As discussed in the NPRM (84 FR 70796 at 70810), we believe that the initial 2-year period will provide sufficient time for SIP Sponsors to implement the authorized SIP. The 2-year authorization period for a SIP would begin when the Importer, or its authorized customs broker, files an electronic import entry for consumption for its first shipment of eligible prescription drugs under the SIP. We further believe, as we explained in the NPRM, that SIPs should terminate after 2 years unless re-authorized because importation under section 804 of the FD&C Act is novel and by the end of a 2-year period we can evaluate how the SIP performed, such as the extent to which it resulted in cost savings. The final rule provides that an authorized SIP Sponsor would be able to submit a proposal asking for authorization to extend the SIP for additional 2-year periods.

(Comment 33) One comment recommends that FDA clarify what kinds of changes warrant submission of an amendment to an authorized SIP. The comment also recommends that FDA allow the SIP to continue to operate while an amendment to the SIP is under consideration. The comment further recommends that FDA include a prompt and reasonable timeframe for responding to amendment requests.

(Response 33) A SIP Sponsor must not make any changes or permit any changes to be made to a SIP without first securing FDA’s authorization of a supplemental proposal. For example, as described in the NPRM, if a SIP Sponsor wishes to amend the list of eligible prescription drugs it seeks to import or to work with a different Foreign Seller, Importer, or qualifying laboratory, the SIP Sponsor must submit a supplemental proposal. The final rule provides that a SIP Sponsor can propose to add Foreign Sellers or Importers to an authorized SIP once it has consistently imported eligible prescription drugs in accordance with section 804 of the FD&C Act and the final rule. The final rule also provides that a SIP Sponsor may request that FDA extend the authorization period of an authorized SIP. Consistent with responses to comments and an assessment of a timeframe given that this depends on, among other factors, the quality and complexity of submissions and Agency resource constraints. Moreover, because this program is novel, we do not have sufficient information to estimate a timeframe for these reviews.

E. Comments on Certain Requirements for Section 804 Importation Programs

(Comment 34) Several comments suggest that Importers’ screening of eligible prescription drugs for evidence regarding whether they are adulterated, counterfeit, damaged, tampered with, or expired is not sufficient. One comment notes that visual inspection does not replace the need for Statutory Testing. (Response 34) The final rule, like the proposed rule, sets out a number of steps, including Statutory Testing, that a SIP Sponsor and others would need to take to ensure that the supply chain is secure and importation will pose no additional risk to the public’s health and safety. Visual inspection does not replace the need for Statutory Testing in accordance with the requirements of section 804 and the rule. Additionally, FDA reviews import entries to ensure that they do not contain articles that appear to violate the FD&C Act and takes samples of FDA-regulated products for examination when appropriate. Arrivals and entries of eligible prescription drugs under a SIP will be limited to a port authorized by FDA in order to facilitate our admissibility review of entries containing eligible prescription drugs. (Comment 35) Several comments address whether the labeling for an eligible prescription drug needs to be the same as the manufacturer’s FDA-approved labeling. For example, one comment suggests that because Canadian drug packaging and instructions are written in English already, relabeling is unnecessary. Another comment asserts that differentiation between eligible prescription drugs and other drugs could inadvertently lead to the misperception that eligible prescription drugs are less safe. Several comments agree with conspicuous label requirements; some comments suggest additional ways to distinguish eligible prescription drugs. One comment says that under the FD&C Act, if a United States Pharmacopeia (USP) monograph exists for an eligible prescription drug, the labeling requirements in the monograph play a role in ensuring that the drug is labeled according to U.S. labeling requirements.

(Response 35) Pursuant to section 804(d)(1)(K)(ii) of the FD&C Act, this final rule requires that an eligible prescription drug imported in accordance with this rule meet all labeling requirements under the FD&C Act. Additionally, pursuant to section 804(c)(1) of the FD&C Act, this final rule requires that each eligible prescription drug imported under this rule comply with sections 501, 502, and 505 of the FD&C Act. Generally, even if there is a USP monograph, the labeling for an imported eligible prescription drug will be the same as the FDA-approved prescription drug labeling under the NDA or the ANDA, except the labeling
will need to display a National Drug Code (NDC) and serial number that is unique to the eligible prescription drug, it will need to provide information about the Importer, and it will need to include the labeling statement required by this rule. If the SIP maintains a website, the labeling statement could also include the website address. As discussed below, we have revised the required labeling statement as follows: “[This drug was/These drugs were] imported from Canada without the authorization of [Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program.” We have also revised the rule to provide that NDC(s) must be included on the immediate container label and outside package. Also, as discussed in the NPRM, if an eligible prescription drug’s container is too small to fit the additional information required by this rule, the SIP would consider a supplemental proposal to modify the labeling of an eligible prescription drug. (Comment 36) One comment requests that FDA amend the rule to not allow identification of the manufacturer on the labeling of a drug imported and distributed via a SIP unless the manufacturer consents to such identification.

(Response 36) We decline to make this change. In the NPRM, we proposed to require that if the FDA-approved labeling of a drug imported and distributed via a SIP did not include the name and place of business of the manufacturer, then the name and place of business of the manufacturer be added. We have decided that it is not necessary to add the name and place of business of the manufacturer if that information is not already included on the FDA-approved labeling. The labeling will include the name and place of business of the manufacturer, packer or distributor that appears on the FDA-approved labeling and it will also include the name and place of business of the Importer. This will ensure that those responsible for the product can be identified. We note that the final rule includes the addition of a phrase in the labeling statement explaining that the drug is imported without the manufacturer’s authorization, which will help to prevent potential misperceptions regarding whether the manufacturer authorized the product to be imported.

(Comment 37) Comments ask that the proposed labeling statement that Importers are required to add to the labeling of a section 804 drug not include the phrase “reduce its cost to the American consumer.” A comment says that this statement would not be consistent with FDA regulations and the purpose of labeling, which the comment says is to provide safety and effectiveness and use information. Another comment notes that generic drugs typically are not permitted to be labeled with comparative cost information.

(Response 37) We have determined that it is not necessary to include the phrase “to reduce its costs to the American consumer” in the labeling statement that § 251.13(b)(4)(iv) requires Importers to add to the labeling of a section 804 drug. In the proposed rule, we explained that the purposes of the labeling statement are to help avoid potential confusion between products with the same name and to help pharmacists distinguish a section 804 product when selecting the product on the pharmacy shelf (84 FR 70796 at 70819). The labeling statement may also aid in pharmacovigilance (84 FR 70796 at 70820). The phrase “to reduce its costs to the American consumer” is not necessary to achieve these ends.

(Comment 38) One comment seeks clarification regarding whether, if a manufacturer updates the labeling or packaging of a product, the labeling for an eligible prescription drug would also need to be updated. The comment also requests clarification regarding whether paper labeling will be included in the package of the imported prescription drug. Another comment questions who would be responsible for ensuring that labeling of drugs imported under the rule reflects safety labeling updates.

(Response 38) As discussed in the NPRM, an Importer is responsible for relabeling a drug, or arranging for it to be relabeled, to meet the requirements of the final rule. The relabeling and associated limited repackaging activities must meet applicable requirements, including applicable current good manufacturing practice (CGMP) requirements under parts 210 and 211 (21 CFR parts 210 and 211). Consistent with the NPRM, we have clarified in the final rule that at the time an eligible prescription drug is sold or dispensed by the Importer, it has to be relabeled to be consistent with the FDA-approved labeling, including the carton and container labeling, Prescribing Information, and patient labeling, such as Medication Guides, Instructions for Use, and patient package inserts. In addition, the eligible prescription drug needs to have been assigned a product identifier in compliance with section 582 of the FD&C Act. The relabeled eligible prescription drug will be considered consistent with the FDA-approved labeling if it varies from the FDA-approved labeling, including carton and container labeling. Prescribing Information, and patient labeling, solely to the extent described in this final rule.

(Comment 39) One comment says that failure to relabel a container closure system, such as a blister pack, could lead to consumer confusion or medication errors, but relabeling could breach or otherwise damage the container system. (Response 39) If it is not possible to relabel a product without affecting the container closure system, such as a blister pack, then the product cannot be imported under a SIP. Certain repackaging that is necessary to perform the relabeling described in the final rule is permissible under this rule, but the rule does not allow repackaging of drugs that breaches the container closure system, such as a blister pack, which would introduce unnecessary risk of adulteration, degradation, and fraud for drugs imported under a SIP.

(Comment 40) Several comments express concern about the availability of new NDC numbers.

(Response 40) FDA is considering options to address potential demand for new labeler codes for NDC numbers to ensure availability.

(Comment 41) Several comments recommend that FDA assign a Canadian NDC as a unique labeler code and maintain the U.S. NDC product code and package size code. One comment also recommends that the use and assignment of NDC labeler codes under this rule be aligned with FDA’s draft guidance for industry titled “Importation of Canadian FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act,” available at https://www.fda.gov/media/133646/download. One comment suggests that different NDCs for imported drugs sharing the same proprietary name as FDA-approved drugs may help in accurately capturing reports on counterfeits or suspect products for the imported drug.

(Response 41) Generally, FDA does not mandate the use of particular NDC numbers. The final rule provides that imported drugs sharing the same proprietary name as FDA-approved drugs will have different NDCs from their FDA-approved counterparts.

(Comment 42) Several comments express concerns that the rule, as proposed, would open the “closed” U.S. drug distribution system for prescription drugs and could increase the opportunity for counterfeit and

1 When final, this guidance will represent FDA’s current thinking on this topic.
other substandard drugs to enter the supply chain. Several comments also assert that the proposed rule would undermine developments in supply chain security in the United States. Several comments express concerns about law enforcement resources. One comment suggests that the HHS Task Force Report regarding importation of prescription drugs that was submitted to Congress in December 2004 (Ref. 3) is still relevant today because there is still no Canadian system in place to ensure the pedigree of a product originally intended for Canada that becomes intended for the United States, nor are there any new international authorities to address the pedigree of the imported product and international recalls.

Several comments support the proposed supply chain security requirements.

(Response 42) As described in the NPRM, we believe that section 804 of the FD&C Act can be implemented in a manner consistent with the section 804(f)(1) certification criteria through programs, overseen by States or Indian Tribes, or in certain future circumstances by pharmacists or wholesale distributors, and their cosponsors, if any, that require authorization by and reporting to FDA. The final rule includes requirements relating to the types of drugs eligible for importation, the distribution channels and methods used for product traceability, and the testing of eligible prescription drugs for authenticity and degradation. In addition, in accordance with section 804 of the FD&C Act, the final rule requires that drugs imported under section 804 meet the specifications of an FDA-approved NDA or ANDA. These programs must also demonstrate significant cost reductions to the American consumer. In addition, as described in the NPRM (84 FR 70796 at 70800), in the intervening years since the Task Force Report was issued in 2004, Canada has amended its regulations to strengthen its oversight of both pharmaceutical manufacturing practices (Ref. 4) and pharmaceutical supply chain participants (Ref. 5), and regulatory requirements between Canada and the United States has increased. As noted elsewhere, the final rule does not open the closed U.S. distribution system; instead, it expands it. The SIP Sponsor must demonstrate, among other things, how it will ensure that the supply chain in the SIP is secure, as required by §251.3(d)(11).

(Comment 43) Several comments express concern that some product tracing provisions of the FD&C Act could strengthen the rule’s safety requirements, but those provisions will not be widely implemented for several years. Several comments recommend that the final rule should not be implemented before the development of national standards for wholesale distribution licensure and State adoption of those standards because those standards will be a key element of FDA and State oversight over wholesale drug distributors and pharmacists, in addition to manufacturers.

(Response 43) Key traceability requirements added by the DSCSA, including product tracing, product identification (which involves serialization), and verification for handling of suspect and illegitimate product, have been in effect for several years and have been implemented by trading partners in the U.S. pharmaceutical distribution system. FDA acknowledges and agrees that there are other important DSCSA supply chain security requirements that will be phased-in over the next several years, including national standards for licensure of wholesale distributors and third-party logistics operators, that will be vital to further securing the U.S. pharmaceutical supply chain, once implemented. However, FDA believes the final rule includes sufficient provisions to secure the supply chain, including requirements on direct purchasing of drugs and recordkeeping. With regard to the comments recommending that the final rule should not be implemented before the development of national standards for wholesale distribution licensure and State adoption of those standards, as described in the NPRM (84 FR 70796 at 70801), States provide the primary oversight of wholesale distributors’ storage, handling, and distribution practices to ensure the quality of drugs is maintained. States also ensure that pharmacies and pharmacists comply with statutes and regulations governing the practice of pharmacy, which includes dispensing of drugs to patients. States have the authority to inspect pharmaceutical supply chain participants and to take disciplinary action against them if warranted. States also have tools that they can use to respond rapidly should activities under a SIP adversely affect the public health.

However, in considering these and other comments regarding licensure of wholesale distributors as discussed in the NPRM, we have modified the definition of “wholesaler” in the final rule. Section 804(a)(5) of the FD&C Act states that “wholesaler” means, in general, “a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).” Several years after the addition of section 804(a)(5), the DSCSA amended section 503(e) of the FD&C Act such that section 503(e)(2)(A) no longer addressed the licensure of wholesalers or distributors (section 503(e)(2)(A) currently sets forth reporting obligations for persons engaged in wholesale distribution). Accordingly, in the NPRM, FDA defined “wholesaler” as, in general, “a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(1) of the Federal Food, Drug, and Cosmetic Act.” Upon further consideration, and in light of comments received on wholesale distribution licensure, FDA has further modified the definition of “wholesaler” in the final rule to mean a licensed wholesale distributor, as the terms “licensed” and “wholesale distributor” are defined in sections 581(9)(A) and (29) of the FD&C Act, respectively, of the FD&C Act. This modification is consistent with section 804(a)(5) of the FD&C Act, which incorporates section 503(e)(2)(A) as it had applied prior to DSCSA. At the time it was incorporated into part 804, section 503(e)(2)(A) had required that, in accordance with FDA regulations that were later established in 21 CFR part 205, “no person may engage in the wholesale distribution in interstate commerce of drugs subject to [section 503(b)] in a State unless such person is licensed by the State.” (See Prescription Drug Marketing Act of 1987, Public Law 100–293, Sec. 6). The incorporation into this rule of definitions in sections 581(9)(A) and 581(29) added by DSCSA clarifies that even prior to Federal standards being effective, a wholesale distributor must have a license under either section 503(e) or section 582(a)(6), as applicable. Section 582(a)(6) provides that having a valid license under State law is sufficient for a wholesale distributor to be considered “licensed” or “authorized” for purposes of meeting the DSCSA requirements that this rule incorporates.

This clarifies our intent, as expressed in the NPRM, that wholesalers participating in a SIP as Importers are subject to all applicable DSCSA regulations in section 582 of the FD&C Act. This modification also ensures that such wholesale distributors are considered to be “authorized” for purposes of DSCSA in advance of FDA’s establishment of national standards for wholesale distributor licensure, as prescribed in section 583 of the FD&C Act.

Finally, we also conclude that defining “wholesaler” through use of the term “wholesale distributor,” rather than “wholesaler or distributor,” as stated in section 804, aligns with DSCSA, and, because it is more in line
with current terminology and usage in the supply chain industry, adds clarity and consistency.

(Comment 44) Several comments say that it is not uncommon for prescription drugs to be purchased and imported directly into Canada in bulk by a manufacturer and then be repackaged and relabeled by a third party. The comments therefore recommend allowing the importation, repackaging, and relabeling of “bulk” eligible prescription drugs that lack finished packaging and labeling. One comment suggests that the final rule should allow importation of drugs that have not been approved in Canada. Other comments express concern about risks posed by transshipments and counterfeits from or through Canada.

(Response 44) We decline to make these changes in the final rule. The final rule provides that a SIP Sponsor must ensure that each drug imported under the SIP is HPFB-approved and labeled for sale in Canada from the point of manufacture to the Foreign Seller. To help ensure that drugs imported under a SIP are not transshipped through Canada and to reduce opportunities for counterfeiting or other forms of fraud, the final rule requires that each drug imported under the SIP and manufactured outside Canada must be authorized for import into Canada by the manufacturer, labeled by the manufacturer for the Canadian market, and imported into Canada before importation under the SIP. In addition, each drug imported under the SIP must be sold by the manufacturer directly to a Foreign Seller, which ships the drug directly to the Importer in the United States. The Importer(s) and Foreign Seller(s) identified in the SIP must meet the applicable requirements of the final rule and section 582(c) and (d) of the FD&C Act.

(Comment 45) Several comments address whether imported eligible prescription drugs might be considered suspect. One comment asks what a Foreign Seller should do with suspect products. One comment suggests additional reporting requirements. One comment recommends adding a requirement for a Foreign Seller to report to FDA and trading partners any suspect product and any product that is at a high risk of illegitimacy. One comment supports adding provisions in the proposed rule requiring notification of illegitimate products based on requirements in the FD&C Act. Section 581 of the FD&C Act defines various terms for purposes of meeting the requirements of the DSCSA.

Although imported eligible prescription drugs, like other products that enter the U.S. drug supply chain, may be considered “suspect” or “illegitimate” for a variety of reasons per section 581(21) and (8), respectively, as noted in the NPRM (84 FR 70796 at 70816), the Agency would not consider the eligible prescription drugs imported in accordance with the requirements of this rule to be “diverted” for the purpose of meeting verification obligations under DSCSA, solely as a result of being imported under section 804 of the FD&C Act and this final rule. However, such a product could still be found to be “suspect” or “illegitimate” for having other characteristics listed in section 581(21) and (8) of the FD&C Act (e.g., counterfeit or stolen).

We also note that separate from the definitions of “suspect product” and “illegitimate product,” as those terms are used for the purposes of meeting verification requirements under the DSCSA, the NPRM introduced, and this rule establishes, the terms “suspect foreign product” and “illegitimate foreign product” with regard to obligations that the Foreign Seller must meet for the drugs it receives from the manufacturer and intends to send to the importer under a SIP. Under the final rule, a Foreign Seller must have systems in place to determine whether a drug in its possession or control that it intends to sell to the Importer under a SIP is a suspect foreign product. If the Foreign Seller determines that a drug in its possession or control is a suspect foreign product, or if the Foreign Seller receives a request for verification from FDA that the Foreign Seller has determined that a product within its possession or control is a suspect foreign product, a Foreign Seller must: (1) quarantine the product within its possession or control until the product is cleared or dispositioned; (2) promptly conduct an investigation, in coordination with the importer and the manufacturer, as applicable, to determine whether the product is an illegitimate foreign product, and verify the product at the package level, including the SSI; and (3) if the Foreign Seller makes the determination that a suspect foreign product is not an illegitimate foreign product, promptly notify FDA of the determination for those products that FDA has requested verification (the product may be further distributed). The final rule requires steps for the Foreign Seller to quarantine and properly disposition illegitimate foreign product to ensure that the product is not further distributed, in addition to notifying FDA and the importer of products determined to be illegitimate foreign products.

We also note that the definitions of “suspect foreign product” and “illegitimate foreign product” proposed in the NPRM, and finalized here, include the use of the term “diverted.” In investigating a potentially suspect foreign product or identifying an illegitimate foreign product, a Foreign Seller may conclude a drug it receives is “diverted,” which refers to the purposes of these obligations means that there was not a direct transaction of the drug from the manufacturer to the Foreign Seller as required under this rule. For example, a Foreign Seller may conclude that a drug it receives from the manufacturer is “diverted,” if the product left the Canadian pharmaceutical supply chain and is reintroduced in Canada in a transaction with the manufacturer or other supply chain entity; or the product is labeled for sale in a non-Canadian and non-U.S. market and is introduced into the Canadian pharmaceutical distribution supply chain through a transaction with the manufacturer or other supply chain entity.

Finally, the requirement in the DSCSA that a covered drug that is at high risk of illegitimacy be reported to the FDA and immediate trading partners is an obligation limited to manufacturers who may have specific programs in place that could generate such information. We believe that the final rule includes sufficient additional provisions to secure the supply chain without a “high risk of illegitimacy” provision that is similar to that which pertains only to manufacturers under DSCSA.

(Comment 46) Several comments suggest that Foreign Sellers should be required to comply with all requirements for relabelers in the United States. Some of these comments highlight the importance of a short, secure supply chain. One comment proposes that Foreign Sellers be subject to the requirements of repackers.

(Response 46) FDA declines to make changes in response to these comments, because we believe the final rule’s requirements (which include requirements to ensure a short, secure supply chain) are sufficient to maintain supply chain security. Specifically, under the final rule, a Foreign Seller is responsible for relabeling drug products solely to affix the SSI to or imprint the SSI on each package and homogenous case of the eligible prescription drug(s). The Foreign Seller is required to adhere to all applicable CGMP requirements in
ability of Importers and Foreign Sellers to quickly identify potentially suspect or illegitimate foreign products.  
(Comment 48) Several comments suggest that the rule should allow relabeling of drugs to occur in Canada.

(Comment 48) FDA declines to make this change. The final rule requires that relabeling only take place after the Agency has accepted the results of the Statutory Testing, which takes place at a qualifying laboratory in the United States. This avoids the potential diversion that could occur if eligible prescription drugs are relabeled for the U.S. market prior to import, and then fail the testing requirements. If eligible prescription drugs were relabeled in Canada before they were tested in the United States, diversion could happen before or after export of the refused drugs to Canada. Eligible prescription drugs cannot be relabeled in Canada after they are tested in the United States, because, as explained later, sampling upon arrival in the United States helps ensure that the sample is selected from the actual drugs that arrives in the United States. In addition, if the drugs are counterfeit, they would be counterfeits of the Canadian drug. Relabeling the drugs in Canada would destroy the evidence of counterfeiting which is often found on the label. The Importer and FDA would, therefore, be impeded in our efforts to detect that a drug being imported under a SIP is a counterfeit.

(Comment 49) Several comments raise concerns about whether the product identifier that would be affixed or imprinted by an Importer, if the Importer intends to place the product into further transactions in commerce, provides sufficient information about the product’s origin.

(Comment 49) The final rule provides that once the Importer receives an eligible prescription drug from the Foreign Seller, relabeling would need to include affixing or imprinting a product identifier that is associated with the SSI that the Foreign Seller assigned to the product before sending it to the Importer. As noted in the NPRM (84 FR 70796 at 70815), a relabeler who contracts with the Importer to affix a product identifier on the Importer’s behalf must, even if not engaged in a repackaging operation with respect to the eligible prescription drug, have systems and processes in place to meet applicable requirements of a “repackager” under section 582(e) of the FD&C Act for any transaction involving the eligible prescription drug.

As described in the NPRM (84 FR 70796 at 70814), a relabeler that associates a product identifier with a manufacturer-affixed product identifier. Furthermore, the final rule clarifies that the lot number that is included in the product identifier is that assigned by the manufacturer of the eligible prescription drug.

(Comment 50) Several comments urge FDA to require product identifiers to be affixed on all products imported pursuant to the final rule, including where an Importer intends to directly dispense the product to patients.

(Comment 50) We agree with these comments and have accordingly modified the rule to clarify that the requirement to affix or imprint a product identifier applies to all eligible prescription drugs. The final rule provides that an Importer must facilitate affixation or imprinting of a product identifier on each package or homogenous case of an eligible prescription drug upon receiving it from the Foreign Seller. In the NPRM (84 FR 70796 at 70815), we had signaled that if an Importer is a pharmacist who directly dispenses the product to patients, a product identifier would not be required to be affixed or imprinted on each package and homogenous case of the eligible prescription drug. However, after consideration of comments, we agree that in the context of the section 804 program, all eligible
prescription drugs (which must meet the definition of “product” under the DSCSA) warrant a product identifier that is affixed or imprinted by the Importer or by a relabeled that the Importer authorizes. Even in the instances of an Importer who is a pharmacist intending to dispense the product directly to patients, the affixing or imprinting of a product identifier is needed in order to facilitate verification activities through the Importer’s maintenance of records associating the product identifier at the package level with the SSI that had been placed by the Foreign Seller, thus enhancing supply chain security.

(Comment 51) Several comments oppose providing exemptions to Importers from certain DSCSA requirements, citing concerns about opening a path for counterfeit and unsafe drugs into the U.S. supply chain.

(Response 51) The final rule identifies specific exemptions from DSCSA requirements in section 582 of the FD&C Act, as section 582 of the FD&C Act do not compromise the security of the supply chain for drugs imported under section 804 of the FD&C Act. The final rule includes additional safeguards to protect the public health. For example, under the final rule, an Importer is exempt from the prohibition on receiving a product for which the previous owner did not provide the transaction history, transaction information, and transaction statement, under section 582(c)(1)(A) or (d)(1)(A) of the FD&C Act as applicable, provided the Importer receives from the Foreign Seller certain transaction-related information that is adequate to ensure no additional risk to supply chain security. These additional safeguards are authorized under section 804(c)(3) of the FD&C Act and are necessary for the Secretary to certify that implementation of section 804 of the FD&C Act would pose no additional risk to the public’s health and safety.

(Comment 52) Some comments question FDA’s authority to allow exemptions from DSCSA through rulemaking, because the provisions have been established by Congress through statute.

(Response 52) Congress established in DSCSA that exemptions from section 582 of the FD&C Act are permissible; indeed, the Secretary was given explicit authority to identify such exemptions through a process established by the Agency in guidance (see section 582(a)(3)(A)(iii) of the FD&C Act). The exemptions that were proposed in the NPRM, which is being finalized here, are established in accordance with this statutory authority. Although FDA is establishing these exemptions through rulemaking rather than guidance, we believe this is an appropriate exercise of the section 582 authority because the statute does not foreclose FDA from establishing exemptions through notice-and-comment rulemaking. Because the exemptions identified by FDA in the final rule would apply to SIP participants generally, and because we believe that these exemptions are appropriate only in the context of the requirements established by this rule, including safeguards to protect supply chain security, providing these exemptions concurrently with establishing such safeguards is a sensible and appropriate exercise of FDA’s statutory authority in this circumstance. FDA intends to continue to consider and, as appropriate, grant other exemptions consistent with the statutory authority provided in section 582 of the FD&C Act.

(Comment 53) Several comments ask about the availability of laboratories that would meet the statutory and regulatory criteria to become approved qualifying laboratories. In particular, some comments express concerns that the requirements that qualifying laboratory have an FDA inspection history could result in insufficient options for laboratory partners for SIPs.

(Response 54) The final rule does not require qualifying laboratories to hold CGMP certification. Qualifying laboratories need to comply with the applicable elements of the CGMP requirements, including provisions regarding laboratory controls in §211.160 and regarding laboratory records in §211.194.

(Comment 55) One comment suggests that because the proposed rule allows the potential for multiple SIP Proposals that include a particular eligible prescription drug, it is important to have clear and consistent quality standards to help ensure that medications have the correct identity, strength, and purity when consumed by patients.

(Response 55) Section 804 of the FD&C Act and the final rule contain numerous provisions that work together to help ensure the quality of products imported under this rule. Among other things, the statute and this final rule require that Statutory Testing either be performed by the manufacturer of an eligible prescription drug or, if such testing is performed by the Importer, that the manufacturer supply the information the Importer needs to authenticate the drug. The final rule specifies that this information includes, among other things, any relevant testing protocols that the manufacturer has developed.

(Comment 56) Several comments suggest that, if a manufacturer does not conduct testing itself, Importers should be allowed to conduct Statutory Testing, or sampling for that testing, in Canada and other foreign countries before importation.

(Response 56) FDA declines to make the requested change. Section 804 of the FD&C Act provides that Statutory Testing must be conducted by a qualifying laboratory, and a qualifying laboratory must be in the United States.
and approved by the Secretary. Sampling upon arrival in the United States helps ensure that the sample is selected from the actual shipment of drugs that arrives in the United States.

(Comment 57) One comment urges FDA to clarify that manufacturers cannot satisfy the Statutory Testing requirements through preexisting release or conformance testing. The comment also recommends that, if drug products have already undergone release or conformance testing at a qualifying laboratory in the United States, Statutory Testing should be conducted at a separate, independent laboratory to ensure thorough analysis before the products enter the U.S. market.

(Response 57) Section 804 of the FD&C Act and the rule provide that the manufacturer or the Importer must arrange for samples from shipments of eligible prescription drugs to be tested by a qualifying laboratory. We believe it is sufficiently clear that the statute and this regulation do not allow manufacturers to provide testing results, such as those from the manufacturer’s batch release or conformance testing. If the manufacturer performs the testing required under section 804(e)(1) of the FD&C Act, the following information must be submitted in electronic format directly to FDA via the Electronic Submissions Gateway (ESG) or to an alternative transmission point identified by FDA: (1) The testing results, (2) a complete set of laboratory records, (3) a detailed description of the selection methods used, (4) the testing methods used, (5) complete data derived from all tests necessary to ensure that the eligible prescription drug meets the specifications of the FDA-approved drug that are established in the NDA or ANDA, (6) a Certificate of Analysis, and (7) any other documentation demonstrating that the testing meets the requirements under section 804(e)(1) of the FD&C Act. We do not believe that it is necessary to require in the final rule, for drug products that have undergone release or conformance testing at a qualifying laboratory in the United States, that Statutory Testing be conducted at another, independent laboratory, as long as the approved and CGMP-compliant methods are used.

(Comment 58) One comment recommends that FDA require that sampling be done according to standards issued by the American National Standards Institute (ANSI).

(Response 58) The NPRM proposed to require that a statistical sample of a batch or shipment of section 804 drugs be randomly selected from the batch or shipment being tested or, in the alternative, that the sample be representative of the batch or shipment. We sought comment on whether we should specify a sampling method. We also sought comment on whether we should require that sampling be done according to an established standard such as those issued by the ANSI or by ASTM International. We did not conclude that the comments received provided adequate support for specifying a standard. At this time, we are not specifying a standard in the final rule but may consider providing future guidance on this subject.

(Comment 59) One comment recommends that a manufacturer be allowed no more than 10 calendar days to provide required information to an Importer.

(Response 59) We agree with the comment that a set timeframe for providing required information is appropriate but disagree with the proposed 10-day schedule. We have revised the final rule to require a manufacturer to provide information to an Importer, within 30 calendar days of receiving a request, the required attestation and information statement, batch records, transaction information, Statutory Testing information, and authorization to use the FDA-approved labeling for the manufacturer’s drug. The 30-day deadline aligns with the timeline for the Importer to submit a Pre-Import Request, which must be submitted 30 days prior to the entry or arrival of a shipment of eligible prescription drugs into the United States.

(Comment 60) One comment contends that drugs refused admission to the United States should be destroyed at the foreign trade zone or at the secured warehouse, and Importers should not be permitted to export them.

(Response 60) We decline to make these changes. The NPRM proposed that if FDA refuses admission into the United States the drugs must be exported or destroyed by the Importer within 90 calendar days of the refusal. This is consistent with section 804(a) and (d)(1) of the FD&C Act, neither of which bar exportation.

In response to the suggestion in the comment that FDA prohibit export for all refused drugs offered for import under a SIP, we recognize that there may be some circumstances where export could be appropriate. For example, in the NPRM we stated that FDA would intend to refuse admission if 6 months have passed from the entry date of the shipment. It is possible that these drugs would not have been relabelled for the market and may be saleable in Canada. Destruction could prevent the SIP from recouping their loss by exporting the drugs back to the Foreign Seller and add additional cost to the SIP.

Finally, if we have concerns regarding drugs offered for import under a SIP that are refused admission being exported back to Canada or another country, FDA and CBP have tools to address this, such as pursuing destruction of the drugs or notifying the country to which the product would be exported.

(Comment 61) Several comments suggest that if a SIP Sponsor determines that a drug, manufacturer, Foreign Seller, Importer, qualifying laboratory, or other participant in or element of the supply chain in the authorized SIP does not meet all applicable requirements of the FD&C Act, FDA regulations, and the authorized SIP, the SIP Sponsor should not need to immediately stop importation of all drugs under the SIP. One comment asserts that identification of an illegitimate product in the SIP should be grounds for automatic, temporary suspension and potential full revocation of the SIP. The comment notes that if identification of illegitimate product introduced by a SIP were to lead to automatic revocation of the SIP’s authorization, it could have the counterproductive result of making trading partners less inclined to identify and report the illegitimate product.

(Response 61) As discussed in the NPRM, under certain circumstances set forth in section 804(g) of the FD&C Act, FDA is required to suspend importation. Section 804(g) of the FD&C Act provides that the Secretary must require that importations of a specific prescription drug or importations by a specific Importer under section 804(b) be immediately suspended on discovery of a pattern of importation of that specific prescription drug or by that specific Importer of drugs that are counterfeit or in violation of any requirement under section 804, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under section 804(b). In some circumstances, as described in the NPRM, FDA may suspend a SIP in whole or in part or FDA may revoke authorization of a SIP, in whole or in part. To ensure that FDA has current relevant information about SIP participants, we have revised the rule to require a SIP Sponsor to inform FDA of any new applicable criminal conviction, violation of law, or disciplinary action.

(Comment 62) Several comments ask FDA to limit requirements that they characterize as redundant, citing adverse event reports, individual case safety reports (ICSRs),
and recall requirements. In addition, one comment suggests that patients might not know whom to contact regarding an adverse event or a question about medication.

(Comment 62) FDA declines to make substantive changes in response to these comments. We have made some minor revisions from the provisions in the NPRM for clarity. For example, in one instance we have revised the wording to align with existing comparable requirements in 21 CFR 314.80 (under § 251.18(d)(9)), an Importer must “develop” written procedures to meet their obligations under that subpart because this encompasses the requirement to “maintain” and “follow” such written procedures, but such clarifications do not change FDA’s interpretation of the scope of existing responsibilities under § 314.80 or other existing safety reporting requirements.

We do not believe the reporting requirements in the final rule are duplicative or redundant. The rule requires an Importer to establish and maintain records and submit to FDA and the manufacturer reports of all adverse events associated with the use of the drug products it imports under section 804 of the FD&C Act and this final rule. An ICSR is a description of an adverse event related to an individual patient or subject. The final rule outlines when and how an Importer must submit ICSRs for domestic adverse events, and follow up reports, to FDA and the manufacturer. As described in the NPRM (84 FR 70796 at 70821), these reports, by the manufacturer in its pharmacovigilance efforts, and it will provide FDA with information that may be relevant to its review of SIP Proposals and Pre-Import Requests as well as to its oversight of drugs imported under section 804 of the FD&C Act and section 804 in general. In the event of a recall, Importers must, upon request by FDA, provide to FDA the transaction history, information, and statement, as those terms are defined in section 581(25), (26), and (27) of the FD&C Act, for recalled drugs. We have clarified in the final rule that, in the event of a recall, Foreign Sellers must also provide certain transaction information to FDA upon request.

(Comment 63) Several comments assert that it is inappropriate to establish “medication error” reporting requirements only for SIPs.

(Comment 63) We have decided not to establish medication error reporting requirements for SIPs at this time, before establishing such requirements for prescription drugs generally, and have revised the final rule to remove requirements related to reporting medication errors. FDA might at a later time consider whether it should establish medication error reporting requirements for SIPs.

(Comment 64) Several comments request clarification regarding recall responsibilities. One comment says that the timeframe for adverse event reporting could lead to significant delays in recalls.

(Comment 64) The rule requires that each SIP proposal include a recall plan that explains how the SIP Sponsor will obtain additional recall or market withdrawal information, such as by obtaining recall information from an Importer, and how the SIP Sponsor will ensure that recall or market withdrawal information is shared among the SIP Sponsor, the Foreign Seller, the Importer, and FDA, and provided to the manufacturer. In addition, the rule requires that each SIP must have a written recall plan that describes the procedures to perform a recall of the product and specifies who will be responsible for performing the procedures. The recall plan must cover recalls mandated or requested by FDA and recalls initiated by the SIP Sponsor, as well as recalls in Canada or the United States initiated by a drug’s manufacturer that implicate a drug imported under a SIP, with which the Foreign Seller or Importer must cooperate. If FDA or any participant in a SIP determines that a recall is warranted, the SIP Sponsor must effectuate the recall in accordance with its written recall plan. We have revised the rule to clarify an Importer’s and a Foreign Seller’s responsibilities in a recall. We do not believe that the timeframes for adverse event reporting, which are consistent with other FDA requirements for adverse event reporting, would lead to significant delays in effectuating a recall.

(Comment 65) One comment suggests that allowing section 804-imported drug products to coexist on the market with manufacturers’ drugs would introduce confusion to real-world data (RWD) collection and bias real-world evidence (RWE) analyses.

(Comment 65) The comment assumes that an eligible prescription drug will have quality concerns that could not be accounted for in RWD sources and RWE analysis. However, an eligible prescription drug would need to meet the conditions in an FDA-approved NDA or ANDA, including quality specifications. In addition, there may be ways of distinguishing eligible prescription drugs required under section 804 of the FD&C Act in RWD sources, for example, by NDC.

F. Certification

(Comment 66) Several comments address the certification that is required under section 804(l) of the FD&C Act. One comment argues that the certification cannot become null and void for any reason once it is made. Instead, the comment argues that the proper way to address problematic importations is to adopt a proposed new codification provision that would give the Secretary the authority to order the cessation of a particular SIP under certain specified circumstances.

(Comment 66) As stated in the NPRM (84 FR 70796 at 70803), the Secretary’s certification rests on the authorities and requirements outlined in the regulation issued to implement section 804. If any one of those provisions is invalidated, certification would become null and void because it was based on an understanding regarding how section 804 would be implemented that, under this scenario, would be factually incorrect and legally invalid. We decline to add the codified provision proposed in the comment because this final rule includes § 251.7, also included in the proposed rule, which provides FDA the authority to suspend or revoke a SIP under the circumstances set forth in that section or § 251.18.

(Comment 67) Several comments assert that the NPRM contained no assessment of whether importation under section 804 of the FD&C Act would result in a significant reduction in the cost of covered products to the American consumer and that section 804(l) requires factual findings on cost savings before the certification can be made.

(Comment 67) We disagree. For section 804 to become effective, subsection (l) requires the Secretary to certify that the implementation of this section will pose no additional risk to the public’s health and safety, and result in a significant reduction in the cost of covered products to the American consumer. Through this final rule, implementation of section 804(b) through (h) will result in a significant reduction in the cost of covered products to the American consumer. In particular, § 251.3(s)(9), as revised, requires the SIP Sponsor’s importation plan to explain, in a manner sufficiently detailed to allow for a meaningful evaluation, how the Sponsor will ensure that the SIP will result in a significant reduction in the cost to the American consumer; and § 251.7(c) provides that FDA may revoke the authorization of a SIP if, among other reasons, the Agency determines that continued implementation of the SIP will not
result in a significant reduction in the cost of drugs covered by the SIP to the American consumer. Together, these provisions will ensure that there is a meaningful assessment of whether drugs imported under a particular SIP will result, and are resulting, in a significant reduction in the cost of covered products to the American consumer, which, in turn, allows the Secretary to make the cost-related finding for the certification under section 804(f).

(Comment 68) One comment contends that the Secretary is impermissibly relying on States and Indian Tribes to support his certification decision under section 804(f) because such reliance on third parties to make the certification findings is contrary to the plain language of section 804 of the FD&C Act. The comment further contends that this rule would effectively subdelegate HHS’s fact-finding role to SIP Sponsors and cites U.S. Telecom Ass’n v. FCC, 359 F.3d 554 (D.C. Cir. 2004) for the proposition that delegating fact-finding to the states is unlawful absent congressional authorization.

[Response 68] In conjunction with this final rule, the Secretary is certifying that implementation of section 804(b)–(h) will pose no additional risk to the public’s health and safety, and result in a significant reduction in the cost of covered products to the American consumer. The final rule is designed to ensure that FDA and other components of HHS receive the necessary information to ensure this certification applies to a particular SIP. Ultimately, it will be the Secretary, acting through FDA, who will find that a particular SIP proposal meets the certification requirements based on the information received as part of the proposal. We note that it is a prohibited act under section 301(aa) of the FD&C Act to import a prescription drug in violation of section 804, falsify any record required to be maintained or provided to the Secretary under such section, or violate the regulations issued under such section. Accordingly, unless the Secretary has reason not to do so, he may consider the information he receives pursuant to this final rule and FDA’s evaluation of such information to ensure that a SIP will pose no additional risk to the public’s health and safety, and result in a significant reduction in the cost of covered products to the American consumer. The Secretary has not delegated the certification decision or any other finding to the states or any other third party. Consequently, the comment’s reference to U.S. Telecom Ass’n v. FCC is inapprropriate because in that case the court considered, in relevant part, whether a federal agency delegated its authority to make certain determinations to a state.

(Comment 69) One comment argues that in order to make the certification under section 804(l), the Secretary must find that implementation of all of section 804 will pose no additional risk to the public’s health and safety, and result in a significant reduction in the cost of covered products to the American consumer. The comment argues that if the Secretary cannot make this finding with regard to section 804(j), then the certification cannot be made solely with regard to section 804(b)–(h) of the FD&C Act. The comment cites Vermont v. Leavitt, 405 F. Supp. 2d 466 (D.Vt. 2006), in which the court stated that interpreting section 804(j)(1) to apply to only section 804(b)–(h) is “a convoluted and implausible interpretation” and “is undermined by the fact that Congress used the term ‘subsection’ in other provisions of section [804].” The comment also cites Montgomery County v. Leavitt, 445 F.Supp.2d 505, 508 (D. Md. 2006) to support the assertion that FDA has concluded that the certification requirement in section 804 applies to the entire section and does not authorize a specific waiver for a discrete state pilot program.

[Response 69] We disagree that a certification under section 804(l) must cover all of section 804 of the FD&C Act. In general, section 804 contains two importation pathways: (1) Commercial importation of drugs from Canada under subsections (b)–(h), and (2) personal importation under subsection (j). Each importation pathway must be certified by the Secretary under section 804(l) to be effective. However, section 804 does not explicitly require a certification to cover both pathways. In stating that this section only becomes effective if the implementation of the section meets the certification criteria, section 804(l) accomplishes two objectives: (1) Ensuring that any provision in section 804 does not take effect unless the Secretary certifies that implementation of the provision would meet the certification criteria; and (2) providing for the possibility that implementation could take different forms, including implementing section 804 in a way that only pertains to the commercial importation pathway or the personal importation pathway.

The court’s decision in Vermont v. Leavitt does not support the comment’s assertion. In that case, the state of Vermont argued that the personal importation provisions in section 804(j) of the FD&C Act should be implemented without a certification because the certification provision in section 804(l) only applies to the commercial importation pathway outlined in section 804(b)–(h). The court found this interpretation implausible. We agree with the court’s decision that for any provision in section 804 to be in effect, it must be covered by a certification from the Secretary in accordance with section 804(f). The court did not also hold that any certification under section 804(l) must cover all of section 804. In fact, the court expressly did not reach this decision. See Vermont v. Leavitt, 405 F. Supp. 2d at 479.

Similarly, in Montgomery County v. Leavitt, the plaintiff argued that the certification requirement in section 804(l) of the FD&C Act did not apply to all of section 804, and that FDA could authorize a specific waiver for the proposed importation program before any certification is made. The court held that the certification provision applies to all of section 804 and, therefore, FDA’s denial of the county’s waiver request for its proposed importation program was mandated by Federal law because no certification had yet been made. Again, we agree with the court’s decision that the certification provision applies to all of the provisions of section 804; accordingly, there must be a certification in place for the commercial importation pathway, the personal importation pathway, or both pathways, prior to implementation of such pathway[s].

(Comment 70) One comment argues that the certification under section 804(l) of the FD&C Act can only be made broadly and not with regard to only specific approved SIPs because section 804 contemplates a broad certification finding before the section goes into effect. In support of this argument, the comment states that: (1) Section 804 does not provide that certification can be based on state-specific plans for only certain state residents, and if that was the Congressional intent, it could have been so limited; (2) the certification provision refers to the American consumer, not specific American consumers under particular plans; and (3) section 804 permits the opening of the closed U.S. drug distribution system that protects patients from counterfeit and substandard drugs. In addition, the comment cites Montgomery County v. Leavitt and a letter from FDA to Montgomery County to support the proposition that the certification provision in section 804 does not authorize a specific waiver for a discrete state pilot program. The comment also cites to a government brief filed in the Vermont v. Leavitt litigation that it argues is inconsistent with the Agency’s position on this issue in this final rule.
(Response 70) The Secretary’s certification is based on the requirements and safeguards in this final rule. Through this implementation, the certification can be made because importation of drugs under section 804(b)–(h) of the FD&C Act will not increase the risk to the public’s health and safety, and will lead to a significant reduction in the cost of covered products to the American consumer. Although the certification provision in section 804(l) does not expressly address the review of sponsored plans for importation, there is nothing in the provision that precludes the Secretary from basing the certification on an implementing regulation that ensures any importations made under section 804 meet appropriate standards, including a requirement that importation plans be sponsored by certain entities and reviewed and authorized by the Secretary. In fact, the certification provision contemplates that the Secretary will base his decision on certain requirements or other policies established by him because the provision asks whether implementation of section 804 will lead to the findings necessary to make the certification.

With regard to the argument that because the certification provision refers to the American consumer, the certification must be broad, it is not clear what is meant by the term broad. We do not believe that reference to the American consumer means that before a certification can be made, there must be a finding that all American consumers will benefit from importation of drugs under section 804. A SIP or combination of SIPs could be broad in scope and provide significant cost savings to numerous Americans.

It is not clear how the argument that section 804 opens the closed U.S. distribution system supports the assertion that the certification in section 804(l) of the FD&C Act must be broad. In any case, this final rule does not open the closed U.S. distribution system; instead, it expands it. The SIP Sponsor must demonstrate, among other things, how it will ensure that the supply chain in the SIP is secure, as required by § 251.3(e)(11).

The references to Montgomery County v. Leavitt, the letter from FDA to Montgomery County mentioned in that decision do not support this comment’s arguments. The Court’s decision and the cited letter from FDA refer to the ability of FDA to authorize a specific waiver for a discrete state pilot program in the absence of a certification under section 804(l). This case, along with the decision in Vermont v. Leavitt, agreed with FDA’s position and found that such a program could not be authorized before the Secretary makes the required certification under section 804(l) of the FD&C Act.

As noted in the comment, the Secretary’s certification in this final rule do not limit the number of American consumers who could benefit from importation of drugs under section 804 of the FD&C Act. All states can participate under the rule and, as noted elsewhere, pharmacists or wholesalers may, under certain circumstances, be able to sponsor a SIP without the cosponsorship of a State or Indian Tribe. The involvement of a sponsor does not limit the scope of imports; instead it is meant to provide additional oversight to ensure that any such imports are safe.

As stated above, although section 804(l) does not expressly address implementation of section 804 will lead to the findings necessary to make the certification. This rule is designed to ensure that any authorized SIP poses no additional risk to the public’s health and safety and results in a significant reduction in the cost of covered products to the American consumer. Section 804(l), itself, does not impose any requirements on how implementation of section 804 of the FD&C Act would be done in order to enable those findings under the certification. This rule is designed to ensure that any authorized SIP poses no additional risk to the public’s health and safety and results in a significant reduction in the cost of covered products to the American consumer, in accordance with the Secretary’s certification.

(Comment 71) One comment notes that the proposed rule cites section 804 of the FD&C Act as part of the legal authority for the rule, and that section 804 is not in effect until the Secretary makes the certification required under section 804(l). The comment argues that the proposed rule must be withdrawn because it was issued without an effective statutory basis.

(Response 71) In accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(b)), the proposed rule includes reference to the legal authorities under which it was proposed. As noted by the comment, the referenced legal authorities in the proposed rule include section 804 of the FD&C Act. At the proposed rule stage, the rule is proposed to be issued under one or more legal authorities. The proposed rule does not have legal effect at the time it is issued; therefore, the cited legal authorities do not necessarily need to be in effect at that time. The Secretary is making the required certification under section 804(l) concurrent with this final rule. Therefore, section 804 is in effect as a legal authority for this final rule. Furthermore, the certification requirement was included in section 804 so that the section would not be implemented before a certification is made. We do not believe that Congress intended for the provision to preclude the issuance of a proposed rule proposing how the section could be implemented in a manner that meets the basis for a certification, once that certification is made. Moreover, under the comment’s reasoning, section 804(l) effectively repeals by implication the notice and comment provision of the APA. The Court has consistently noted that repeal by implication is disfavored. See Morton v. Mancari, 417 U.S. 535, 549–550 (1974).

(Comment 72) One comment contends that the certification required under section 804(l) of the FD&C Act is a rule within the meaning of the APA and is not subject to any exception from notice and comment requirements in that act. The comment argues that the notice and comment requirements were not met because the public did not have access to the information the Secretary relied on to make the certification and, therefore, could not meaningfully comment on it. The comment goes on to state that FDA should withdraw the proposed rule, place in the public record any basis the Secretary has for certification, and allow the public to comment.

(Response 72) A rule, as defined in the APA, 5 U.S.C. 551(4), is the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, weights, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or
allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing. We do not agree that the certification under section 804(f) of the FD&C Act is a rule that must undergo notice and comment rulemaking in accordance with the APA. The certification is a finding that functions as a procedural step that does not itself affect the rights or interests of outside parties. Cf. Batterton v. Marshall, 648 F.2d 694, 707–08 (D.C. Cir. 1980). In accordance with section 804(f), the certification is made to Congress. While the certification made by the Secretary leads to section 804(b–h) becoming effective, the only consequence of making section 804(b–h) effective is that, per section 804(b), the Agency can issue a regulation that was subject to the very process requested by the commenter (notice and comment rulemaking). Thus, the certification has no independent effect on outside parties that warrants notice and comment under section 553 of the APA. Moreover, because this rulemaking constitutes the basis for the certification, the certification is effectively undergoing notice and comment in the context of the rulemaking, and any additional notice and comment processes for the certification would be duplicative. We also note that, even if the certification were an agency action under the APA, it is more in the nature of a declaratory order that clarifies FDA’s position on the matters presented in section 804. See 5 U.S.C. 554(e) (“the agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty”); Wilson v. A.H. Belo Corp., 87 F.3d 393, 397 (9th Cir. 1996) (upholding a declaratory order that was issued sua sponte, in the absence of any parties before the Agency); Time Warner Entm’t Co., L.P. v. FCC, 240 F.3d 1126, 1141 (2001) (an agency has “very broad discretion whether to proceed by way of adjudication or rulemaking”). Finally, unlike other provisions of section 804, section 804(f) does not direct the Secretary to implement the provision by issuing a regulation. The lack of such direction indicates that Congress did not intend for the notice and comment requirements to apply.

In any case, we do not agree that the public did not have an opportunity to meaningfully comment on the Secretary’s certification. As stated above, the public did have an opportunity to comment on the certification in that it had an opportunity to comment on the rule, which constitutes the basis for the certification. Section 804(f) states that section 804 of the FD&C Act will become effective only if the Secretary certifies to Congress that the implementation of this section will pose no additional risk to the public’s health and safety and result in a significant reduction in the cost of covered products to the American consumer. The Secretary is making this certification on the basis of this final rule, which contains provisions and safeguards to ensure that any SIP that is authorized by FDA will be consistent with the certification. As stated in response to Comment 67, implementation of section 804(b–h) through this rule will result in a significant reduction in the cost of covered products to the American consumer because it requires, among other things, that the SIP Sponsor’s importation plan explain, in a manner sufficiently detailed to allow for a meaningful evaluation, how the Sponsor will ensure that the SIP will result in a significant reduction in the cost to the American consumer. Other provisions of this rule ensure that a SIP will not pose an additional risk to the public’s health and safety. The Agency sought and received comments on the proposed rule and is issuing this final rule after considering these comments. Because the certification relies on this final rule, the public had an opportunity to meaningfully comment on it.

G. FD&C Act Requirements

(Comment 73) One comment says that the proposed rule would not ensure that each prescription drug imported under section 804 complies with sections 501, 502, and 505 of the FD&C Act, as is required by section 804(c)(1) of FD&C Act. The comment says that as a result FDA will be required to refuse admission to section 804 drugs under section 801(a). The comment says that a drug imported under this rule will be unapproved because it will differ from the drug approved in the NDA and ANDA. Manufacturing information, specifically information about the relabeler and about the relabeling of a section 804 drug, will not be in the NDA or ANDA of its FDA-approved counterpart, and there will be certain differences set forth in the rule between the labeling of a section 804 drug and the labeling in an FDA-approved NDA or ANDA. The comment says that FDA should apply its procedures for drug approval to each drug imported under section 804.

The comment also says that drugs imported under this rule will be misbranded because their labeling will falsely represent that they are FDA-approved and because the labeling could lead a consumer to mistakenly attribute the drug to the drug’s manufacturer. Finally, the comment says that the rule will increase the likelihood that adulterated drugs will enter the U.S. market.

(Comment 73) We agree with the comment that for drugs imported under section 804 there will not be “an approval of an application” under section 505(a) of the FD&C Act. Section 804 drugs will not themselves be the subject of an approved NDA or ANDA. They will, however, meet the requirement in section 804(c)(1) of the FD&C Act that they “comply[] with section 505 (including with respect to being safe and effective for the intended use of the prescription drug).” Specifically, FDA interprets compliance with section 505 to mean that the HPFB-approved drug meets the conditions in an FDA-approved NDA or ANDA. Before a section 804 drug is imported pursuant to this rule, FDA must make a determination, on the basis of the Statutory Testing and information provided by the drug’s manufacturer, that the drug meets the conditions in an approved NDA or ANDA.

The comment’s alternative interpretation, requiring approval of an application under section 505 of the FD&C Act for drugs imported under section 804 of the FD&C Act, would render section 804 superfluous. If an Importer sought and obtained FDA approval of a drug that was previously only approved for sale in Canada, it would not need to import the drug under section 804. Instead, it could simply import the drug under section 801 of the FD&C Act without meeting any of the additional safeguards imposed under section 804. Thus, it is reasonable for FDA to interpret “complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug)” to mean that the HPFB-approved drug meets the conditions in an FDA-approved NDA or ANDA, without itself having an approved NDA or ANDA.

Section 804 drugs generally will bear the labeling of their FDA-approved counterparts, with certain exceptions set forth in this rule. Specifically, the labeling of a section 804 drug may differ from the approved labeling to the extent that it includes: (1) The section 804 drug’s NDC number, which will help with supply chain management and security, among other things, (2) the name of the Importer, which will ensure that the persons responsible for the product can be identified, (3) the labeling statement required by
§ 251.13(b)(4)(iv), which will help avoid confusion between products with the same name, help pharmacists distinguish a section 804 product when selecting the product on the pharmacy shelf, and, potentially, help with pharmacovigilance, and (4) the SIP’s website address, which will also help avoid confusion by educating pharmacists, healthcare providers, pharmacy benefit managers, health insurance issuers and plans, as appropriate, and patients.

We disagree with the comment’s assertion that section 804 drugs will be misbranded under section 502 of the FD&C Act because they are not FDA-approved. Section 804(h) of the FD&C Act requires that the manufacturer of a section 804 drug authorize the Importer to use the approved labeling for the drug, while section 804(c)(3) provides that the regulations implementing section 804 must require that safeguards be in place to ensure that section 804 drugs comply with section 502, among other provisions. Section 804 would not require that Importers be authorized to use the approved labeling if doing so would make section 804 drugs misbranded and so not comply with section 502. In addition, the labeling will not mislead consumers about the manufacturer’s role in the importation of a section 804 drug because of the labeling statement required by § 251.13(b)(4)(iv), which will make clear that the drug was imported under a SIP without the manufacturer’s authorization. Likewise, there is not an increased likelihood that section 804 drugs will be adulterated in violation of section 501 of the FD&C Act, because of the supply chain security, Statutory Testing, and other protections in section 804 and this rule. For these reasons, we disagree with the comment that FDA will be required to refuse admission to section 804 drugs under section 801(a)(3) of the FD&C Act, which provides that articles shall be refused admission if, among other things, they are “adulterated, misbranded, or in violation of section 505.”

H. First Amendment

(Comment 74) One comment asserted that the proposed rule, if finalized, would violate the First Amendment on two grounds: (1) The manufacturer’s attestation and information statement and Statutory Testing requirements amount to compelled speech and a compelled subsidy and (2) compelled authorization to use the labeling amounts to compelled speech and a compelled subsidy. The comment asserts that, because the speech at issue does not propose any commercial transaction, strict scrutiny applies and the rule would fail under that standard. The comment also asserts that the proposed rule would fail to pass muster under the four-part Central Hudson test applied to government regulation of commercial speech.

(Response 74) We disagree with the comment’s premise that these provisions should be understood as speech regulations that implicate the First Amendment. “[I]t has never been deemed an abridgment of freedom of speech . . . to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.” Rumsfeld v. Forum for Academic and Institutional Rights, Inc., 547 U.S. 47, 62 (2006) (citation omitted); see also Nicopure Labs, LLC v. FDA, 944 F.3d 267, 291 (D.C. Cir. 2019) (“A ‘kernel of expression . . . is not sufficient to bring the activity within the protection of the First Amendment.’”) (quoting City of Dallas v. Stanglin, 490 U.S. 19, 25 (1989)). The final rule requires the manufacturer to include in the authentication and quality assurance process for drugs imported under a SIP. Manufacturers can participate directly, by conducting the Statutory Testing themselves, or they can facilitate the process by providing the necessary testing information to the Importer. Manufacturers must also provide the attestation and information statement and the executed batch records required by § 251.5(c)(4)(xii), to establish that a section 804 drug meets the conditions in the FDA-approved NDA or ANDA, including any process-related or other requirements for which compliance cannot be established through laboratory testing. Participating in and facilitating authentication and quality assurance are not fundamentally expressive activities, even though there is necessarily information exchanged. Similarly, authorizing the use of FDA-approved labeling neither restricts a manufacturer’s speech nor compels it to express ideas with which it disagrees. A market regulation that “applies to conduct and is imposed ‘for reasons unrelated to the communication of ideas’” does not implicate the First Amendment and is subject to rational-basis review. Nicopure Labs, 944 F.3d 267 at 291–92 (quoting Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 569 (2001)). As described earlier, these provisions easily survive rational-basis review because they are needed to ensure that drugs imported under a SIP comply with sections 501, 502, and 505 of the FD&C Act and are in compliance with any process-related or other requirements that cannot be established through laboratory testing (84 FR 70796 at 70817–70818). The FDA-approved labeling is necessary to ensure that prescribers, pharmacists, and patients have the information they need to prescribe, dispense, and use the drugs appropriately. Without these provisions, it would not be possible to ensure that drugs imported under section 804 meet U.S. legal and regulatory requirements and thus pose no additional risk to the public’s health and safety.

Moreover, compelled-speech cases that are subject to review under the First Amendment typically involve a requirement that a speaker “must personally speak the government’s message” or “host or accommodate another speaker’s message.” Rumsfeld, 547 U.S. at 63. The fundamental First Amendment concern in such cases is that the government will compel the speaker “to voice ideas with which [it] disagree[s].” Janus v. AFSCME, Council 31, 138 S. Ct. 2448, 2464 (2018). That is not the case here, where there is no message being compelled. Manufacturers are simply being called upon to help with the process of product authentication, quality control, and product identification.

For example, the comment asserts that the regulatory program as set out in the proposed rule—requiring the manufacturer to make available its product labeling, to provide an attestation and information statement and executed batch records, and to either conduct testing or disclose testing information—would amount to a significant economic subsidy from the manufacturer to the importer. The comment claims, citing Janus v. AFSCME, Council 31, that this economic subsidy is impermissible under the First Amendment unless the government can show that the compelled subsidy serves a compelling state interest that cannot be achieved through means significantly less restrictive of associational freedoms. This caselaw, however, is inapposite. First, as the comment admits, under this rule, there is no direct monetary payment from the manufacturer to the importer. Moreover, the Court in Janus found that the subsidies at issue meant that individuals were “coerced into betraying their convictions” by “endorse[ing] ideas they find
objectionable.” 138 S. Ct. at 2464. See also United States v. United Foods, 533 U.S. 405, 410–411 (2001) (finding First Amendment implicated where producers were required to “subsidize speech with which they disagree.”) (emphasis added). By contrast, here, the manufacturer is not compelled to itself convey any ideas or subsidize the conveyance of ideas by others.

While the requirement that a drug’s manufacturer authorize an Importer to use the drug’s FDA-approved labeling does not equate to a requirement that the manufacturer advertise or subsidize the conveyance of an idea, the comment argues that consumers could mistakenly conclude from the inclusion of a manufacturer’s name and trademarks on the labeling that, among other things, the manufacturer vouches for the safety, efficacy, and quality of its drug when imported by a SIP. The comment also argues that consumers could mistakenly conclude that a manufacturer authorized the importation of its drug by the SIP. The comment contends that such mistakes could occur despite the labeling statement required by proposed § 251.13(b)(6)(i): “[This drug was imported from Canada under the [Name of SIP Sponsor] and of Its Co-Sponsors, If Any] Section 804 Importation Program to reduce its cost to the American consumer.” To address the concern that the use of the FDA-approved labeling might create the misleading impression that the manufacturer is conveying or subsidizing the conveyance of ideas through the labeling of a section 804 drug, we have revised § 251.13(b)(4)(iv) to require the following disclosure: “[This drug was/These drugs were] imported from Canada without the authorization of [Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program.” As explained earlier, we have determined that it is not necessary to require the addition of the manufacturer’s name and place of business if they do not already appear on the FDA-approved labeling. We have also determined that it is necessary to require disclosure of the phrase “to reduce its costs to the American consumer” in the labeling statement.

Even if the First Amendment were implicated, any minimal burdens on speech are more than adequately justified by the purposes served by this program. The comment appears to suggest that, because this program does not regulate communications in the realm of commercial marketing, neither Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985) nor Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n, 447 U.S. 557 (1980) apply, and instead the requirements of this program should be analyzed under strict scrutiny. We disagree. The Supreme Court has applied strict scrutiny in First Amendment cases involving compelled speech on matters of conscience, and it “trivializes the freedom protected” by those cases to assert that incidental burdens on speech are subject to the same protections. Zauderer, 547 U.S. at 62.

Accordingly, to the extent a court were to analyze this program under the First Amendment, it would likely apply, instead of strict scrutiny, the test for compelled speech established by Zauderer or one of the other more relaxed frameworks under which courts compare the burden on speech to the asserted government interest. See S.F. Arts & Athletics, Inc. v. USOC, 483 U.S. 522, 537 n.16 (1987). Under the framework set out in Zauderer and its progeny, which describe the test generally applied to required disclosures of factual and uncontroversial information related to non-subsidized speech, the Government may require disclosures that are justified by a governmental interest and do not unduly burden protected speech. The provisions at issue here—attesting that a product meets the conditions in its approved NDA or ANDA and supplying related information, supplying testing protocols and executed batch records, and authorizing the use of labeling—all relate to the conveyance of factual and uncontroversial information. The government interest is clear. Prescription drug spending in the United States has increased dramatically in recent years and is projected to account for an increasing share of the country’s health care spending. This program is designed to address that problem by allowing for the importation of lower cost prescription drugs from Canada into the United States. And there is no burden on protected speech—nothing in any of these provisions limits manufacturers’ ability to speak freely about their products.

The comment asserts that the regulations would compel the manufacturer to provide a false or misleading attestation. We disagree. The rule does not require a manufacturer to attest to anything that the manufacturer does not know or cannot attest to truthfully. If, for example, the drug that the manufacturer manufactures for sale in Canada does not meet the conditions in the FDA-approved NDA or ANDA, a manufacturer could not and should not attest that “but for the fact that [a drug] bears the HPFB-labeling,” the drug “meets the conditions in the FDA-approved NDA or ANDA.” This is clarified in the final rule in § 251.5(d), which states that if the manufacturer cannot provide the attestation and information statement, it must notify FDA and the Importer of its inability and articulate with specificity the reason or reasons for it. In addition, a manufacturer’s attestation and information statement would be as of the date that the drug in question left the manufacturer’s control. A manufacturer could not and should not attest, for example, that the Foreign Seller held the manufacturer’s drug in compliance with CGMP.

The program also would be constitutional if reviewed under intermediate scrutiny. Under the test for restrictions on commercial speech articulated in Central Hudson, agencies can regulate commercial speech where the regulation directly advances a substantial Government interest and is not more extensive than necessary to serve that interest. Central Hudson does not require that the means chosen by the Government be the least restrictive means available for addressing an issue, see Boards of Trustees, v. Fox, 492 U.S. 469, 480 (1989), but the Supreme Court has in any event observed that required factual disclosures are less intrusive from a First Amendment perspective than are restrictions on speech. Zauderer, 471 U.S. at 651. Because the Government’s interest in the goals of this program is substantial and the regulation is no more extensive than necessary to directly advance that interest, the rule withstands review under Central Hudson. The increasing cost of prescription drugs is causing hardship to American consumers (84 FR 70796 at 70798–70801). The regulation would directly address this by providing for the importation of lower cost prescription drugs from Canada to significantly reduce the cost of covered products to the American consumer, while posing no additional risk to the public’s health and safety. The information that the manufacturer is required to supply is no more extensive than necessary to ensure that section 804 drugs are authentic, not degraded, and meet the conditions in an FDA-approved NDA or ANDA, all of which serves to ensure that the drugs are safe and effective. Likewise, the FDA-approved labeling is necessary to ensure that prescribers, pharmacists, and patients have the information they need to prescribe, dispense, and use the drugs as needed. As noted earlier, the required labeling statement will help avoid potential confusion between
products with the same name and help pharmacists distinguish a section 804 product when selecting the product on the pharmacy shelf (84 FR 70796 at 70819). The labeling statement may also aid in pharmacovigilance (84 FR 70709 at 70820). Finally, the addition of the explanation that the drug was imported from Canada without the manufacturer’s authorization will prevent prescribers, pharmacists, or patients from mistakenly concluding that the manufacturer is conveying an idea or subsidizing the conveyance of an idea.

I. Fifth Amendment Takings

(Comment 75) Some comments say that certain provisions in section 804 and this rule would take manufacturers’ private property for public use, entitling manufacturers to just compensation under the Fifth Amendment of the U.S. Constitution. The comments contend that the information that manufacturers would be required to disclose to Importers and qualifying laboratories, including information to be used to conduct the Statutory Testing, could include confidential commercial information and trade secrets in which manufacturers have a constitutionally cognizable property interest. Comments also contend that the provisions of section 804 of the FD&C Act and this rule that require manufacturers to authorize Importers to use the FDA-approved labeling for drugs imported under this rule would effect an unconstitutional taking if the labeling included trademarks such as brand names, company names, logos, and the trade dress reflected in the overall packaging design.

One comment says that because the statute explicitly provides in section 804(h) that manufacturers must provide authorization to use the labeling at no cost, but does not include similar language elsewhere, section 804 of the FD&C Act must be interpreted to permit manufacturers to charge Importers for information (such as the attestation and information statement, the executed batch records, and the Statutory Testing information) or services (such as conducting Statutory Testing) that section 804 and this rule require them to provide. The comment says that this interpretation is necessary to avoid a Fifth Amendment Takings Clause issue.

(Response 75) “The focus of the regulatory takings analysis is on fundamental fairness—is it fair for the government to impose the cost of a regulation on private parties rather than on the public as a whole through public spending?” (Gardens v. United States, 503 F.3d 1266, 1278 (Fed. Cir. 2007) (citing Palazzolo v. Rhode Island, 533 U.S. 606, 618 (2001); Penn Central Transp. Co. v. New York City, 438 U.S. 104, 123 (1978)). “[T]he touchstone of the economic impact question is proportionality: the size of a liability only weighs in favor of finding a taking insofar as it is out of proportion to the legitimate obligations society may impose on individual entities.” (B&G Constr. Co. v. Dir., OWCP, 662 F.3d 233, 260 (3d Cir. 2011) (citation and internal quotations omitted)). Indeed, courts have rejected regulatory takings claims even where the government’s actions “impose considerable costs on private actors in the regulated industry.” (Mobile Relay Assocs. v. FCC, 457 F.3d 1, 12 (D.C. Cir. 2006)). In addition, as a general rule, the government is not required to pay for the incidental effects of its laws and regulations. (See Penn Central, 438 U.S. at 124. “Government hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law.” (Pennsylvania Coal Co. v. Mahon, 260 U.S. 393, 413 (1922)).

In this case, the pharmaceutical industry operating in the United States has benefitted from Federal laws and regulations that allow manufacturers to recoup the costs of pharmaceutical research and development and to be rewarded for their investments in it. As explained in the preamble to the proposed rule, however, the increasing cost of prescription drugs is placing a heavy burden on American consumers (84 FR 70796 at 70798–70801). That Congress placed an incidental burden on the pharmaceutical industry to reduce the cost of prescription drugs does not offend any principle of fundamental fairness.

The Supreme Court has explained that takings analysis involves “essentially [an] ad hoc, factual inquiry[.]” (See Penn Central, 438 U.S. at 124). A threshold step in that analysis is determining whether the claimant possesses a property interest protected by the Takings Clause. (Ruckelshaus v. Monsanto, 467 U.S. 721, 1000 (1984)). The comments assert that manufacturers have property interests in trade secrets and trademarks. The Supreme Court found in Ruckelshaus v. Monsanto (467 U.S. at 1003–04) that in certain circumstances there can be a property interest in trade secrets for purposes of the Fifth Amendment’s Takings Clause (“the property right [in a trade secret] is defined by the extent to which the owner of the secret protects his interest from disclosure to others”). We will assume for purposes of this discussion that some of the information that manufacturers are required to disclose under section 804 and this rule would meet the relevant state law definition of a trade secret. The comments did not cite, and we have not found, a case in which a court has held that a manufacturer has a cognizable property interest in a trademark for purposes of the Fifth Amendment Takings Clause, and courts have found that other forms of intellectual property, namely copyrights and patents, do not create cognizable property interests for Takings Clause purposes (Univ. of Hous. Sys. v. Jim Olive Photography, 580 SW3d 360, 377 (Tex. App. 2019); Christy, Inc. v. U.S., 141 Fed. Cl. 641, 660 (2019). The question arises whether trademarks are more akin to trade secrets or to copyrights and patents for Fifth Amendment Takings Clause purposes. We find it unnecessary to answer this question here because, even if trademarks were private property protected under the Takings Clause, there has been no taking.

The Supreme Court has held that two categories of regulatory actions are generally per se takings: (1) When the government “requires an owner to suffer a permanent physical invasion of her property;” and (2) when regulations “completely deprive an owner of ‘all economically beneficial use[s]’ of her property” (Lingle v. Chevron U.S.A. Inc., 544 U.S. 528, 538 (2005) (quoting Lucas v. S.C. Coastal Council, 505 U.S. 1003, 1019 (1992))). Neither of those circumstances is present here.

In other circumstances, the Supreme Court has held that “when a regulation impedes the use of property without depriving the owner of all economically beneficial use, a taking still may be found based on ‘a complex of factors,’” including: (1) The economic impact of the regulation on the claimant; (2) the extent to which the regulation has interfered with distinct investment-backed expectations; and (3) the character of the governmental action” (Murr v. Wisconsin, 137 S. Ct. 1933, 1943 (2017) (citing Palazzolo v. Rhode Island, 533 U.S. at 617) (citing Penn Central, 438 U.S. at 124)). The force of any one of these three factors may be “so overwhelming . . . that it disposes of the taking question” (Ruckelshaus, 467 U.S. at 1005).

1. Provision of Trade Secrets and Confidential Commercial Information

With regard to the first Penn Central factor, the economic impact of section 804 of the FD&C Act and this regulation on manufacturers, we note that the government’s action here is limited. The Supreme Court has explained that “where an owner possesses a full ‘bundle’ of property rights, the
destruction of one ‘strand’ of the bundle is not a taking because the aggregate must be viewed in its entirety” (Andrus v. Allard, 444 U.S. 51, 65–66 [1979]). (See also Village of Euclid v. Amberl Realty Co., 272 U.S. 365, 384 [1926] (75 percent diminution in value insufficient to prove taking); Hadacheck v. Sebastian, 239 U.S. 394, 405 [1915] (92.5 percent diminution insufficient to prove taking)). Because manufacturers will retain the right to exclude everyone except Importers and qualifying laboratories from the use of their trade secrets and commercial or financial information that is privileged or confidential, their trade secrets and commercial or financial information that is privileged or confidential will retain significant value. An Importer or qualifying laboratory’s use of a manufacturer’s trade secrets or commercial or financial information that is privileged or confidential will be limited to conducting the Statutory Testing and establishing that an eligible prescription drug meets the requirements of the FD&C Act and the rule. Consistent with section 804 of the FD&C Act, the rule mandates that the trade secrets and commercial or financial information that is privileged or confidential that the manufacturer provides be used only for purposes of testing or otherwise complying with the FD&C Act and the rule. Moreover, the government action here may be further constrained by the fact that there will be a limited number of SIPs working with a limited number of Importers and qualifying laboratories, and by the fact that the SIPs will be time-limited.

The economic impact of the rule will also be constrained by the fact that manufacturers will retain their right to protect their trade secrets against disclosure (Pharm. Care Mgmt. Ass’n v. Rowe, 307 F. Supp. 2d 164, 179 [D. Me. 2004] [holding that a “statute’s protection from further disclosure inures it from constitutional infirmity”). As required by section 804(e)(2) of the FD&C Act, the final rule mandates in § 251.16(g) that the Importer keep any information that the manufacturer provides to authenticate a prescription drug being tested and confirm that the labeling of the prescription drug complies with labeling requirements under the FD&C Act in strict confidence. The final rule also requires that any trade secrets or commercial or financial information that is privileged or confidential that the manufacturer supplies for the purposes of testing or that complies with the FD&C Act be kept in strict confidence. Moreover, manufacturers have the option of conducting the Statutory Testing themselves, which would obviate the need to disclose the Statutory Testing information to the Importer. While the manufacturer would still need to disclose the Statutory Testing information and results to FDA, FDA would ensure that any trade secrets or confidential commercial information remain confidential consistent with the law (Full Value Advisors, LLC v. Securities & Exchange Comm., 633 F.3d 1101, 1110 [D.C. Cir. 2011] (finding that disclosure to the Securities & Exchange Commission produced no economic harm because the Commission ensured that the information remained confidential). Turning to the second Penn Central factor—interference with distinct investment-backed expectations—regulated industry has been on notice since at least October 28, 2000, when the predecessor to the current section 804 of the FD&C Act was signed into law as part of the Medicine Equity and Drug Safety (MEDS) Act of 2000, that they could be required to disclose information needed for safe importation. Thus, sponsors of NDAs or ANDAs submitted after that date could not have a reasonable investment-backed expectation that is inconsistent with section 804. While a comment points to the fact that prior HHS Secretaries did not make the section 804(l) certification to Congress, it would not be reasonable for manufacturers to expect that such a certification could never be made, especially given the widely-known developments described in the preamble to the proposed rule, including the continued rise of prescription drug prices which has raised concerns among policymakers, healthcare professionals, and American consumers (64 FR 70796 at 70798–70801). With regard to drugs the applications for which were submitted before October 28, 2000, it still would not have been reasonable for manufacturers to expect that a provision like section 804 would not be enacted. Courts have held that those who do business in highly regulated fields are on notice that changes are possible (Maine Educ. Ass’n Benefits Trust v. Cioppa, 695 F.3d 145, 154 [1st Cir. 2012] [finding that “[g]iven the historically heavy and continuous regulation of insurance in Maine, the [Plaintiff], in choosing how and where to allocate its resources, ought to at least be aware of the heightened possibility that new insurance regulations might hinder the use or value of its loss information” (internal citations omitted)); Connolly v. Pension Ben. Guar. Corp., 475 U.S. 211, 226–227 (1986)). The prescription drug industry is such a highly regulated field (New York v. Actavis PLC, 787 F.3d 638, 643 (2d Cir. 2015) (describing the pharmaceutical industry as “complex and highly-regulated”).

One comment contends that the protections against disclosure of certain information in the Federal Trade Secrets Act at 18 U.S.C. 1905, in sections 301(j) and 505(f) of the FD&C Act, and in FDA’s regulations at 21 CFR 20.61 and 314.430 support manufacturers’ expectation that they would not have to supply the information specified in section 804 and this rule. In Ruckelshaus v. Monsanto, the Supreme Court held that an explicit guarantee of exclusive use created a reasonable investment-backed expectation that EPA would not consider the data when evaluating the application of a subsequent applicant (Ruckelshaus, 467 U.S. at 1011). None of the provisions that the comment cites creates an explicit or implicit guarantee that section 804 would not be implemented or that regulations would not be issued requiring manufacturers to provide testing and other information to Importers. We note that we have determined that it is not necessary for FDA to provide Statutory Testing information to Importers, and so we are not finalizing proposed § 251.16(l), which would have provided that “FDA may transmit information that the manufacturer is required to provide to an Importer under this section on the manufacturer’s behalf.” If the manufacturer has not transmitted such information to the Importer in a timely fashion and if such information is available to FDA in the NDA or ANDA.” Manufacturers that choose not to conduct the Statutory Testing are required to provide the Statutory Testing information covered by § 251.16(l) to Importers themselves.

The Supreme Court has described the final Penn Central factor, the “character of the governmental action,” as a way to assess whether the challenged action “amounts to a physical invasion or instead merely affects property interests through ‘some public program adjusting the benefits and burdens of economic life to promote the common good.” ’ (Lingle, 544 U.S. at 539 (quoting Penn Central, 438 U.S. at 124)). Here, section 804 of the FD&C Act and the rule do not amount to a physical invasion and they have a legitimate public purpose, to significantly reduce the cost of covered products to the American consumer without any additional risk to the public’s health and safety. As noted earlier, the increasing cost of
prescription drugs is placing a heavy burden on American consumers. To promote the common good, section 804 and the rule would require manufacturers of certain drugs—those imported under SIPs—to provide limited information to Importers or qualified laboratories under limited circumstances. For these reasons, the third factor of the takings analysis, like the first two factors, compels the conclusion that neither section 804 nor this rule amounts to a regulatory taking of manufacturers’ property that requires compensation under the Fifth Amendment.

We do not agree that section 804 of the FD&C Act is best interpreted to permit manufacturers to charge Importers for information (such as the attestation and information statement, the executed batch records, and the Statutory Testing information) or services (such as conducting Statutory Testing) that section 804 and this rule require them to provide. Section 804(h) explicitly requires manufacturers to authorize Importers to use a drug’s approved labeling at no cost. This does not mean that manufacturers can charge for information or services that they are required to provide. If manufacturers were permitted to charge it would directly undermine section 804’s cost-reducing goal. Moreover, interpreting section 804 to permit manufacturers to charge Importers is not necessary to avoid a Fifth Amendment Takings Clause issue because, as explained earlier, neither section 804 nor this rule effects a taking under the Fifth Amendment.

2. Authorization To Use FDA-Approved Labeling

With regard to the first Penn Central factor, the requirement in section 804 of the FD&C Act and this regulation that a manufacturer authorize an Importer to use the FDA-approved labeling for an eligible prescription drug is likely to have little to no impact on the value of the manufacturer’s trademarks. Trademarks do not have inherent value (Marshak v. Green, 746 F.2d 927, 929 (2d Cir. 1984)). Their only value is in the goodwill with which they are associated. Under this rule, there will be little or no diminution in the goodwill associated with manufacturers’ trademarks because section 804 drugs will meet the conditions of the relevant FDA-approved NDA or ANDA. In addition, as discussed earlier, the labeling statement will make it clear that the section 804 drug was imported without the manufacturer’s authorization. Turning to the second Penn Central factor, a manufacturer could not have a reasonable investment-backed expectation that it would not have to authorize an Importer to use its labeling. Such an expectation would be inconsistent with the current version of section 804. With regard to drugs developed before December 8, 2003, it still would not have been reasonable for manufacturers to expect that a provision like section 804(h) requiring that the manufacturer of a section 804 drug authorize the use of the FDA-approved labeling would not be enacted. Finally, as explained earlier, the third Penn Central factor also weighs against a finding that section 804 and this rule effect a regulatory taking, because significantly reducing the cost of covered products to the American consumer without any additional risk to the public’s health and safety “promote[s] the common good” (Lingle, 544 U.S. at 539 (quoting Penn Central, 438 U.S. at 124)).

Comment 76 One comment says that section 804 of the FD&C Act and this rule violate provisions of the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Specifically, the comment says that section 804 and this rule violate Article 39 of the TRIPS Agreement by requiring manufacturers to disclose trade secrets and confidential commercial information and Article 21 of the TRIPS Agreement by requiring manufacturers to authorize the use of labeling that could include trademarks.

Comment 76 We disagree that section 804 of the FD&C Act and this rule violate the TRIPS Agreement. As a general matter, we note that the United States is in full compliance with its international obligations under the TRIPS Agreement. Article 39 of TRIPS provides that member countries “shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.” Under section 804 and this rule, Importers and qualified laboratories obtain information from manufacturers under the authority of a statute and implementing regulation. The final rule provides in §251.16(g), that information supplied by the manufacturer to authenticate the prescription drug being tested and confirm that the labeling of the prescription drug complies with labeling requirements under the FD&C Act, and any trade secrets or commercial or financial information that is privileged or confidential that the manufacturer supplies for the purpose of testing or otherwise complying with the FD&C Act and this rule, must be kept in strict confidence and used only for the purposes of testing or otherwise complying with the FD&C Act and this rule.

With regard to data submitted to governments or governmental agencies, as discussed earlier, we have determined that it is not necessary for FDA to provide Statutory Testing information to Importers, and so we are not finalizing §251.16(i) from the proposed rule, which would have provided that FDA may transmit information that the manufacturer is required to provide to an Importer under this section on the manufacturer’s behalf if the manufacturer has not transmitted such information to the Importer in a timely fashion and if such information is available to FDA in the NDA or ANDA.

We also disagree that section 804 of the FD&C Act and this rule violate Article 21 of TRIPS, which states that “compulsory licensing of trademarks shall not be permitted.” The requirement that a manufacturer of a prescription drug authorize an Importer to use the drug’s FDA-approved labeling does not constitute compulsory licensing of trademarks. This is at least because the labeling is only used referentially and does not associate the trademark with the Importer. As noted above, the United States is in full compliance with its international obligations under the TRIPS Agreement.

J. Disclosure

Comment 77 A comment says that FDA’s determination that a drug is an eligible prescription drug that can be imported by a SIP discloses trade secrets and confidential commercial information about that drug. When FDA determines that a drug can be imported, FDA has determined that, but for the fact that the drug bears the HPFB-approved labeling when marketed in Canada, it meets the conditions in an FDA-approved NDA or ANDA. The comment says that the information upon which FDA’s determination is based—whether a drug manufactured for sale in Canada meets the conditions in an FDA-approved NDA or ANDA—is confidential. Another comment says that FDA should specify that when a manufacturer notifies an Importer that it cannot or will not make the §251.5(c)(4)(xii) attestation, because its drug does not meet the conditions in an FDA-approved NDA or ANDA or for some other reason, that is confidential information that the importer should not be able to disseminate or use.

Response 77 Section 804 of the FD&C Act directs the Secretary to issue regulations permitting pharmacists and
wholesalers to import from Canada drugs that, among other requirements, comply with section 505 of the FD&C Act. FDA interprets compliance with section 505 to mean that the HPFB-approved drug meets the conditions in an FDA-approved NDA or ANDA. Through its labeling requirements, the statute also directs that FDA’s determination that a Canadian drug complies with section 505 will be publicly available information, as reflected, for example, in product labeling.

The final rule clarifies in § 251.5(d) that if a manufacturer cannot provide the attestation and information statement, the manufacturer must notify FDA and the importer and articulate with specificity the reason or reasons why it cannot provide the attestation and information statement. The final rule also requires, in § 251.16(g), that importers keep any trade secrets or commercial or financial information that is privileged or confidential, that the manufacturer supplies for the purposes of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part, in strict confidence. We note that manufacturers can choose to mark any trade secrets or commercial or financial information that is privileged or confidential that is contained in any of the information that they are required to provide.

We do not believe that the fact that the manufacturer cannot or will not provide the attestation and information statement is likely to be a trade secret or commercial or financial information that is privileged or confidential. The reasons that the manufacturer gives for not providing the attestation and information statement, by contrast, may be trade secrets or commercial or financial information that is privileged or confidential, which would mean that the importer would be legally obligated to keep them in “strict confidence” under § 251.16(g).

K. FDA Authority

(Comment 78) A comment states that FDA lacks the authority under section 804 to issue certain provisions regarding manufacturers’ information and manufacturers’ participation in the importation of their drugs by SIPs. The comment states that FDA cannot provide the importer with the information contained in an approved NDA or ANDA as is provided for by proposed § 251.16(i). The comment also states that FDA cannot require the manufacturer to supply “testing methodologies and protocols that the manufacturer has developed” as FDA proposed in § 251.16(b). The comment states that FDA lacks the authority to issue § 251.5(c)(4)(xii), which requires manufacturers to provide an attestation and information statement that establishes that the drug proposed for import, but for the fact that it bears the HPFB-approved labeling, meets the conditions in the FDA-approved NDA or ANDA. The comment also states that, with regard to § 251.13(a), FDA lacks the authority to deem the manufacturer to have provided authorization to use the FDA-approved labeling for the manufacturer’s drug, if the manufacturer does not provide written authorization to the importer in a timely fashion. Finally, the comment asks FDA to clarify that section 804(e) of the FD&C Act, which, the comment states, relates to testing, not supply chain information, does not give FDA the authority to issue § 251.14, which requires a manufacturer to provide an importer with transaction information.

(Response 78) We have determined that it is not necessary to include proposed § 251.16(i) in the final rule. That provision stated that FDA may transmit information that the manufacturer is required to provide to an importer under this section on the manufacturer’s behalf if the manufacturer has not transmitted such information to the importer in a timely fashion and if such information is available to FDA in the NDA or ANDA. Manufacturers are required to provide the statutory testing information covered by § 251.16(i) themselves. If they fail to do so, they will have committed a violation of the FD&C Act. In addition, as discussed earlier, violations of section 804(e) of the FD&C Act are subject to a penalty under section 303(b)(6) of the FD&C Act.

It is necessary, however, and within FDA’s authority under section 804 of the FD&C Act, to issue §§ 251.16(b) and (d), which require that the manufacturer provide the importer with the information that the importer needs to conduct the statutory testing. Section 804(b) requires the Secretary to issue regulations permitting the importation of certain drugs under section 804.

Section 804(e) specifies that these regulations shall require the manufacturer to provide the importer with the information needed to authenticate the prescription drug being tested. Sections 804(d)(1)(I)(i)(III) and 804(d)(1)(L) specify that the regulations shall require the importer to submit to FDA documentation demonstrating that section 804 drugs were tested “for authenticity and degradation” and that the importer submit to FDA laboratory records including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards. While sections 804(d)(1)(I)(i)(III) and 804(d)(1)(L) do not state that the regulations must require manufacturers to provide the information needed to conduct these tests, FDA has the authority to require this under section 804(c)(1), which directs the Secretary to issue regulations that require that safeguards be in place to ensure that section 804 drugs comply with section 501, 502, and 505 of the FD&C Act, and under section 804(c)(3), which directs the Secretary to issue regulations that contain any additional provisions determined by the Secretary to be a means to facilitate the importation of prescription drugs.

With regard to the manufacturer’s attestation and information statement described in § 251.5(c)(4)(xii), section 804(c)(1) of the FD&C Act specifies that the regulations must require that safeguards be in place to ensure that each drug imported under the regulations complies with the FD&C Act, including sections 501, 502 and 505. It would not be possible to ensure that each drug imported under the regulations complies with sections 501, 502, and 505, as required by section 804(c)(1), without the information from the manufacturer that is captured in the attestation and information statement. For example, only the manufacturer knows whether a drug that was originally intended for the Canadian market was manufactured “in conformity with current good manufacturing practice,” as required by section 501. The comment notes that another provision, section 804(d)(1)(K), does not state that the regulations must require the manufacturer to provide the importer with the information captured in the attestation and information statement. Under section 804(d)(1)(K), the regulations under section 804(b) must require the importer to submit to FDA a certification from the importer or the manufacturer that the imported drugs are approved for marketing in the United States and are not adulterated or misbranded, and that they meet all the labeling requirements under the FD&C Act. If the importer provides the section 804(d)(1)(K) certification, the importer will need information from the manufacturer, including information about how the drug was manufactured. While section 804(d)(1)(K) does not expressly mandate that the Secretary require the manufacturer to provide the importer with the information it needs for certification, it is implied because the importer could not make the
certification without certain information from the manufacturer. In any case, the Secretary clearly has the authority to do so under section 804(c)(1) and under section 804(c)(3), which authorizes the Secretary to include regulatory provisions that the Secretary determines to be appropriate as a safeguard to protect the public health or as a means to facilitate importation of prescription drugs.

With regard to § 251.13(a), the comment contends that FDA would need express statutory authority to deem the manufacturer to have the provided authorization to use the FDA-approved labeling for the manufacturer’s drug, if the manufacturer does not provide such authorization in a timely fashion. We disagree. While section 804(h) of the FD&C Act, which requires manufacturers to authorize Importers to use their drugs’ FDA-approved labeling, does not expressly state that FDA can deem manufacturers to have given their authorization if they fail to do so in a timeframe that FDA determines is reasonable under the circumstances, other provisions of section 804 give FDA the necessary authority. Section 804(c)(1) specifies that the regulations that the Secretary issues must require that safeguards be in place to ensure that each drug imported under the regulations complies with the FD&C Act and section 804(c)(3) directs the Secretary to issue regulatory provisions that it determines will facilitate importation. The provision at issue here will help ensure that section 804 drugs comply with the FD&C Act’s labeling requirements and are not misbranded, and will facilitate importation because it will prevent manufacturers from causing unwarranted delay by withholding their authorization to use the FDA-approved labeling.

With regard to § 251.14(b), which requires the manufacturer to provide to the Importer a copy of any transaction documents that were provided from the manufacturer to the Foreign Seller, FDA’s authority to require this derives from section 804(c)(3) and (e) of the FD&C Act. Under section 804(e)(2)(A)(i), if the Importer does the Statutory Testing, the manufacturer has to provide certain information, including “information needed to... authenticate the prescription drug being tested.” The information needed to authenticate a section 804 drug includes the transaction documents that the manufacturer provides to the Importer under § 251.14(b). These documents enable theImporter and FDA to conduct a cross check of the transaction documents that the Foreign Seller provides to the Importer under § 251.14(c)(6). This cross check is valuable supporting evidence of the authenticity of the drug, helping to ensure that importation under section 804 poses no additional risk to the public’s health and safety.

Under § 251.14(b), manufacturers must provide the transaction documents needed for the cross check regardless of whether the Importer or the manufacturer conducts the Statutory Testing. FDA’s authority to require this when the manufacturer conducts the testing derives from section 804(c)(3) of the FD&C Act, which provides that the regulations “shall contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.” As noted earlier, the cross check of the transaction documents from the sale of the drug by the manufacturer to the Foreign Seller is a valuable safeguard that protects the public health by providing evidence of the drug’s authenticity.

L. Procedural Requirements

(Comment 79) One comment states that the proposed rule failed to comply with certain procedural requirements set forth in statute and Executive orders, including the Regulatory Flexibility Act, the Unfunded Mandates Reform Act, the E-Government Act of 2002, and Executive Orders 12866, 13175, 12630, and 13045.

(Response 79) FDA disagrees with this comment. This rulemaking adheres to procedural provisions set forth in statutes and Executive orders. For example, as noted in the Final Regulatory Impact Analysis, FDA conducted economic analysis under the Unfunded Mandates Reform Act and the Regulatory Flexibility Act. Further, we do not believe the final rule establishes a new collection of information under the E-Government Act of 2002. In addition, the final rule describes FDA’s Economic Analysis of Impacts under Executive Order 12866, the solicitation of comment from Indian Tribes in accordance with Executive Order 13175 and from States in accordance with Executive Order 13132, and FDA considered the applicability of other Executive orders in the development of the rule.

(Comment 80) One comment states that former Acting Commissioner Brett Giroir did not have authority to sign the proposed rule because he was not the Acting Commissioner on December 18, 2019, which is the date on which the comment asserts the rule was filed with the Federal Register.

(Response 80) This statement is incorrect. Acting Commissioner Giroir had signing authority for the proposed rule because he served in the role of Acting Commissioner at the time he signed the rule on December 11, 2019. The date of filing with the Federal Register is determined by the time the signed, original, clear and legible copies of a document are received (1 CFR 18.3(c)).

(Comment 81) A comment says that under the Administrative Procedure Act and the Due Process Clause of the U.S. Constitution, NDA or ANDA holders listed in a SIP Proposal must have an opportunity to comment on the SIP Proposal before FDA authorizes it. The comment says that a SIP Proposal is either a rule or an informal adjudication and that, as a result, authorization should not proceed before NDA or ANDA holders have the opportunity to seek judicial review. The comment says that allowing NDA or ANDA holders to comment on SIP Proposals would allow FDA to receive input on appropriate drugs and control processes that might otherwise be spent on unworkable or dangerous SIP Proposals.

(Response 81) We disagree with the comment that FDA’s authorization of a SIP Proposal is a rule. Such an authorization would be an order. Under the Administrative Procedure Act (5 U.S.C. 551(4)), a rule is defined as “the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency.” An order is the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rulemaking but including licensing. 5 U.S.C. 551(6). Thus, “[t]he term ‘order’ is defined to exclude rules.” S. Rep. 79–752 at 11 (November 19, 1945). While this final rule interprets and implements section 804 of the FD&C Act, when FDA authorizes a SIP Proposal, it will be applying this rule.

We also disagree that the manufacturers that hold the NDAs or ANDAs of the FDA-approved counterparts of the eligible prescription drugs that a SIP seeks to import would necessarily be entitled to participate in FDA’s review of the SIP Proposal or to seek judicial review of FDA’s authorization of a SIP Proposal before it proceeds. Under 21 CFR 10.25, “[a]n interested person may petition the Commissioner of the FDA to issue, amend, revoke a rule, order, or to take or refrain from taking any other form of administrative action.”
Under 21 CFR 10.35, an interested person may also “request the Commissioner to stay the effective date of any administrative action.” FDA’s regulations further provide that a final administrative decision on such a petition or request for a stay is a prerequisite to filing suit in court (21 CFR 10.45). A manufacturer can follow the procedures set forth in these regulations to petition FDA with regard to, or seek a stay of, the authorization of a SIP.

Finally, we do not believe that FDA’s review of a SIP Proposal would necessarily benefit from input from NDA or ANDA holders. The comment says that NDA or ANDA holders could offer information such as that antimicrobial, antiviral, or oncology drugs could have a high potential for resistance or death if misbranded or adulterated. We do not think that this is necessary because drugs imported under section 804 of the FD&C Act and this rule will not be any more likely to be adulterated or misbranded than drugs imported with their manufacturer’s authorization.

M. Technical Amendments

We are revising § 1.74(a)(2) (21 CFR 1.74(a)(2)) to remove the reference to a biological product regulated by FDA’s Center for Drug Evaluation and Research (CDER) that is required to have an approved NDA. In the NPRM, we proposed that information filed in ACE must include, for a biological product regulated by FDA’s CDER that is required to have an approved new drug application or an approved biologics license application (BLA), the number of the applicable application. As revised, the text refers to a biological product regulated by FDA’s CDER that is required to have an approved BLA. This amendment reflects that after March 23, 2020, a marketing application for a biological product (that previously could have been submitted under section 505 of the FD&C Act) must be submitted in a BLA under section 351 of the PHS Act (see section 7002(e) of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148)). On March 23, 2020, an approved application for a biological product under section 505 of the FD&C Act was deemed to be a license for the biological product (i.e., an approved BLA) under section 351 of the PHS Act (see section 7002(e)(4)(A) of the BPCI Act; see also section 7002(e)(4)(B) of the BPCI Act). As proposed in the NPRM, we are also adding § 1.74(b), which sets forth the information that ACE filers must submit when they file entry in ACE for drugs that are imported or offered for import under section 804. This information will facilitate the importation of drugs under section 804 and is a safeguard to ensure that FDA’s review of such importation is as protective of the public’s health and safety as the Agency’s review of entries for other drugs. We have revised the authority citation for part 1 to reflect that fact that we added § 1.74(b) pursuant to our authority in section 804(c)(3).

In § 251.9(b), we are including language to clarify that when Foreign Sellers register with FDA under section 804 of the FD&C Act, they must submit a unique facility identifier in accordance with the system specified under section 510 of the FD&C Act (21 U.S.C. 360). We have made conforming revisions to § 1.74(b)(1) and the definitions in proposed § 251.2. These revisions align the Foreign Seller registration requirements under section 804 of the FD&C Act with drug establishment registration requirements under section 510 of the FD&C Act.

The definition of “eligible prescription drug” in § 251.2 includes revisions from the definition proposed in the NPRM to clarify that the drug is currently commercially marketed in the United States. This revision aligns the definition with the certification requirement in proposed § 251.19(e). We have made a conforming revision to proposed § 251.3(d)(6).

In § 251.14 we clarify, as discussed in the NPRM, that a Foreign Seller, upon receiving a shipment of eligible prescription drugs from the manufacturer, must, among other things, maintain records associating the SSI with the Canadian DIN and all the records it received from the manufacturer upon receipt of the original shipment intended for the Canadian market for not less than 6 years.

We are making a number of changes throughout the rule for clarity and readability.

VI. Effective/Compliance Date(s)

This rule is effective November 30, 2020.

VII. Economic Analysis of Impacts

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

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. This rule does not impose new regulatory requirements on small entities that do not participate in SIPs, however, we cannot anticipate whether sponsors will contract with small entities to implement their authorized SIP Proposals or whether, under certain circumstances, a small pharmacist or wholesaler might become a sponsor. We also lack information to quantify the total impacts of the final rule. Because we do not have enough information about the effect of the final rule on small entities, we are not certifying that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is $156 million, using the most current (2019) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount. The final rule allows commercial importation of certain prescription drugs from Canada through time-limited SIPs, sponsored by a State or Indian Tribe, or in certain future circumstances by a pharmacist or wholesaler, with possible cosponsorship by a State, Indian Tribe, pharmacist, or wholesale distributor. If such programs allow Importers to leverage drug price differences between the United States and Canada, they may result in cost savings for U.S. consumers.

We received a number of comments on the preliminary economic analysis,
including general comments on the analysis as well as comments on costs, benefits, distributional effects, international effects, and effects on small entities. We respond to these comments in the final economic analysis.

Costs of the final rule may accrue to the Federal Government, SIP Sponsors, Importers, and manufacturers of imported eligible prescription drugs. The Federal Government will incur costs to implement the final rule and conduct oversight of authorized programs. SIP sponsors will face costs to prepare proposals, implement approved programs, and produce records and program reports. Drug manufacturers will have to provide certain information to Importers if their drugs are imported into the United States from Canada. SIPs may offer cost savings to patients, as well as participating wholesale drug distributors, pharmacies, hospitals, and third-party payers. As drug distributors realize savings in acquiring imported eligible prescription drugs and pass some of these savings to consumers and other payors, it is possible that U.S.-based drug manufacturers may experience a transfer in U.S. sales revenues to these parties.

We are unable to estimate the cost savings from this final rule, because we lack information about the likely size and scope of SIPs, the specific eligible prescription drugs that may be imported, the degree to which these imported drugs will be less expensive than non-imported drugs available in the United States, and which eligible prescription drugs are produced by U.S.-based drug manufacturers.

We lack information about the likely size and scope of SIPs, the specific prescription drug products that may become eligible for importation, which eligible prescription drugs are produced by U.S.-based drug manufacturers, and the degree to which these imported drugs will be less expensive than non-imported drugs available in the United States, to estimate the present and annualized values of the costs and cost savings of the final rule over an infinite period.

### Table 1—Summary of Benefits, Costs, and Distributional Effects of Final Rule

<table>
<thead>
<tr>
<th>Category</th>
<th>Primary estimate</th>
<th>Low estimate</th>
<th>High estimate</th>
<th>Units</th>
<th>Notes</th>
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<tbody>
<tr>
<td><strong>Benefits:</strong></td>
<td></td>
<td></td>
<td></td>
<td>Year</td>
<td>Discount</td>
</tr>
<tr>
<td>Annualized Monetized $millions/year</td>
<td></td>
<td></td>
<td></td>
<td>dollars</td>
<td>rate</td>
</tr>
<tr>
<td>Annualized Quantified</td>
<td></td>
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<td></td>
<td>%</td>
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<tr>
<td>Qualitative</td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Costs:</strong></td>
<td></td>
<td></td>
<td></td>
<td>Year</td>
<td>Discount</td>
</tr>
<tr>
<td>Annualized Monetized $millions/year</td>
<td></td>
<td></td>
<td></td>
<td>dollars</td>
<td>rate</td>
</tr>
<tr>
<td>Annualized Quantified</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>%</td>
</tr>
<tr>
<td>Qualitative</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Transfers:</strong></td>
<td></td>
<td></td>
<td></td>
<td>Year</td>
<td>Discount</td>
</tr>
<tr>
<td>Federal Annualized Monetized $millions/year</td>
<td></td>
<td></td>
<td></td>
<td>dollars</td>
<td>rate</td>
</tr>
<tr>
<td>From/To</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Annualized Monetized $millions/year</td>
<td></td>
<td></td>
<td></td>
<td>dollars</td>
<td>rate</td>
</tr>
<tr>
<td>From/To</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Effects:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>State, Local or Tribal Government</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small Business</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Wages</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Growth</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
time horizon. Therefore, we exclude the Executive Order 13771 summary table from this analysis. This is a deregulatory action because the rule is opening a pathway for legal importation that is not currently allowed.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts, including responses to public comments submitted, is available in the docket for this final rule (Ref. 6) and at https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) and 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

**Title:** Section 804 Importation Program Proposals—21 CFR part 251.

**Description:** The final rule provides that a SIP Sponsor that seeks to implement a SIP to import eligible prescription drugs from Canada must submit a proposal that includes, among other things, information about the SIP Sponsor, cosponsors if any, and the SIP Sponsor’s importation plan including the SIP’s compliance plan. In addition, SIP Sponsors must provide FDA with data and information on the eligible prescription drugs the SIP imports and on the SIP’s cost savings to the American consumer. Importers have a number of responsibilities related to submitting a Pre-Import Request; screening eligible prescription drugs; and arranging for importation, testing, and relabeling. Manufacturers provide an attestation and information statement, batch records, transaction information, and information needed to test eligible prescription drugs for compliance with section 804 of the FD&C Act and the rule.

FDAs anticipates submissions will be made in electronic format through the ESG or to an alternative transmission point identified by FDA.

FDA estimates that there will be 10 SIP Sponsors requiring 360 hours each to research, prepare, and administer requirements annually; 10 Pre-Import Requests requiring 24 hours each annually; and 20 manufacturers also requiring 24 hours each annually to participate in the program. In addition, FDA estimates that a recordkeeping burden of 52 hours will be imposed annually on each of the 10 Importers and the 20 manufacturers. The 20 manufacturers anticipated to participate in the program will also incur an estimated burden of 24 hours each for copying and providing records to SIP Sponsors and Importers of foreign transactions.

FDA estimates the burden of this collection of information as follows:

### TABLE 2—Estimated Annual Reporting Burden

<table>
<thead>
<tr>
<th>Type of information collection activity/respondent</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIP Sponsor §§ 251.3; 251.8; 251.14—SIP Proposal Submission Requirements; 251.18—Post-Importation Requirements; 251.19—Reports to FDA</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>392</td>
<td>3,920</td>
</tr>
<tr>
<td>Importer §§ 251.5; 251.12; 251.13; 251.17—Pre-Import Request and Importation Requirements</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>20</td>
<td>200</td>
</tr>
<tr>
<td>Manufacturer § 251.16 Laboratory Testing Requirements</td>
<td>20</td>
<td>1</td>
<td>20</td>
<td>28</td>
<td>560</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>10</strong></td>
<td><strong>1</strong></td>
<td><strong>4,680</strong></td>
<td><strong>880</strong></td>
<td><strong>4,680</strong></td>
</tr>
</tbody>
</table>

1 There are no capital costs or operating and maintenance costs associated with this collection of information.

### TABLE 3—Estimated Annual Recordkeeping Burden

<table>
<thead>
<tr>
<th>Type of information collection activity/respondent</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIP Sponsor § 251.8—Modification or Extension of Authorized Importation Programs</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>52</td>
<td>520</td>
</tr>
<tr>
<td>Importer §§ 251.14(d)—Supply Chain Security Requirements; 251.17—Importation Requirements; 251.18 Post-Importation Requirements</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>24</td>
<td>240</td>
</tr>
<tr>
<td>Manufacturer § 251.14(b)—Supply Chain Security Requirements</td>
<td>20</td>
<td>1</td>
<td>20</td>
<td>24</td>
<td>480</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>10</strong></td>
<td><strong>1</strong></td>
<td><strong>1,240</strong></td>
<td><strong>240</strong></td>
<td><strong>1,240</strong></td>
</tr>
</tbody>
</table>

1 There are no capital costs or operating and maintenance costs associated with this collection of information.
The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. Before the effective date of this final rule, FDA will publish a notice in the Federal Register announcing OMB’s decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XII. 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.


List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 251

Exports, Labeling, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 251 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1 is revised to read as follows:


■ 2. Revise §1.74 to read as follows:

§1.74 Human drugs.

In addition to the data required to be submitted in §1.72, an ACE filer must submit the following information at the time of filing entry in ACE for drugs, including biological products and eligible prescription drugs as defined in §251.2 of this chapter that are imported or offered for import under section 804 of the Federal Food, Drug, and Cosmetic Act, intended for human use that are regulated by the FDA Center for Drug Evaluation and Research.

(a) For a drug intended for human use that is not an eligible prescription drug covered under paragraph (b) of this section:

(1) Registration and listing. The Drug Registration Number and the Drug Listing Number of the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offer for import into the United States is required to register and list the drug under part 207 of this chapter. For the purposes of this section, the Drug Registration Number that must be submitted at the time of entry filing in ACE is the unique

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Table 4—Estimated Annual Third-Party Disclosure Burden

<table>
<thead>
<tr>
<th>Type of information collection activity/respondent</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer §§251.5—Pre-Import Request; 251.14(b)—Supply Chain Security Requirements</td>
<td>20</td>
<td>1</td>
<td>20</td>
<td>24</td>
<td>480</td>
</tr>
</tbody>
</table>

† There are no capital costs or operating and maintenance costs associated with this collection of information.
facility identifier of the foreign establishment where the human drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510(b) of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number of the human drug article being imported or offered for import.

(2) Drug application number. For a drug intended for human use that is the subject of an approved application under section 505(b) or 505(j) of the Federal Food, Drug, and Cosmetic Act, the number of the new drug application or abbreviated new drug application. For a biological product regulated by the FDA Center for Drug Evaluation and Research that is required to have an approved biologics license application, the number of the applicable application.

(3) Investigational new drug application number. For a drug intended for human use that is the subject of an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act, the number of the investigational new drug application.

(b) For an eligible prescription drug as defined in § 251.2 of this chapter that is imported or offered for import under section 804 of the Federal Food, Drug, and Cosmetic Act, the number of the investigational new drug application.

(1) Registration and listing. The Drug Registration Number and the Drug Listing Number. For the purposes of this section, the Drug Registration Number that must be submitted in ACE is the unique facility identifier submitted by the Foreign Seller registrant under § 251.9 of this chapter in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number that the Importer will use when relabeling the eligible prescription drug as required in § 251.13 of this chapter.

(2) Drug application number. The number of the new drug application or abbreviated new drug application for the counterpart FDA-approved drug.

(3) Lot or control number. The lot or control number assigned by the manufacturer of the eligible prescription drug.

(4) FDA Quantity. FDA Quantity, which is the quantity of each eligible prescription drug in an import line delineated by packaging level, including the type of package from the largest packaging unit to the smallest packaging unit; the quantity of each packaging unit; and the volume and/or weight of each of the smallest of the packaging units.

(5) Pre-Import Request number. The Pre-Import Request number assigned by FDA.

3. Add part 251 to read as follows:

PART 251—SECTION 804 IMPORTATION PROGRAM

Subpart A—General Provisions
Sec. 251.1 Scope of the part.
251.2 Definitions.

Subpart B—Section 804 Importation Program Proposals and Pre-Import Requests
251.3 SIP proposal submission requirements.
251.4 Review and authorization of importation program proposals.
251.5 Pre-Import Request.
251.6 Termination of authorized importation programs.
251.7 Suspension and revocation of authorized importation programs.
251.8 Modification or extension of authorized importation programs.

Subpart C—Certain Requirements for Section 804 Importation Programs
251.9 Registration of Foreign Sellers.
251.10 Reviewing and updating registration information for Foreign Sellers.
251.11 Official contact and U.S. agent for Foreign Sellers.
251.12 Importer responsibilities.
251.13 Labeling of eligible prescription drugs.
251.14 Supply chain security requirements for eligible prescription drugs.
251.15 Qualifying laboratory requirements.
251.16 Laboratory testing requirements.
251.17 Importation requirements.
251.18 Post-importation requirements.
251.19 Reports to FDA.
251.20 Severability.
251.21 Consequences for violations.


Subpart A—General Provisions

§ 251.1 Scope of the part.

(a) This part sets forth the procedures that Section 804 Importation Program sponsors (SIP Sponsors) must follow when submitting plans to implement time-limited programs to begin importation of drugs from Canada under section 804 of the Federal Food, Drug, and Cosmetic Act. This part also sets forth certain requirements that are necessary for such programs to be authorized by the Food and Drug Administration (FDA). Additionally, this part sets forth requirements for eligible prescription drugs and requirements for entities that engage in importation of eligible prescription drugs.

(b) This part includes provisions that exempt eligible prescription drugs that meet certain requirements from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act. This part also includes provisions that exempt certain transactions involving eligible prescription drugs from certain requirements in section 582 of the Federal Food, Drug, and Cosmetic Act.

§ 251.2 Definitions.

The definitions of terms in section 804 of the Federal Food, Drug, and Cosmetic Act apply to the terms used in this part, if not otherwise defined in this section. The following definitions apply to this part:

Active ingredient has the meaning set forth in § 314.3 of this chapter.

Adverse event means any untoward medical occurrence associated with the use of a drug product in humans, whether or not it is considered related to the drug product. An adverse event can occur in the course of the use of a drug product; from overdose of a drug product, whether accidental or intentional; from abuse of a drug product; from discontinuation of the drug product (e.g., physiological withdrawal); and it includes any failure of expected pharmacological action.

Combination product has the meaning set forth in § 3.2(e) of this chapter.

Constituent part has the meaning set forth in § 4.2 of this chapter.

Disability means a substantial disruption of a person’s ability to conduct normal life functions.

Eligible prescription drug.

(1) Means a drug subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act that has been approved and has received a Notice of Compliance and a Drug Identification Number (DIN) from the Health Products and Food Branch of Health Canada (HPFB) and, but for the fact that it deviates from the required U.S. labeling, also meets the conditions in an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) for a drug that is currently commercially marketed in the United States, including those relating to the drug substance, drug product, production process, quality controls, equipment, and facilities.

(2) The term eligible prescription drug does not include:

(i) A controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));
(ii) A biological product (as defined in section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1))); 
(iii) An infused drug (including a peritoneal dialysis solution); 
(iv) An intravenously injected drug; 
(v) A drug that is inhaled during surgery; 
(vi) An intrathecally or intraocularly injected drug; 
(vii) A drug that is subject to a risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act; or 
(viii) A drug that is not a “product” for purposes of section 582 as defined in section 581(13) of the Federal Food, Drug, and Cosmetic Act.

Entered (or entry) for consumption has the meaning set forth in 19 CFR 141.0a(f).

Entry means the information or data filed electronically in the Automated Commercial Environment (ACE) or any other U.S. Customs and Border Protection (CBP)-authorized electronic data interchange system to secure the release of imported merchandise from CBP, or the act of filing that information or data.

Foreign Seller means an establishment within Canada engaged in the distribution of an eligible prescription drug that is imported or offered for importation into the United States. A Foreign Seller must have an active Drug Establishment License to wholesale drugs by Health Canada. A Foreign Seller must be registered with provincial regulatory authorities to distribute HPFB-approved drugs. A Foreign Seller must not be licensed by a provincial regulatory authority with an international pharmacy license that allows it to distribute drugs that are approved by countries other than Canada and that are not HPFB-approved for distribution in Canada. A Foreign Seller must also be registered with FDA under section 804 of the Federal Food, Drug, and Cosmetic Act in accordance with the requirements described in this part.

Illegitimate foreign product means a drug purchased by a Foreign Seller from a manufacturer, and intended for sale to the Importer in the United States, where the Foreign Seller has credible evidence that shows that the product:
(1) Is counterfeit, diverted, or stolen;
(2) Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
(3) Is the subject of a fraudulent transaction; or
(4) Is otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

Importer means a pharmacist or wholesaler. An Importer must be a State-licensed pharmacist, or a State- or FDA-licensed wholesale distributor, who is the U.S. owner of an eligible prescription drug at the time of entry into the United States. The Importer’s pharmacist license or wholesale distributor license (if issued by a State and not FDA) must be issued by a State that is a SIP Sponsor or SIP Co-Sponsor. An Importer’s pharmacist or wholesale distributor license must be in effect (i.e., not expired) and the Importer’s license must be in good standing with the licensor.

Individual case safety report (ICSR) means a description of an adverse event related to an individual patient or subject.

ICSR attachments means any document related to the adverse event described in an ICSR, such as medical records, hospital discharge summaries, or other documentation.

Life-threatening adverse event means any adverse event that places the patient, in the view of the initial reporter, at immediate risk of death from the adverse event as it occurred, i.e., it does not include an adverse event that, had it occurred in a more severe form, might have caused death.

Manufacturer means an applicant, as defined in § 314.3 of this chapter, or a person who owns or operates an establishment that manufactures an eligible prescription drug. Manufacturer also means a holder of a drug master file containing information necessary to conduct the Statutory Testing, prepare the manufacturer’s attestation and information statement, or otherwise comply with section 804 of the Federal Food, Drug, and Cosmetic Act or this part.

Minimum data set for an adverse event means the minimum four elements required for reporting an ICSR of an adverse event: An identifiable patient, an identifiable reporter, a suspect drug product, and an adverse event.

Pharmacist means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

Pre-Import Request means a request made to FDA by an Importer that must be granted by FDA before the Importer can start importation under a Section 804 Importation Program.

Qualifying laboratory means a laboratory in the United States that has been approved by FDA for the purposes of section 804 of the Federal Food, Drug, and Cosmetic Act.
Section 804  Importation Program Co-Sponsor (“SIP Co-Sponsor”) means any other State or Indian Tribe, or a pharmacist or a wholesale distributor that, with the SIP Sponsor, signs a proposal to FDA that describes a program to facilitate the importation of prescription drugs from Canada under section 804 of the Federal Food, Drug, and Cosmetic Act.

Section 804  Serial Identifier (“SSI”) means a unique alphanumeric serial number of up to 20 characters that is assigned and placed on or affixed by the Foreign Seller to each package and homogenous case of the product that the Foreign Seller intends to sell to an Importer. For purposes of the SSI, “package” means the smallest individual saleable unit of product for distribution that is intended by the Foreign Seller for sale to an Importer located in the United States, and “individual saleable unit” means the smallest container of product sold by the Foreign Seller to the Importer.

Serious adverse event means:

(1) An adverse event is considered “serious” if it results in any of the following outcomes:
   (i) Death;
   (ii) A life-threatening adverse event;
   (iii) Inpatient hospitalization or prolongation of existing hospitalization;
   (iv) A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; and/or
   (v) A congenital anomaly/birth defect.
(2) Other events that may be considered serious adverse events:
   Important medical events that may not result in one of the listed outcomes in this definition may be considered serious adverse events when, based upon appropriate medical judgment, they may jeopardize the patient or study subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples include: Allergic bronchospasm requiring intensive treatment in an emergency department or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of product dependency or product abuse.

Statutory Testing means the testing of an eligible prescription drug as required by section 804(d)(1)(J) and (L) and section 804(e) of the Federal Food, Drug, and Cosmetic Act, including for authenticity, for degradation, and to ensure that the prescription drug is in compliance with established specifications and standards.

Suspect foreign product means a drug purchased by a Foreign Seller from a manufacturer, and intended for sale to an Importer in the United States, for which the Foreign Seller has reason to believe that such product:

(1) Is potentially counterfeit, diverted, or stolen;
(2) Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
(3) Is potentially the subject of a fraudulent transaction; or
(4) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Transaction means the transfer of product between persons in which a change of ownership occurs, in accordance with section 581(24) of the Federal Food, Drug, and Cosmetic Act. For the purposes of this part, “transaction” includes the sale and transfer of product between the manufacturer and Foreign Seller. The sale and transfer of product between Foreign Seller and Importer also constitutes a “transaction.”

Unexpected adverse event means an adverse event that is not included in the current U.S. labeling for the drug product. Events that may be symptomatically or pathophysiologically related to an adverse event included in the labeling but differ from the labeled event because of greater severity or specificity would be considered unexpected. “Unexpected,” as used in this definition, also refers to adverse events that are mentioned in the product labeling as occurring with a class of products or anticipated from the pharmacological properties of the product but are not specifically mentioned as occurring with the particular product.

(1) Example of greater severity. Under this definition, hepatic necrosis would be unexpected if the labeling referred only to elevated hepatic enzymes or hepatitis.
(2) Example of greater specificity. Cerebral thromboembolism and cerebral hemorrhage would be unexpected if the labeling included only cerebrovascular accidents.

Unique facility identifier means the identifier required to be submitted by the registrant for drug establishment registration under section 510 of the Federal Food, Drug, and Cosmetic Act in accordance with §207.25 of this chapter. For Foreign Sellers registering under section 804 of the Federal Food, Drug, and Cosmetic Act, the term “unique facility identifier” means the identifier required to be submitted under §251.9 in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act.

Wholesaler means a person licensed as a wholesale distributor, as the terms “licensed” and “wholesale distributor” are defined in section 581(9)(A) and 581(29), respectively. The term “wholesaler” does not include a person authorized to import drugs under section 801(d)(1).

Subpart B—Section 804 Importation Program Proposals and Pre-Import Requests

§251.3  SIP proposal submission requirements.

(a) A SIP Sponsor may delegate implementation activities to a SIP co-sponsor but the SIP Sponsor remains responsible for oversight of the implementation of the program.

(b) A SIP Sponsor must only designate one Foreign Seller and one Importer per initial proposal. Additional Foreign Sellers and Importers may be added to an authorized SIP through a supplemental proposal under §251.8.

(c) A SIP Sponsor that intends to implement a SIP under this part must submit a proposal to FDA in electronic format via FDA’s Electronic Submissions Gateway (ESG) or to an alternative transmission point identified by FDA. The proposal must include:

(1) A cover sheet containing the following:
   (i) Name or names of SIP Sponsor and co-sponsors, if any;
   (ii) Name and contact information for a person authorized to serve as the point of contact with FDA during its review of the proposal; and
   (iii) The signature of the SIP Sponsor and co-sponsors, if any, or authorized representative who is an employee or agent of the Sponsor or co-sponsor and has been authorized to sign the proposal for the Sponsor or co-sponsor. The signatory must reside or have a place of business within the United States, and the proposal cover sheet must contain the name, title, and business address of the signatory.
(2) A table of contents;
(3) An introductory statement that includes an overview of the SIP Sponsor’s SIP Proposal; and
(4) The SIP Sponsor’s importation plan.

(d) The overview of the SIP Proposal must include:

(1) The name of the SIP, if any, and the name or names and address or addresses of the SIP Sponsor and co-sponsors, if any;
(2) The name, email address, and telephone number of the responsible individual(s):
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(3) The name and DIN of each eligible prescription drug that the SIP Sponsor seeks to include in the SIP.

(4) The name and address of the applicant that holds the approved NDA or ANDA for each eligible prescription drug’s FDA-approved counterpart, and the approved NDA or ANDA number.

(5) The name and address of the manufacturer of the finished dosage form of the eligible prescription drug, if known or reasonably known.

(6) The name and address of the manufacturer of the active ingredient or ingredients of the eligible prescription drugs, if known or reasonably known.

(7) The name and address of the Foreign Seller.

(8) A copy of the Foreign Seller’s Health Canada Drug Establishment License.

(9) The name and address of the Importer.

(10) The name and address of the FDA-registered repackager or relabeler, if different from the Importer, that will relabel the eligible prescription drugs (including any limited repackaging in accordance with the requirements in this part), along with adequate evidence of registration and of satisfactory resolution of any objectionable conditions or practices identified during its most recent FDA inspection, if applicable; and

(11) A summary of how the SIP Sponsor will ensure that:

(i) The imported eligible prescription drugs meet the Statutory Testing requirements;

(ii) The supply chain is secure;

(iii) The labeling requirements of the Federal Food, Drug, and Cosmetic Act and this part are met;

(iv) The post-importation pharmacovigilance and other requirements of the Federal Food, Drug, and Cosmetic Act and this part are met;

and

(v) The SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the SIP Sponsor seeks to import.

(e) The SIP Sponsor’s importation plan must:

(1) Identify the SIP Sponsor, including any co-sponsors, identify the responsible individual(s), and identify the applicant that holds the approved NDA or ANDA for each eligible prescription drug’s FDA-approved counterpart, the manufacturer(s) of the finished dosage form and the active ingredient or ingredients of each eligible prescription drug that the SIP Sponsor seeks to import, if known or reasonably known, the Foreign Seller, if known or reasonably known, and the Importer, and explain the legal relationship, if any, of each of these entities to the SIP Sponsor.

(2) Include an attestation and information statement containing a complete disclosure of any past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against or by the responsible individual(s), Foreign Seller, or Importer or an attestation that the responsible individual(s), Foreign Seller, or Importer has not been involved in, or convicted of, any such violations. Such attestation and information statement must include principals, any shareholder who owns 10 percent or more of outstanding stock in any non-publicly held corporation, directors, officers, and any facility manager or designated representative of such manager.

(3) Include a list of all disciplinary actions, to include the date of and parties to any action imposed against the responsible individual(s), Foreign Seller, or Importer by State, Federal, or Canadian regulatory bodies, including any such actions against the principals, owners, directors, officers, quality unit, or any facility manager or designated representative of such manager for the previous 7 years prior to submission of the SIP Proposal.

(4) Include:

(i) The Health Canada inspectional history for the Foreign Seller for the previous 5 years or, if the Foreign Seller has been licensed for less than 5 years, for the duration of its period of licensure;

(ii) The State and Federal inspectional history for the Importer for the previous 5 years or, if the Importer has been licensed for less than 5 years, for the duration of its period of licensure.

(5) Include the proprietary name (if any), the established name, the approved application numbers, and the DIN and National Drug Code (NDC) for each eligible prescription drug that the SIP Sponsor seeks to import from Canada and for its FDA-approved counterpart. The SIP Sponsor’s importation plan must also include as much of the information that is required by §251.5 about the HPFB-approved labeling and the approved drug labeling for the FDA-approved counterpart as is available, including the name and quantity of the active ingredient, the inactive ingredients, and the dosage form.

(6) Provide adequate evidence that each HPFB-approved drug’s FDA-approved counterpart drug is currently commercially marketed in the United States.

(7) Describe, to the extent possible, the testing that will be done to establish that the HPFB-approved drug meets the conditions in the NDA or ANDA for the HPFB-approved drug’s FDA-approved counterpart. The SIP Sponsor’s importation plan must also identify the qualifying laboratory that will conduct the Statutory Testing for the Importer, if the Importer is responsible for conducting the Statutory Testing, and it must establish that the laboratory is qualified in accordance with §251.15 to conduct the tests.

(8) Include a copy of the FDA-approved drug labeling for the FDA-approved counterpart of the eligible prescription drug, a copy of the proposed labeling that will be used for the eligible prescription drug, and a side-by-side comparison of the FDA-approved labeling and the proposed labeling, including the Prescribing Information, carton and container labeling, and patient labeling (e.g., Medication Guide, Instructions for Use, patient package inserts), with all differences annotated and explained. The SIP Proposal must also include a copy of the HPFB-approved labeling.

(9) Explain how the SIP Sponsor will ensure that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the SIP Sponsor seeks to import. The explanation must include any assumptions and uncertainty, and it must be sufficiently detailed to allow for a meaningful evaluation.

(10) Explain how the SIP Sponsor will ensure that all the participants in the SIP comply with the requirements of section 804 of the Federal Food, Drug, and Cosmetic Act and this part.

(11) Describe the procedures the SIP Sponsor will use to ensure that the requirements of this part are met, including the steps that will be taken to ensure that:

(i) Storage, handling, and distribution practices of supply chain participants, including transportation providers, meet the requirements of part 205 of this chapter and do not affect the quality or impinge on the security of the eligible prescription drugs;

(ii) Supply chain is secure;

(iii) Importer screens the eligible prescription drugs it imports for evidence that they are adulterated, counterfeit, damaged, tampered with, expired, suspect foreign product, or illegitimate foreign product; and

(iv) Importer fulfills its responsibilities to submit adverse event, field alert, and other reports required by the SIP, the Federal Food, Drug, and Cosmetic Act, or this part.

(12) Explain how the SIP Sponsor will educate pharmacists, healthcare
providers, pharmacy benefit managers, health insurance issuers and plans, as appropriate, and patients about the eligible prescription drugs imported under its SIP. 

(13) Include the SIP’s recall plan, including an explanation of how the SIP Sponsor will obtain recall or market withdrawal information and how it will ensure that recall or market withdrawal information is shared among the SIP Sponsor, the Foreign Seller, the Importer, and FDA and provided to the manufacturer. 

(14) Include the SIP’s return plan, including an explanation of how the SIP Sponsor will ensure that product that is returned after distribution in the United States is properly dispositioned in the United States, if it is a non-saleable return, in order to protect patients from expired or unsafe drugs, and an explanation of how the SIP Sponsor will prevent the non-saleable returned eligible prescription drugs from being exported from the United States. In the event that a returned eligible prescription drug may be considered saleable, include an explanation for how the returned product will be determined to be saleable and under what circumstances such eligible prescription drugs may be re-distributed in the United States. 

(15) Include the SIP’s compliance plan, which must include: 

(i) A description of the division of responsibilities among co-sponsors, if any, which includes a plan for timely communication of any compliance issues to the SIP Sponsor; 

(ii) Identification of responsible individual(s) and a description of the respective area(s) of the SIP, the Federal Food, Drug, and Cosmetic Act, or this part that will be under each responsible individual’s oversight; 

(iii) The creation of written compliance policies, procedures, and protocols; 

(iv) The provision of education and training to ensure that Foreign Sellers, Importers, qualifying laboratories, and their employees understand their compliance-related obligations; 

(v) The creation and maintenance of effective lines of communication, including a process to protect the anonymity of complainants and to protect whistleblowers; and 

(vi) The adoption of processes and procedures for uncovering and addressing noncompliance, misconduct, or conflicts of interest. 

(16) Explain how the SIP Sponsor will ensure that any information that the manufacturer supplies to authenticate a prescription drug being tested and confirm that the labeling of the prescription drug complies with labeling requirements under the Federal Food, Drug, and Cosmetic Act, and any trade secrets or commercial or financial information that is privileged or confidential that the manufacturer supplies for the purposes of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part, are kept in strict confidence and used only for the purposes of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part. 

§251.4 Review and authorization of importation program proposals. 

Based on a review of a SIP Proposal or supplemental proposal submitted under this part, FDA may authorize a SIP, modify a SIP, or extend the authorization period of a SIP, that meets the requirements of this part. FDA may use a phased review process to review a SIP Proposal that does not identify a Foreign Seller in an initial submission, under which FDA may notify the Sponsor of such a SIP Proposal whether the Sponsor’s SIP Proposal otherwise meets the requirements of this part. In such a case, the required information regarding importers, relabelers, and repackagers still must be included in the initial submission of the SIP Proposal, and the SIP Proposal will be denied if a Foreign Seller is not identified within 6 months of the initial submission date of the SIP Proposal. 

(a) FDA may deny a request for authorization, modification, or extension of a SIP, including if a SIP Proposal or supplemental proposal does not meet the requirements of this part. When a SIP Proposal or supplemental proposal meets the requirements of this part, FDA may nonetheless decide not to authorize the SIP Proposal or supplemental proposal. For example, FDA may decide not to authorize a SIP Proposal or supplemental proposal because of potential safety concerns with the SIP; because a Foreign Seller is not identified within 6 months of the initial submission of the SIP Proposal; because of the degree of uncertainty that the SIP Proposal or supplemental proposal would adequately ensure the protection of public health; because of, based on the recommendation of another Department of Health and Human Services (HHS) component as directed by the Secretary, the relative likelihood that the SIP Proposal or supplemental proposal would result in significant cost savings to the American consumer; because of the potential for conflicts of interest; or in order to limit the number of authorized SIPs so FDA can effectively and efficiently carry out its responsibilities under section 804 of the Federal Food, Drug, and Cosmetic Act in light of the amount of resources allocated to carrying out such responsibilities. 

(b) FDA may notify a SIP Sponsor in writing when FDA receives the SIP Sponsor’s SIP Proposal or supplemental proposal. 

(c) FDA will make a reasonable effort to promptly communicate to a SIP Sponsor about any information required by §251.3 that was not submitted in a SIP Proposal. 

(1) FDA may notify a SIP Sponsor if FDA believes additional information would help FDA’s review of a SIP Proposal or supplemental proposal. 

(2) FDA will notify a SIP Sponsor in writing whether FDA has decided to authorize or not to authorize the SIP Sponsor’s SIP Proposal or supplemental proposal. 

§251.5 Pre-Import Request. 

(a) An eligible prescription drug may not be imported or offered for import under this part unless the Importer has filed a Pre-Import Request for that drug in accordance with this section and FDA has granted the Pre-Import Request. 

(b) The Importer must submit a complete Pre-Import Request in electronic format via the ESG, or to an alternative transmission point identified by FDA, at least 30 calendar days prior to the scheduled date of arrival or entry for consumption, whichever occurs first, of an eligible prescription drug covered under an authorized SIP. 

(c) A complete Pre-Import Request must include, at a minimum: 

(1) Identification of the Importer, including Importer name; business type (wholesale distributor or pharmacist); U.S. license number(s) and State(s) of license; business address; unique facility identifier if required to register with FDA as an establishment under section 510 of the Federal Food, Drug, and Cosmetic Act or FDA establishment identification number if not required to register under section 510 of the Federal Food, Drug, and Cosmetic Act; and the name, email address, and phone number of a contact person. 

(2) Identification of the FDA-authorized SIP, including the name of the SIP, if any; the name or names of the SIP Sponsor and co-sponsors, if any; business address; and the name, email address, and phone number of a contact person. 

(3) Identification of the Foreign Seller, including the name of the Foreign Seller; business address; unique facility identifier; any license numbers issued by Health Canada or a provincial...
regulatory body; and the name, email address, and phone number of a contact person.

(4) Identification and description of each drug covered by the Pre-Import Request, including, for each drug, the following information:
   (i) Established and proprietary name of the HPFB-approved drug, as applicable; DIN; and complete product description, including strength, description of dosage form, and route(s) of administration.
   (ii) Active pharmaceutical ingredient (API) information, including:
      (A) Name of API;
      (B) Manufacturer of API and its unique facility identifier; and
      (C) Amount of API and unit measure in the eligible prescription drug.
   (iii) Established name and proprietary name, as applicable, of the FDA-approved counterpart drug and NDA or ANDA number.
   (iv) Manufacturer of the eligible prescription drug with the business address and unique facility identifier.
   (v) Copies of the invoice and any other documents related to the manufacturer’s sale of the drug to the Foreign Seller that was provided by the manufacturer to the Importer, and copies of the same documents provided by the Foreign Seller to the Importer.
   (vi) Quantity, listed separately by dosage form, strength, batch and lot or control number assigned by the manufacturer to the eligible prescription drug intended to be imported under this Pre-Import Request, compared to the quantity of each batch and lot or control number originally received by the Foreign Seller from the manufacturer, and the date of such receipt.
   (vii) Expiration date of the HPFB-approved drug, listed by lot or control number assigned by the manufacturer.
   (viii) Expiration date to be assigned to the eligible prescription drug when relabeled by the Importer with a complete description of how that expiration date was determined using the manufacturer’s stability studies in accordance with the FDA-approved NDA or ANDA.
   (ix) NDC proposed for assignment by the Importer.
   (x) FDA product code for the eligible prescription drug(s) to be imported.
   (xi) Unless the manufacturer has notified the Importer that it intends to conduct the required testing as provided in § 251.16(e), a Statutory Testing plan that includes:
      (A) A description of how the samples will be selected from a shipment for the Statutory Testing;
      (B) The named location of the qualifying laboratory in the United States that will conduct the Statutory Testing; and
      (C) A description of the testing method(s) that will be used to conduct the Statutory Testing.
   (xii) Attestation and information statement from the manufacturer that establishes that the drug proposed for import, but for the fact that it bears the HPFB-approved labeling, meets the conditions in the FDA-approved NDA or ANDA, including any process-related or other requirements for which compliance cannot be established through laboratory testing. Accordingly, the attestation and information statement must include, at a minimum:
      (A) Confirmation that the HPFB-approved drug has the active ingredient(s), active ingredient source(s) (including manufacturing facility or facilities), inactive ingredient(s), dosage form, strength(s), and route(s) of administration described in the FDA-approved drug’s NDA or ANDA.
      (B) Confirmation that the HPFB-approved drug conforms to the specifications in the FDA-approved drug’s NDA or ANDA regarding the quality of the drug substance(s), drug product, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of the drug.
      (C) Confirmation that the HPFB-approved drug was manufactured in accordance with the conditions described in the FDA-approved drug’s NDA or ANDA, including with regard to the facilities and manufacturing lines that are used, and in compliance with current good manufacturing practice requirements set forth in section 501 of the Federal Food, Drug, and Cosmetic Act and parts 210, and 211 of this chapter.
      (D) Original date of manufacture or batch record, including the number of the executed batch record, including the number of the execution date, and appropriate facility control number.
      (E) Information about where the relabeled drug will be stored pending relabeling, and other requirements for which compliance cannot be established through laboratory testing. Accordingly, the attestation and information statement must include, at a minimum:
         (A) Confirmation that the HPFB-approved drug has the active ingredient(s), active ingredient source(s) (including manufacturing facility or facilities), inactive ingredient(s), dosage form, strength(s), and route(s) of administration described in the FDA-approved drug’s NDA or ANDA.
         (B) Confirmation that the HPFB-approved drug conforms to the specifications in the FDA-approved drug’s NDA or ANDA regarding the quality of the drug substance(s), drug product, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of the drug.
         (C) Confirmation that the HPFB-approved drug was manufactured in accordance with the conditions described in the FDA-approved drug’s NDA or ANDA, including with regard to the facilities and manufacturing lines that are used, and in compliance with current good manufacturing practice requirements set forth in section 501 of the Federal Food, Drug, and Cosmetic Act.
         (D) Original date of manufacture or batch record, including the number of the executed batch record, including the number of the execution date, and appropriate facility control number.
         (E) Information about where the relabeled drug will be stored pending relabeling, and other requirements for which compliance cannot be established through laboratory testing. Accordingly, the attestation and information statement must include, at a minimum:
            (A) Confirmation that the HPFB-approved drug has the active ingredient(s), active ingredient source(s) (including manufacturing facility or facilities), inactive ingredient(s), dosage form, strength(s), and route(s) of administration described in the FDA-approved drug’s NDA or ANDA.
            (B) Confirmation that the HPFB-approved drug conforms to the specifications in the FDA-approved drug’s NDA or ANDA regarding the quality of the drug substance(s), drug product, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of the drug.
            (C) Confirmation that the HPFB-approved drug was manufactured in accordance with the conditions described in the FDA-approved drug’s NDA or ANDA, including with regard to the facilities and manufacturing lines that are used, and in compliance with current good manufacturing practice requirements set forth in section 501 of the Federal Food, Drug, and Cosmetic Act.
            (D) Original date of manufacture or batch record, including the number of the executed batch record, including the number of the execution date, and appropriate facility control number.
            (E) Information about where the relabeled drug will be stored pending relabeling, and other requirements for which compliance cannot be established through laboratory testing. Accordingly, the attestation and information statement must include, at a minimum:
               (A) Confirmation that the HPFB-approved drug has the active ingredient(s), active ingredient source(s) (including manufacturing facility or facilities), inactive ingredient(s), dosage form, strength(s), and route(s) of administration described in the FDA-approved drug’s NDA or ANDA.
               (B) Confirmation that the HPFB-approved drug conforms to the specifications in the FDA-approved drug’s NDA or ANDA regarding the quality of the drug substance(s), drug product, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of the drug.
               (C) Confirmation that the HPFB-approved drug was manufactured in accordance with the conditions described in the FDA-approved drug’s NDA or ANDA, including with regard to the facilities and manufacturing lines that are used, and in compliance with current good manufacturing practice requirements set forth in section 501 of the Federal Food, Drug, and Cosmetic Act.
               (D) Original date of manufacture or batch record, including the number of the executed batch record, including the number of the execution date, and appropriate facility control number.
               (E) Information about where the relabeled drug will be stored pending relabeling, and other requirements for which compliance cannot be established through laboratory testing. Accordingly, the attestation and information statement must include, at a minimum:
                  (A) Confirmation that the HPFB-approved drug has the active ingredient(s), active ingredient source(s) (including manufacturing facility or facilities), inactive ingredient(s), dosage form, strength(s), and route(s) of administration described in the FDA-approved drug’s NDA or ANDA.
                  (B) Confirmation that the HPFB-approved drug conforms to the specifications in the FDA-approved drug’s NDA or ANDA regarding the quality of the drug substance(s), drug product, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of the drug.
                  (C) Confirmation that the HPFB-approved drug was manufactured in accordance with the conditions described in the FDA-approved drug’s NDA or ANDA, including with regard to the facilities and manufacturing lines that are used, and in compliance with current good manufacturing practice requirements set forth in section 501 of the Federal Food, Drug, and Cosmetic Act.
                  (D) Original date of manufacture or batch record, including the number of the executed batch record, including the number of the execution date, and appropriate facility control number.
                  (E) Information about where the relabeled drug will be stored pending relabeling, and other requirements for which compliance cannot be established through laboratory testing. Accordingly, the attestation and information statement must include, at a minimum:
                     (A) Confirmation that the HPFB-approved drug has the active ingredient(s), active ingredient source(s) (including manufacturing facility or facilities), inactive ingredient(s), dosage form, strength(s), and route(s) of administration described in the FDA-approved drug’s NDA or ANDA.
                     (B) Confirmation that the HPFB-approved drug conforms to the specifications in the FDA-approved drug’s NDA or ANDA regarding the quality of the drug substance(s), drug product, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of the drug.
                     (C) Confirmation that the HPFB-approved drug was manufactured in accordance with the conditions described in the FDA-approved drug’s NDA or ANDA, including with regard to the facilities and manufacturing lines that are used, and in compliance with current good manufacturing practice requirements set forth in section 501 of the Federal Food, Drug, and Cosmetic Act.
                     (D) Original date of manufacture or batch record, including the number of the executed batch record, including the number of the execution date, and appropriate facility control number.
                     (E) Information about where the relabeled drug will be stored pending relabeling, and other requirements for which compliance cannot be established through laboratory testing. Accordingly, the attestation and information statement must include, at a minimum:
                        (A) Confirmation that the HPFB-approved drug has the active ingredient(s), active ingredient source(s) (including manufacturing facility or facilities), inactive ingredient(s), dosage form, strength(s), and route(s) of administration described in the FDA-approved drug’s NDA or ANDA.
                        (B) Confirmation that the HPFB-approved drug conforms to the specifications in the FDA-approved drug’s NDA or ANDA regarding the quality of the drug substance(s), drug product, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of the drug.
                        (C) Confirmation that the HPFB-approved drug was manufactured in accordance with the conditions described in the FDA-approved drug’s NDA or ANDA, including with regard to the facilities and manufacturing lines that are used, and in compliance with current good manufacturing practice requirements set forth in section 501 of the Federal Food, Drug, and Cosmetic Act.
§ 251.6 Termination of authorized importation programs.

(a) Unless an extension is granted under this part, authorization for a SIP automatically terminates after 2 years, or a shorter period of time if a shorter period of time is specified in the authorization for the SIP.

(b) The authorization period for a SIP begins when the Importer, or its authorized customs broker, files an electronic import entry for consumption for its first shipment of drugs under the SIP.

(c) Notwithstanding paragraph (a) of this section, authorization for a SIP terminates if the Importer, or its authorized customs broker, does not file an electronic import entry for consumption for a shipment of eligible prescription drugs under the SIP within 1 year of the date that the SIP was authorized.

(d) FDA will terminate authorization of a SIP upon request from the SIP Sponsor.

(e) An eligible prescription drug cannot be shipped into the United States under this part, and is subject to refusal of admission into the United States, if the authorization of the SIP has terminated.

§ 251.7 Suspension and revocation of authorized importation programs.

(a) FDA may suspend a SIP under any of the circumstances set forth in § 251.18, or under any other circumstances in FDA’s discretion. An eligible prescription drug cannot be shipped into the United States under this part, and is subject to refusal of admission into the United States, if FDA has suspended the SIP or revoked its authorization.

(b) SIP Sponsors and other SIP participants must agree to submit to audits of their books and records and inspections of their facilities as a condition of participation in a SIP. If a SIP Sponsor, manufacturer, Foreign Seller, Importer, qualifying laboratory, or other participant in the supply chain delays, denies, or limits an inspection, or refuses to permit entry, inspection, or audit of its facility or its records, FDA may suspend the SIP, in whole or in part, immediately.

(c) FDA may revoke authorization of a SIP, in whole or in part, including with respect to one or more drugs in the SIP, at any time if FDA determines that:

(1) The SIP Proposal contained an untrue statement of material fact; or

(2) The SIP Proposal omitted material information; or

(3) The SIP no longer meets the requirements of section 804 of the Federal Food, Drug, and Cosmetic Act, this part, or the SIP, including, among other things, if FDA finds that the manufacturer, the Foreign Seller, the Importer, or any other supply chain participant is found to be not compliant with section 501(a)(2)(A) or (B) of the Federal Food, Drug, and Cosmetic Act; or

(4) Continued implementation of the SIP is reasonably likely to pose significant additional risk to the public’s health and safety; or

(5) Confidential manufacturer information was disclosed in violation of § 251.16; or

(6) Continued implementation of the SIP is not reasonably likely to result in a significant reduction in the cost of the drugs covered by the SIP to the American consumer; or

(7) Continued monitoring of the SIP imposes too much of a burden on FDA or HHS resources for carrying out this part or is inconsistent with FDA or HHS prioritization of resources; or

(8) Continued implementation of the SIP is otherwise inappropriate; or

(9) Grounds exist for suspension of a SIP in accordance with paragraph (a) or (b) of this section and FDA determines it should revoke, either instead of, or after, suspension.

§ 251.8 Modification or extension of authorized importation programs.

(a) A supplemental proposal to modify or extend an authorized SIP must be submitted in electronic format via the ESG, or to an alternative transmission point identified by FDA, for FDA’s consideration.

(b) FDA’s review and authorization of a supplemental proposal to modify or extend an authorized SIP is governed by this part. In reviewing a supplemental proposal, FDA may take into account information learned subsequent to authorization of the SIP.

(c) FDA may authorize a supplemental proposal from a SIP Sponsor to add additional Foreign Sellers or additional Importers to an authorized SIP if FDA determines the SIP Sponsor has adequately demonstrated that the SIP has consistently imported eligible prescription drugs in accordance with section 804 of the Federal Food, Drug, and Cosmetic Act and this part. Each supply chain under a SIP must be limited to one manufacturer, one Foreign Seller, and one Importer.

(d) If FDA authorizes changes to a SIP, the Importer must submit a new Pre-Import Request in accordance with § 251.5.

(e) A SIP Sponsor must not make any changes or permit any changes to be made to a SIP without first securing FDA’s authorization.

(f) A SIP Sponsor may request that FDA extend the authorization period of an authorized SIP. Such a request must be submitted at least 90 calendar days before the SIP’s authorization period will expire. To be eligible for an extension of the authorized SIP, a SIP must be up to date on all of the information and records-related requirements of section 804 of the Federal Food, Drug, and Cosmetic Act and this part. FDA may extend the authorization period for up to 2 years at a time.

Subpart C—Certain Requirements for Section 804 Importation Programs

§ 251.9 Registration of Foreign Sellers.

(a) Any Foreign Seller(s) designated in a SIP Proposal must be registered with FDA before FDA will authorize the SIP Proposal.

(b) To register, a Foreign Seller must provide the following information:

(1) Name of the owner or operator; if a partnership, the name of each partner; if a corporation, the name of each corporate officer and director, and the place of incorporation;

(2) All names of the Foreign Seller, including names under which the Foreign Seller conducts business or names by which the Foreign Seller is known;

(3) Physical address and telephone number(s) of the Foreign Seller;

(4) Registration number, if previously assigned by FDA;

(5) A unique facility identifier in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act;

(6) All types of operations performed by the Foreign Seller;

(7) Name, mailing address, telephone number, and email address of the official contact for the establishment; and

(8) Name, mailing address, telephone number, and email address of:

(i) The U.S. agent;

(ii) The Importer to which the Foreign Seller plans to sell eligible prescription drugs; and

(iii) Each SIP Sponsor with which the Foreign Seller works.

§ 251.10 Reviewing and updating registration information for Foreign Sellers.

(a) Expedited updates. A Foreign Seller must update its registration information no later than 30 calendar days after:

(1) Closing or being sold;

(2) Changing its name or physical address; or
§ 251.11 Official contact and U.S. agent for Foreign Sellers.

(a) Official contact. A Foreign Seller subject to the registration requirements of this part must designate an official contact. The official contact is responsible for:

(1) Ensuring the accuracy of registration information as required by § 251.9; and

(2) Reviewing, disseminating, routing, and responding to all communications from FDA, including emergency communications.

(b) U.S. agent. (1) A Foreign Seller must designate a single U.S. agent. The U.S. agent must reside or maintain a place of business in the United States and may not be a mailbox, answering machine or service, or other place where a person acting as the U.S. agent is not physically present. The U.S. agent is responsible for:

(i) Reviewing, disseminating, routing, and responding to all communications from FDA, including emergency communications;

(ii) Responding to questions concerning those drugs that are imported or offered for import to the United States; and

(iii) Assisting FDA in scheduling inspections.

(2) FDA may provide certain information and/or documents to the U.S. agent. The provision of information and/or documents by FDA to the U.S. agent is equivalent to providing the same information and/or documents to the Foreign Seller.

§ 251.12 Importer responsibilities.

(a) The Importer is responsible for:

(1) In accordance with the procedures set forth in § 207.33 of this chapter, proposing an NDC for assignment for each eligible prescription drug imported pursuant to this part:

(2) Examining the Canadian labeling of a sample of each shipment of eligible prescription drugs to verify that the labeling is that of the HPFB-approved drug, and attesting that such examination has been conducted through reports to FDA required under this part;

(3) Screening eligible prescription drugs for evidence that they are adulterated, counterfeit, damaged, tampered with, expired, suspect foreign product, or illegitimate foreign product;

(4) Ensuring the eligible prescription drug is relabeled with the required U.S. labeling, including the container and carton labeling; Prescribing Information; and patient labeling, such as Medication Guides, Instruction for Use documents, and patient package inserts, in accordance with §§ 251.13 and 251.14(d);

(5) Arranging for an entry to be submitted in accordance with § 251.17;

(6) Collecting and submitting the information to FDA about the imported drug(s) pursuant to section 804(d) of the Federal Food, Drug, and Cosmetic Act, in addition to information about the Foreign Seller, as set forth in § 251.19; and

(7) Submitting the adverse event, field alert, and other reports, and complying with drug recalls, in accordance with § 251.18.

(b) If the Importer is also relabeling the eligible prescription drug, the Importer must also:

(1) Register with FDA as a repackager or relabeler under section 510(b) of the Federal Food, Drug, and Cosmetic Act, in accordance with § 207.25 of this chapter;

(2) Obtain a labeler code from FDA and propose an NDC for each eligible prescription drug pursuant to § 207.33 of this chapter; and

(3) List each eligible prescription drug pursuant to § 207.53 of this chapter.

(c) If the Importer is not itself relabeling the eligible prescription drug, the Importer must:

(1) Obtain its own labeler code from FDA under § 207.33(c) of this chapter;

(2) Ensure that the eligible prescription drug incorporates the NDC the Importer proposed for assignment, which must include the Importer’s labeler code; and

(3) Ensure that the entity relabeling an eligible prescription drug on its behalf proposes an NDC pursuant to § 207.33 of this chapter and lists each eligible prescription drug pursuant to § 207.53 of this chapter.

§ 251.13 Labeling of eligible prescription drugs.

(a) Upon the request of a SIP Sponsor or Importer, the manufacturer of an eligible prescription drug must provide an importer written authorization for the Importer to use, at no cost, the FDA-approved labeling for the drug. If the manufacturer fails to do so within 30 calendar days of receiving the Importer’s request, FDA may deem this authorization to have been given.

(b) In addition to the exemption provided in subpart D of part 201 of this chapter, an eligible prescription drug imported for purposes of this part is exempt from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act if all the following conditions are met:

(1) The Importer or the manufacturer certifies that the drug meets all labeling requirements under the Federal Food, Drug, and Cosmetic Act, including the requirements of this part. The Importer of an eligible prescription drug must either:

(i) Propose an NDC for the drug following the procedures in § 207.33 of this chapter and list the drug following the procedures in § 207.53 of this chapter; or

(ii) Take responsibility to ensure that the entity performing relabeling on its behalf lists each eligible prescription drug and incorporates the NDC the Importer proposed for assignment in accordance with the applicable requirements of part 207 of this chapter.

(2) The drug must be:

(i) In the possession of a person (or his or her agents or employees), including Foreign Sellers and Importers, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs;

(ii) In the possession of a retail, hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs; or

(iii) In the possession of a practitioner licensed by law to administer or prescribe such drugs.

(3) The drug is to be dispensed in accordance with section 503(b) of the Federal Food, Drug, and Cosmetic Act.
(4) At the time the drug is sold or dispensed, the labeling of the drug must be the same as the FDA-approved labeling under the applicable NDA or ANDA, except that the labeling must bear conspicuously:
   (i) The Importer’s NDC for the eligible prescription drug, and such NDC must replace any other NDC otherwise appearing on the label of the FDA-approved drug;
   (ii) The lot number assigned by the manufacturer of the eligible prescription drug, on the carton labeling and on the container label;
   (iii) The name and place of business of the Importer;
   (iv) The statement: “[This drug was/These drugs were] imported from Canada without the authorization of [Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program.” If the SIP maintains a website, the statement could also include the website address. This statement must appear in the HOW SUPPLIED STORAGE AND HANDLING section for products subject to §§ 201.56(d) and 201.57 of this chapter, or in the HOW SUPPLIED section for products subject to §§ 201.56(e) and 201.60 of this chapter. The statement also must be included on the immediate container label and outside package;
   (v) For products subject to §§ 201.56(d) and 201.57(c)(17)(iii) of this chapter, the NDC(s) assigned to the eligible prescription drug in accordance with the procedures in § 207.33 of this chapter must be included in the HOW SUPPLIED STORAGE AND HANDLING section in place of the NDC(s) assigned to the FDA-approved versions of the drug. The NDC(s) also must be included on the immediate container label and outside package;
   (vi) For products subject to §§ 201.56(d) and 201.57(a)(11)(ii) of this chapter, the NDC(s) assigned to the eligible prescription drug in accordance with the Adverse Reaction Contact Reporting Statement under the Adverse Reactions heading in the Highlights of Prescribing Information. This statement must include the Importer’s name and the telephone number of the firm to provide a structured process for reporting suspected adverse events; and
   (vii) For products subject to §§ 201.56(e) and 201.80(k)(3) of this chapter, the NDC(s) assigned to the eligible prescription drug in accordance with the procedures in § 207.33 of this chapter. The NDC(s) must be included in the HOW SUPPLIED section in place of the NDC(s) assigned to the FDA-approved versions of the drug. The NDC(s) also must be included on the immediate container label and outside package.

(c) The Importer is responsible for relabeling the drug, or arranging for it to be relabeled, to meet the requirements of this part. The relabeling and associated limited repackaging activities must meet applicable requirements, including applicable current good manufacturing practice requirements under parts 210 and 211 of this chapter. Except for repackaging that is necessary to perform the relabeling described in this part, further repackaging of drugs imported pursuant to a SIP is prohibited. Repackaging the container closure of a drug is not permitted under this part.

(d) The Importer may submit to FDA, in electronic format via the ESG or to an alternative transmission point identified by FDA, under § 251.8, a supplemental proposal to modify the labeling of an eligible prescription drug, for example if the eligible prescription drug’s container is too small to fit the additional information required by this section.

§ 251.14 Supply chain security requirements for eligible prescription drugs.

(a) SIP Sponsor. A sponsor of an authorized SIP must ensure that:
   (1) Each drug imported under the SIP is HPFB-approved and labeled for sale in Canada by the manufacturer before it reaches the Foreign Seller;
   (2) For each drug that is imported under the SIP and that is manufactured outside Canada, the drug was authorized for import into Canada by the manufacturer and was not transshipped through Canada for sale in another country;
   (3) For each drug imported under the SIP, the drug was sold by the manufacturer directly to a Foreign Seller;
   (4) For each drug imported under the SIP, the Foreign Seller ships the drug directly to the Importer in the United States;
   (5) For each drug imported under the SIP, the Foreign Seller identified in the SIP package applicable supply chain security requirements of this part;
   (6) The Importer identified in the SIP meets the applicable requirements of this part and in sections 582(c) and (d) of the Federal Food, Drug, and Cosmetic Act; and
   (7) Returned eligible prescription drugs are properly dispositioned in, and not exported from, the United States.

(b) Manufacturer. For each transaction of the eligible prescription drug, the manufacturer must provide to the Importer, within 30 calendar days of receiving the Importer’s request, a copy of all transaction documents that were provided from the manufacturer to the Foreign Seller.

(c) Foreign Seller. (1) A Foreign Seller must have systems in place to:
   (i) Determine whether a drug in its possession or control that it intends to sell to the Importer under a SIP is a suspect foreign product. Upon making a determination that a drug in its possession or control is a suspect foreign product, or upon receiving a request for verification from FDA that the Foreign Seller has determined that a product within its possession or control is a suspect foreign product, a Foreign Seller must:
      (A) Quarantine such product within its possession or control until such product is cleared or dispositioned;
      (B) Promptly conduct an investigation, in coordination with the Importer and the manufacturer, as applicable, to determine whether the product is an illegitimate foreign product, and verify the product at the package level, including the SSN; and
      (C) If the Foreign Seller makes the determination that a suspect foreign product is not an illegitimate foreign product, promptly notify FDA of such determination for those products that FDA has requested verification.
   (ii) Determine whether a drug in its possession or control that it intends to sell to the Importer under a SIP is an illegitimate foreign product. Upon making a determination that a drug in its possession or control is an illegitimate foreign product, the Foreign Seller must:
      (A) Quarantine such product within the possession or control of the Foreign Seller from product intended for distribution until such product is dispositioned;
      (B) Disposition the illegitimate foreign product within the possession or control of the Foreign Seller;
      (C) Take reasonable and appropriate steps to assist a manufacturer or Importer to disposition an illegitimate product not in the possession or control of the Foreign Seller; and
      (D) Retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or FDA (or other appropriate Federal or State official) upon request by FDA (or other appropriate Federal or State official), as necessary and appropriate.
   (2)(i) Upon determining that a product in the possession or control of the Foreign Seller is an illegitimate foreign product, the Foreign Seller must notify FDA and the Importer that the Foreign Seller received such illegitimate product not later than 24 hours after making such determination.
(ii) Upon the receipt of a notification from the manufacturer, FDA, the Importer or other wholesale distributor, or dispenser that a determination has been made that a product that has been sold by the Foreign Seller is an illegitimate foreign product, a Foreign Seller must identify all illegitimate foreign product subject to such notification that is in the possession or control of the Foreign Seller, including any product that is subsequently received, and perform the activities to investigate the product described in paragraph (c)(1) of this section.

(iii) Upon making a determination, in consultation with FDA, that a notification is no longer necessary, a Foreign Seller must promptly notify the Importer and person who sent the notification that the notification is terminated.

(iv) A Foreign Seller must keep records of the disposition of an illegitimate foreign product for not less than 6 years after the conclusion of the disposition.

(3) Upon request by FDA, or other appropriate Federal or State official, in the event of a recall or for purposes of investigating a suspect foreign product or an illegitimate foreign product, a Foreign Seller must promptly provide the official with information about its transactions with the manufacturer and the Importer.

(4) A Foreign Seller, upon receiving a shipment of eligible prescription drugs from the manufacturer, must:

(i) Separate the portion of drugs intended for sale to the Importer located in the United States, and store such portion separately from that portion of product intended for sale in the Canadian market;

(ii) Assign an SSI to each package and homogenous case intended for sale to the Importer in the United States, unless each such package and homogenous case displayed a manufacturer-affixed or imprinted product identifier, as such term is defined in section 581(14) of the Federal Food, Drug, and Cosmetic Act, at the time of receipt by the Foreign Seller;

(iii) Affix or imprint the SSI on each package and homogenous case intended for sale to the Importer in the United States. Such SSI must be located on blank space on the package or homogenous case and must not obscure any labeling for the Canadian market, including the DIN; and

(iv) Keep records associating the SSI with the DIN and all the records the Foreign Seller received from the manufacturer upon receipt of the original shipment intended for the Canadian market for not less than 6 years.

(5) Upon receiving a request for verification from the Importer or other authorized repackager, wholesale distributor, or dispenser that is in possession or control of a product such person believes to be distributed by such Foreign Seller, a Foreign Seller must, not later than 24 hours after receiving the request for verification, or in such other reasonable time as determined by the FDA based on the circumstances of the request, notify the person making the request whether the SSI that is the subject of the request corresponds to the SSI affixed or imprinted by the Foreign Seller. If a Foreign Seller responding to a request for verification identifies an SSI that does not correspond to that SSI affixed or imprinted by the Foreign Seller, the Foreign Seller must treat such product as suspect foreign product and conduct an investigation as described in paragraph (c)(1) of this section. If the Foreign Seller determines the product is an illegitimate foreign product, the Foreign Seller must advise the person making the request of such determination at the time such Foreign Seller responds to the request for verification.

(6) For each transaction between the Foreign Seller and the Importer for an eligible prescription drug, the Foreign Seller must provide:

(i) A statement that the Foreign Seller purchased the product directly from the manufacturer;

(ii) The proprietary name (if any) and the established name of the product;

(iii) The strength and dosage form of the product;

(iv) The container size;

(v) The number of containers;

(vi) The lot number of the product assigned by the manufacturer;

(vii) The date of the transaction;

(viii) The date of the shipment, if more than 24 hours after the date of the transaction;

(ix) The business name and address of the person associated with the Foreign Seller from whom ownership is being transferred;

(x) The business name and address of the person associated with the Importer to whom ownership is being transferred;

(xi) The SSI for each package and homogenous case of product; and

(xii) The Canadian DIN for each product transferred.

(7) Upon a request by FDA, or other appropriate Federal or State official, in the event of a recall or for purposes of investigating a suspect foreign product, or an illegitimate foreign product, the Foreign Seller must promptly provide the official with information about its transactions with the manufacturer and the Importer.

(d) Importers. (1) An Importer of an eligible prescription drug must purchase the drug directly from a Foreign Seller in Canada.

(2) Upon receipt of an eligible prescription drug in a transaction from the Foreign Seller, an Importer must facilitate the affixation or imprinting of a product identifier, as defined in section 581(14) of the Federal, Drug, and Cosmetic Act, for all eligible prescription drugs. The Importer must ensure that such affixation or imprinting occurs at the same time the product is relabeled with the required U.S.-approved labeling for the drug product and, except for repackaging necessary to perform the relabeling described in this part, cannot otherwise relabel or repackage the product. The Importer may affix or imprint the product identifier, or the Importer may contract with an entity registered with FDA under part 207 of this chapter to accomplish such relabeling, provided that the entity does not otherwise relabel or repackage the product, except for repackaging that is necessary to perform the relabeling described in this part. Any entity with which the Importer contracts to accomplish such labeling must, even if not engaged in a repackaging operation with respect to the eligible prescription drug, have systems and processes in place to meet applicable requirements of a “repackager” under section 582(e) of the Federal Food, Drug, and Cosmetic Act for any transaction involving the eligible prescription drug.

(3) The repackager that affixes or imprints the product identifier on each package and homogenous case of an eligible prescription drug in accordance with section 582 of the Federal Food, Drug, and Cosmetic Act, which may be the Importer or the Importer’s authorized repackager—

(i) May affix or imprint a product identifier only on a package of an eligible prescription drug that has a serial number that was assigned and affixed by the Foreign Seller;

(ii) Must maintain the product identifier information for such drug for not less than 6 years; and

(iii) Must maintain records for not less than 6 years that associate the product identifier with the repackager affixes or imprints with the serial number assigned by the Foreign Seller and the Canadian DIN.

(4) An Importer must retain records, for not less than 6 years, that allow the Importer to associate the product identifier affixed or imprinted on each
package or homogenous case of product it received from the Foreign Seller, with the SSI that had been assigned by the Foreign Seller, and the Canadian DIN that was on the package when the Foreign Seller received the product from the manufacturer.

(5) An Importer must, upon receipt of an eligible prescription drug and records from a Foreign Seller, compare such information with information the Importer received from the manufacturer, including relevant documentation about the transaction that the manufacturer provided to the Foreign Seller upon its transfer of ownership of the product for the Canadian market.

(6) An Importer must comply with all applicable requirements of section 582 of the Federal Food, Drug, and Cosmetic Act, including requirements that apply to subsequent transactions with trading partners, unless a waiver, exception, or exemption applies.

(7) For transactions of eligible prescription drugs between Importers and Foreign Sellers under a SIP, an Importer is exempt from the following specific supply chain security requirements that are otherwise applicable:

(i) An Importer is exempt from the prohibition on receiving a product for which the previous owner did not provide the transaction history, transaction information, and transaction statement, under sections 582(c)(1)(A) or (d)(1)(A) of the Federal Food, Drug, and Cosmetic Act, as applicable, provided that the Importer receives from the Foreign Seller the information required under paragraph (c) of this section.

(ii) An Importer is exempt from the prohibition on receiving a product that is not encoded with a product identifier, under sections 582(c)(2) or (d)(2) of the Federal Food, Drug, and Cosmetic Act, as applicable, provided that the product the Importer received from the Foreign Seller has an SSI.

(iii) An Importer is exempt from the prohibition on conducting a transaction with an entity that is not an “authorized trading partner,” under sections 582(c)(3) or (d)(3) of the Federal Food, Drug, and Cosmetic Act, as applicable.

(iv) An Importer is exempt from the requirement to verify that a product in the Importer’s possession or control contains a “standardized numerical identifier” at the package level, under sections 582(c)(4)(A)(i)(II) or (d)(4)(A)(i)(II) of the Federal Food, Drug, and Cosmetic Act as applicable, provided that the Importer verifies that each package and homogenous case of the product includes the SSI affixed or imprinted by the Foreign Seller.

§251.15 Qualifying laboratory requirements.

(a) To be considered a qualifying laboratory for purposes of section 804 of the Federal Food, Drug, and Cosmetic Act and this part, a laboratory must have ISO 17025 accreditation.

(b) To be considered a qualifying laboratory for purposes of section 804 of the Federal Food, Drug, and Cosmetic Act and this part, a laboratory must have an FDA inspection history and it must have satisfactorily addressed any objectionable conditions or practices identified during its most recent FDA inspection, if applicable.

(c) To be considered a qualifying laboratory for purposes of section 804 of the Federal Food, Drug, and Cosmetic Act and this part, a laboratory must comply with the applicable current good manufacturing practice requirements, including provisions regarding laboratory controls in §211.160 of this chapter and laboratory records in §211.194 of this chapter.

§251.16 Laboratory testing requirements.

(a) The manufacturer or the Importer must arrange for drugs imported under an authorized SIP to be tested by a qualifying laboratory.

(b) Unless the manufacturer conducts the Statutory Testing, in accordance with this part, the manufacturer of the drugs imported under an authorized SIP must supply to the Importer, within 30 calendar days of receiving the Importer’s request, all information needed to conduct the Statutory Testing, including any testing protocols, Certificate of Analysis, and samples of analytical reference standards that the manufacturer has developed. The manufacturer must also provide the Importer, within 30 calendar days of receiving the Importer’s request, with formulation information about the HPFB-approved drug, a stability-indicating assay, and the FDA-approved drug to facilitate authentication.

(c) Testing done on a statistically valid sample of the batch or shipment, as applicable, must be sufficiently thorough to establish, in conjunction with data and information from the manufacturer, that the batch or shipment is eligible for importation under a SIP. The size of the sample must be large enough to enable a statistically valid statement to be made regarding the authenticity and stability of the quantity of the batch in the shipment or the entire shipment, as applicable.

(d) The statistically valid sample of the HPFB-approved drug must be subjected to testing to confirm that the HPFB-approved drug meets the FDA-approved drug’s specifications and standards, which include the analytical procedures and methods and the acceptance criteria. In addition, to test for degradation, a stability-indicating assay provided by the manufacturer must be conducted on the sample of the drug that is proposed for import.

(e) If the manufacturer performs the Statutory Testing at a qualifying laboratory, the testing results, a complete set of laboratory records, a detailed description of the selection method for the samples, the testing methods used, complete data derived from all tests necessary to ensure that the eligible prescription drug meets the specifications and standards of the FDA-approved drug that are established in the NDA or ANDA, a Certificate of Analysis, and any other documentation demonstrating that the testing meets the requirements under section 804 must be submitted in electronic format directly to FDA via the ESG or to an alternative transmission point identified by FDA. The manufacturer must notify the Importer and FDA of the manufacturer’s intent to perform the Statutory Testing, and identify the qualifying laboratory for FDA review and approval pursuant to section 804 of the Federal Food, Drug, and Cosmetic Act, within 30 calendar days of receipt of the request from the Importer described in paragraph (b) of this section.

(f) Regardless of whether testing under this section is performed by the manufacturer or Importer, the sample of a batch or shipment of drugs must be randomly selected for testing or, in the alternative, the sample must be selected to be representative of the quantity of the batch in a shipment or of a shipment, as applicable.

(g) Information supplied by the manufacturer to authenticate the prescription drug being tested and confirm that the labeling of the prescription drug complies with labeling requirements under the Federal Food, Drug, and Cosmetic Act, and any trade secrets or commercial or financial information that is privileged or confidential that the manufacturer supplies for the purposes of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part, must be kept in strict confidence and used only for the purposes of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part.
(b) To ensure that the information described in paragraph (g) of this section is protected:

(1) The information that the manufacturer supplies about a prescription drug must not be disseminated except for the purpose of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part; and

(2) The SIP Sponsor must take all of the steps set out in the authorized SIP Proposal to ensure that the information is kept in strict confidence and used only for the purpose of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part.

§251.17 Importation requirements.

(a) Importers must ensure that each shipment of eligible prescription drugs imported or offered for import pursuant to this part is accompanied by an import entry for consumption filed electronically as a formal entry in ACE, or another CBP-authorized electronic data interchange system, and designated in such a system as a drug imported pursuant to this part.

(b) The Importer may make entry for consumption and arrival of shipments containing eligible prescription drugs only at the CBP port of entry authorized by FDA to import eligible prescription drugs under section 804 of the Federal Food, Drug, and Cosmetic Act. The Importer must keep the product at a secured warehouse, location within a specific foreign trade zone, or other secure distribution facility controlled by or under contract with the Importer, and under appropriate environmental conditions to maintain the integrity of the products, until FDA issues an admissibility decision. The secured warehouse or other secure distribution facility must be within 30 miles of the authorized Port of Entry for examination.

(c) If the entry for consumption is filed in ACE before the testing and relabeling of the eligible prescription drug, the Importer must submit an application to bring the drug into compliance and must relabel and test the drug in accordance with the plan approved by FDA pursuant to §§ 1.95 and 1.96 of this chapter.

(d) Upon arrival in the United States of an initial shipment that contains a batch of an eligible prescription drug identified in a Pre-Import Request that has been granted by FDA, the Manufacturer must select a statistically valid sample of that batch to send to a qualifying laboratory for Statutory Testing.

(b) In the case of any subsequent shipment composed entirely of a batch of an eligible prescription drug that has already been tested in accordance with this part, the Importer must select a statistically valid sample of the shipment to send to a qualifying laboratory for Statutory Testing.

(2) The Importer must send three sets of the samples sent to the qualifying laboratory in accordance with § 251.16 to the FDA field lab identified by FDA when the Agency granted the Pre-Import Request.

(3) The Importer must submit to FDA a complete set of laboratory records, a detailed description of the sampling method used to select the sample of the eligible prescription drug sent to the qualifying laboratory, the testing protocols used, complete data derived from all tests necessary to ensure that the eligible prescription drug meets the testing standards.

§251.18 Post-importation requirements.

(a) Stopping importation. If at any point a SIP Sponsor determines that a drug, manufacturer, Foreign Seller, Importer, qualifying laboratory, or other participant in or element of the supply chain in the authorized SIP does not meet all applicable requirements of the Federal Food, Drug, and Cosmetic Act, FDA regulations, and the authorized SIP, the SIP Sponsor must immediately stop importation of all drugs under the SIP, notify FDA, and demonstrate to FDA that importation has in fact been stopped.

(b) Field alert reports. Importers must submit NDA and ANDA field alert reports, as described in §§ 314.81(b)(1) and 314.98 of this chapter, to the manufacturer and to FDA.

(c) Additional reporting requirements for combination products. For combination products containing a device constituent part, Importers must submit the reports to the manufacturer and to FDA described in § 4.102(c)(1) of this chapter and maintain the records described in §§ 4.102(c)(1) and 4.105(b) of this chapter.

(d) Adverse event reports—(1) Scope. An Importer must establish and maintain records and submit to FDA and the manufacturer reports of all adverse events associated with the use of its drug products imported under this part.
(2) **Review of safety information.** The Importer must promptly review all domestic safety information for the eligible prescription drugs obtained or otherwise received by the Importer.

(3) **Expedited ICSRs.** The Importer must submit expedited ICSRs for each domestic adverse event to FDA and the manufacturer as soon as possible but no later than 15 calendar days from the date when the Importer has both met the reporting criteria described in this paragraph (d) and acquired a minimum data set for that adverse event.

(i) **Serious, unexpected adverse events.** The Importer must submit expedited ICSRs for domestic adverse event reports to the Importer spontaneously (such as reports initiated by a patient, consumer, or healthcare professional) that are both serious and unexpected, whether or not the Importer believes the events are related to the product.

(ii) **Other adverse event reports to be expedited upon notification by FDA.** Upon notification by FDA, the Importer must submit expedited ICSRs any adverse event reports that do not qualify for expedited reporting under paragraph (d)(3)(i) of this section. The notice will specify the adverse events to be reported and the reason for requiring the expedited reports.

(4) **Followup reports for expedited ICSRs.** The Importer must actively seek any missing data elements under paragraph (d)(7) of this section or updated information for any previously submitted expedited ICSR under paragraph (d)(3)(i) of this section. The Importer must also investigate any new information it obtains or otherwise receives about previously submitted expedited ICSRs. The Importer must submit followup reports for expedited ICSRs to FDA and the manufacturer as soon as possible but no later than 15 calendar days after obtaining the new information. The Importer must document and maintain records of its efforts to obtain missing or incomplete information.

(5) **Nonexpedited ICSRs.** The Importer must submit to FDA and the manufacturer an ICSR for each domestic adverse event not reported under paragraph (d)(3)(i) of this section (all serious, expected adverse events and nonserious adverse events) within 90 calendar days from the date when the Importer has both met the reporting criteria described in this paragraph (d) and acquired a minimum data set for that adverse event.

(6) **Completing and submitting safety reports.** This paragraph (d)(6) describes how to complete and submit ICSRs required under this section.

Additionally, upon written notice, FDA may require the Importer to submit any of this section’s adverse event reports at a different time period than identified in paragraphs (d)(1) through (5) and (7) through (11) of this section.

(i) **Electronic format for submissions.** (A) ICSR and ICSR attachments must be submitted in an electronic format that FDA can process, review, and archive, as described in §314.80(g)(1) of this chapter. (B) The Importer may request, in writing, a temporary waiver of the requirements in paragraph (d)(6)(i)(A) of this section, as described in §314.80(g)(2) of this chapter. These waivers will be granted on a limited basis for good cause shown.

(ii) **Completing and submitting ICSRs—(A) Single submission.** Submit each ICSR only once.

(B) ** Separate ICSR.** The Importer must submit a separate ICSR for each patient who experiences an adverse event reportable under paragraph (d)(3)(i) or (ii) or (d)(4) or (5) of this section.

(C) ** Coding terms.** The adverse event terms described in the ICSR must be coded using standardized medical terminology.

(D) **Minimum data set.** All ICSRs submitted under this section must contain at least the minimum data set for an adverse event. The Importer must actively seek the minimum data set in a manner consistent with its written procedures under paragraph (d)(9) of this section. The Importer must document and maintain records of its efforts to obtain the minimum data set.

(E) **ICSR elements.** The Importer must complete all available elements of an ICSR as specified in paragraph (d)(7) of this section.

(1) **The Importer must actively seek any information needed to complete all applicable elements, consistent with its written procedures under paragraph (d)(9) of this section.**

(2) **The Importer must document and maintain records of its efforts to obtain the missing information.**

(F) **Supporting documentation.** When submitting supporting documentation for expedited ICSRs of adverse events, the Importer must:

(1) **Submit for each ICSR for a domestic adverse event, if available, a copy of the autopsy report if the patient died, or a copy of the hospital discharge summary if the patient was hospitalized.** The Importer must submit each document as an ICSR attachment. The ICSR attachment must be submitted either with the initial ICSR or no later than 15 calendar days after obtaining the document.

(2) **Include in the ICSR a list of available, relevant documents (such as medical records, laboratory results, death certificates) that are held in its drug product safety files.** Upon written notice from FDA, the Importer must submit a copy of these documents within 5 calendar days of the FDA notice.

(7) **Information reported on ICSRs.** ICSRs must include the following information:

(i) **Patient information, which includes:**

(A) **Patient identification code;**

(B) **Patient age at the time of adverse event, or date of birth;**

(C) **Patient gender; and**

(D) **Patient weight.**

(ii) **Adverse event, which includes:**

(A) **Outcome attributed to adverse event;**

(B) **Date of adverse event;**

(C) **Date of ICSR submission;**

(D) **Description of adverse event (including a concise medical narrative);**

(E) **Adverse drug event term(s);**

(F) **Description of relevant tests, including dates and laboratory data; and**

(G) **Other relevant patient history, including preexisting medical conditions.**

(iii) **Suspect medical product(s), which includes:**

(A) **Name;**

(B) **Dose, frequency, and route of administration used;**

(C) **Therapy dates;**

(D) **Diagnosis for use (indication);**

(E) **Whether the product is a combination product;**

(F) **Whether adverse event abated after drug use stopped or dose reduced;**

(G) **Whether adverse event reappeared after reintroduction of drug;**

(H) **Lot number;**

(I) **Expiration date;**

(J) **NDC; and**

(K) **Concomitant medical products and therapy dates.**

(iv) **Initial reporter information, which includes:**

(A) **Name, address, and telephone number;**

(B) **Whether the initial reporter is a healthcare professional; and**

(C) **Occupation, if a healthcare professional.**

(v) **Importer information, which includes:**

(A) **Importer name and contact office address;**

(B) **Importer telephone number;**

(C) **Date the report was received by the Importer;**

(D) **Whether the ICSR is an expedited report;**

(E) **Whether the ICSR is an initial report or followup report; and**

(F) **Whether adverse event abated after drug use stopped or reduced;**

(G) **Whether adverse event reappeared after reintroduction of drug;**

(H) **Lot number;**

(I) **Expiration date;**

(J) **NDC; and**

(K) **Concomitant medical products and therapy dates.**
§ 251.14(a)(6), including transaction documents that were provided from the Foreign Seller specifying the manufacturer of
each eligible prescription drug and the quantity of each lot of the eligible prescription drug(s) received by the Foreign Seller from that manufacturer;

(2) Documentation demonstrating that the eligible prescription drug was received by the Foreign Seller from the manufacturer and subsequently shipped by the Foreign Seller to the Importer;

(3) Documentation of the quantity of each lot of the eligible prescription drug(s) received by the Foreign Seller, demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the Foreign Seller; and

(4) Documentation demonstrating that the sampling and testing requirements described in section 804(d)(1)(J)(i)(III) of the Federal Food, Drug, and Cosmetic Act were met for each shipment of each eligible prescription drug.

(e) The report in paragraph (a) of this section must include certifications from the Importer for each shipment of each eligible prescription drug that the drug is approved for marketing in the United States and is not adulterated or misbranded and meets all labeling requirements under the Federal Food, Drug, and Cosmetic Act. This certification must include:

(1) That there is an authorized SIP;

(2) That the imported drug is covered by the authorized SIP;

(3) That the drug is an eligible prescription drug as defined in this part;

(4) That the FDA-approved counterpart of the drug is currently commercially marketed in the United States;

(5) That the drug is approved for marketing in Canada; and

(6) That the drug is not adulterated or misbranded and meets all labeling requirements under the Federal Food, Drug, and Cosmetic Act.

(f) The report in paragraph (a) of this section must include laboratory records, including complete data derived from all tests necessary to ensure that each eligible prescription drug is in compliance with established specifications and standards, and documentation demonstrating that the Statutory Testing was conducted at a qualifying laboratory, unless the manufacturer conducted the testing and submitted this information directly to FDA.

(g) The report in paragraph (a) of this section must include data, information, and analysis on the SIP’s cost savings to the American consumer for the drugs imported under the SIP.

(h) A SIP Sponsor must submit a report to FDA within 10 calendar days, in electronic format via the ESG or to an alternative transmission point identified by FDA, regarding any applicable criminal conviction, violation of law, or disciplinary action as described in § 251.3(e)(2) and (3).

§ 251.20 Severability.

The provisions of this part are not separate and are not severable from one another. If any provision is stayed or determined to be invalid or unenforceable, the remaining provisions shall not continue in effect.

§ 251.21 Consequences for violations.

(a) An article that is imported or offered for import into the United States in violation of section 804 of the Federal Food, Drug, and Cosmetic Act or this part is subject to refusal under section 801 of the Federal Food, Drug, and Cosmetic Act.

(b) The importation of a prescription drug in violation of section 804 of the Federal Food, Drug, and Cosmetic Act; the falsification of any record required to be maintained or provided to FDA under section 804; or any other violation of this part is a prohibited act under section 301(aa) of the Federal Food, Drug, and Cosmetic Act.


Alex M. Azar II,
Secretary, Department of Health and Human Services.
Securities and Exchange Commission

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change To Amend the Codes of Arbitration Procedure Relating to Requests To Expunge Customer Dispute Information, Including Creating a Special Arbitrator Roster To Decide Certain Expungement Requests; Notice
SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.: Notice of Filing of a Proposed Rule Change To Amend the Codes of Arbitration Procedure Relating to Requests To Expunge Customer Dispute Information, Including Creating a Special Arbitrator Roster To Decide Certain Expungement Requests


Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") 1 and Rule 19b–4 thereunder, 2 notice is hereby given that on September 22, 2020, the Financial Industry Regulatory Authority, Inc. ("FINRA") 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 FINRA. 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

FINRA is proposing to amend the Code of Arbitration Procedure for Customer Disputes ("Customer Code") 3 and the Code of Arbitration Procedure for Industry Disputes ("Industry Code") (together, "Codes") to modify the current process relating to the expungement of customer dispute information.

Specifically, the proposed rule change would amend the Codes to: (1) Impose requirements on expungement requests (a) filed during an investment-related, customer initiated arbitration ("customer arbitration") by an associated person, or by a party to the customer arbitration on-behalf-of an associated person ("on-behalf-of request"), or (b) filed by an associated person separate from a customer arbitration ("straight-in request"); (2) establish a roster of arbitrators with enhanced training and experience from which a three-person panel would be randomly selected to decide straight-in requests; (3) establish procedural requirements for expungement hearings; and (4) codify and update the best practices of the Notice to Arbitrators and Parties on Expanded Expungement Guidance ("Guidance") that arbitrators and parties must follow. 3 In addition, the proposed rule change would amend the Customer Code to specify procedures for requesting expungement of customer dispute information arising from simplified arbitrations. The proposed rule change would also amend the Codes to establish requirements for notifying state securities regulators and customers of expungement requests.

The text of the proposed rule change is available on FINRA’s website at http://www.finra.org, at the principal office of FINRA 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, FINRA 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. FINRA 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

Information regarding customer disputes involving associated persons is maintained in the Central Registration Depository ("CRD") 4, the central licensing and registration system used by the U.S. securities industry and its regulators. 4 FINRA operates the CRD system pursuant to policies developed jointly with NASAA, FINRA works with the SEC, NASAA and other members of the regulatory community to ensure that information submitted and maintained in the CRD system is accurate and complete.

In general, the information in the CRD system is submitted by registered securities firms, brokers and regulatory authorities in response to questions on the uniform registration forms. 5 These forms are used to collect registration information, which includes, among other things, administrative, regulatory, criminal history, financial and other information about brokers, such as customer complaints, arbitration claims and court filings made by customers (i.e., "customer dispute information"). FINRA, state and other regulators use this information in connection with their licensing and regulatory activities, and member firms use this information to help them make informed employment decisions.

Pursuant to rules approved by the SEC, FINRA makes specific CRD information publicly available through BrokerCheck®. 5 BrokerCheck is part of FINRA’s ongoing effort to help investors make informed choices about the brokers and broker-dealer firms with which they may conduct business. BrokerCheck maintains information on the approximately 3,600 registered broker-dealer firms and 624,000 registered brokers. BrokerCheck also provides the public with access to information about formerly registered broker-dealer firms and brokers. 6 In 2019 alone, BrokerCheck helped users conduct more than 40 million searches of firms and brokers.

The regulatory framework governing the CRD system and BrokerCheck has long contemplated the possibility of expunging certain customer dispute

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4 The uniform registration forms are Form BD (Uniform Application for Broker-Dealer Registration), Form BDW (Uniform Request for Broker-Dealer Withdrawal), Form BR (Uniform Branch Office Registration Form), Form U4 (Uniform Application for Securities Industry Registration or Transfer), Form US (Uniform Termination Notice for Securities Industry Registration) and Form U6 (Uniform Disciplinary Action Reporting Form).

5 Section 15A of the Exchange Act requires FINRA to provide registration information to the public. BrokerCheck is one of the tools through which FINRA disseminates this information to the public. There is a limited amount of information in the CRD system that FINRA does not display through BrokerCheck, including personal or confidential information. A detailed description of the information made available through BrokerCheck is available at http://www.finra.org/investors/about-brokercheck.

6 Formerly registered brokers, although no longer in the securities industry in a registered capacity, may work in other investment-related industries or may seek to attain other positions of trust with potential investors. BrokerCheck provides information on more than 17,000 formerly registered broker-dealer firms and nearly 567,000 formerly registered brokers. Broker records are available in BrokerCheck for 10 years after a broker leaves the industry, and brokers who are the subject of disciplinary actions and certain other events remain on BrokerCheck permanently.


The concept for the CRD system was developed by FINRA jointly with the North American Securities Administrators Association ("NASAA"). The CRD system fulfills FINRA’s statutory obligation to establish and maintain a system to collect and retain registration information. NASAA and state regulators play a critical role in the ongoing development and implementation of the CRD system.

information from these systems in limited circumstances, such as where the allegations made about the broker are factually impossible or clearly erroneous. The expungement framework seeks to balance the competing interests of providing regulators broad access to information about customer disputes to fulfill their regulatory obligations, providing a fair process that recognizes a broker’s interest in protecting their reputation and ensuring investors have access to accurate information about brokers.

B. FINRA Rules 2080, 12805 and 13805 Governing Expungement of Customer Dispute Information

A broker can seek expungement of customer dispute information by obtaining a court expungement order (1) by going through the FINRA arbitration process (and then obtaining a court order confirming an arbitration award containing expungement) or (2) by going directly to court (without first going to arbitration).

FINRA rules require arbitrators to perform fact-finding before recommending expungement of customer dispute information and to provide information about the basis for the expungement. Specifically, FINRA Rules 12805 and 13805 require arbitrators to hold a recorded hearing regarding the appropriateness of expungement of customer dispute information and to review settlement documents, the amount of payments made to any party and any other terms and conditions of the settlement.8 In addition, these rules require arbitrators to indicate whether they have awarded expungement because: (1) The claim, allegation or information is factually impossible or clearly erroneous; (2) the associated person was not involved in the alleged investment-related sales practice violation, forgery, theft, misappropriation or conversion of funds; or (3) the claim, allegation or information is false.9 The arbitrators are further required to provide a brief written explanation of the reasons for recommending expungement.10 These requirements are supplemented with extensive guidance and training, including the Guidance, first published in 2013 and expanded further periodically thereafter.11 The Guidance provides arbitrators with best practices and recommendations to follow, in addition to the requirements of FINRA Rules 12805 and 13805, when deciding expungement requests.

Regardless of whether expungement of customer dispute information is sought directly through a court or in arbitration, FINRA Rule 2080, which was developed in close consultation with representatives of NASAA and state regulators, requires a broker-dealer firm or broker seeking expungement to obtain an order of a court of competent jurisdiction directing such expungement or confirming an award containing expungement. FINRA will expunge customer dispute information only after the court orders it to execute the expungement.12

C. Concerns Regarding Expungement

Some stakeholders of the forum have raised concerns about expungement hearings held after the parties settle the customer arbitration that gave rise to the customer dispute information.13 In 2080, the panel’s decision regarding an expungement request is not the final step in the process. A person seeking expungement must obtain a court order confirming an arbitration award for FINRA to expunge the customer dispute information from the CRD system. Accordingly, FINRA believes the word “recommend” more accurately describes the panel’s role in the expungement process. It has been FINRA’s longstanding practice to state in expungement awards that the panel “recommends” rather than “grant,” expungement. See also infra note 12, and accompanying text (stating that the proposed amendments to FINRA Rules 12805(c) and 13805(c) would also provide that the panel would “recommend” rather than “grant” expungement).

12 FINRA Rule 2080 also requires that firms and brokers seeking a court order or confirmation of the arbitration award containing expungement name FINRA as a party, and provides that FINRA will challenge the request in court in appropriate circumstances. FINRA may, however, waive the requirement to name it as a party if a firm or broker requests a waiver and FINRA determines that the award containing expungement is based on factual or otherwise or that the panel has the authority to waive the requirement that it be named in a court proceeding if it determines that the request for expungement and accompanying award are meritorious and expungement would not have a material adverse affect on investor protection, the integrity of the CRD system, or regulatory requirements. See FINRA Rule 2080(b).

13 In its Final Report and Recommendations, the FINRA Dispute Resolution Task Force (‘‘Task Force’”) included a recommendation to create a special arbitration panel consisting of specially trained arbitrators to decide expungement requests in settled cases and in cases where the party did not name the associated person as a respondent in the case. See http://www.finra.org/sites/default/files/FinDA-DR-task-force-report.pdf; see also letter from Barbara Black, Professor of Law, University of Cincinnati College of Law (Retired), to Marcia Asquith, Office of the Corporate Secretary, FINRA, dated February 5, 2018 (‘‘Black’’) (discussing the Task Force’s recommendation) and letter from Joseph Borg, President, NASAA, to Marcia Asquith, Office of the Corporate Secretary, FINRA, dated February 5, 2018 (‘‘NASAA’’) (commenting that post-settlement expungement hearings often consist of one-sided presentations of the facts). These and other letters responding to Regulatory Notice 17–42 (December 2017) (‘‘Notice 17–42’’) are discussed in Item II.C. below.

The Codes provide that no claim shall be eligible for submission to arbitration under the Codes where six years have elapsed from the occurrence or event giving rise to the claim. The panel resolves any questions regarding the eligibility of a claim under this rule. See FINRA Rules 12206(a) and 13206(a) (Time Limitation on Submission of Claim). The eligibility requirement applies to all arbitration claims, including those requesting expungement. Thus, if an associated person requests expungement of a CRD disclosure where six years have elapsed since a customer complaint, arbitration or civil litigation was initially reported, the arbitrator or panel should consider whether the claim is eligible for arbitration.

In addition, FINRA Rules 12409 and 13413 (Jurisdiction of Panel and Authority to Interpret the Code) provide that the panel has the authority to interpret and determine the applicability of all provisions under the Codes. Such interpretations are final and binding upon the parties. Together, the rules grant arbitrators the authority to decide whether a claim is eligible for arbitration under the Codes. See Howsam v. Dean Witter Reynolds, 537 U.S. 79, 85–86 (2002) (finding that an arbitrator properly decides issues of eligibility).

Arbitrators should ensure that an expungement claim is eligible under the Codes and arbitrators may decide the eligibility issue on their own, rather than only in response to a party’s motion. See Horst v. FINRA, No. A-16–777960–C [Dist. Ct. Nevada Oct. 25, 2016] (Order Denying Motion to Vacate Arbitration Award) (ruling that an arbitrator may raise sua sponte the eligibility issue, not only when a party to the arbitration raises it in a motion). Currently, on rare occasion, straight-in requests are filed against a customer. As discussed below, the proposed amendments would prohibit these filings. See infra Item II.A.1.(B).A.2., ‘‘No Straight-in Requests Against Customers.’’

Footnote:

8 In almost every proceeding, all or a majority of the arbitrators considering an expungement request are public arbitrators. Among other requirements, public arbitrators have never been employed by the securities industry; do not devote 20 percent or more of their professional work to the securities industry or to parties in disputes concerning investment accounts or transactions or employment relationships within the financial industry; and do not have immediate family members or co-workers who do so. See FINRA Rule 12100(aa).

9 See FINRA Rules 2080, 12805 and 13805.

10 Although FINRA Rules 12805 and 13805 state that the panel may “grant” expungement of customer dispute information under FINRA Rule 12805 and 13805, a broker-dealer firm or broker seeking expungement to obtain an order of a court of competent jurisdiction directing such expungement or confirming an award containing expungement. FINRA will expunge customer dispute information only after the court orders it to execute the expungement. The Panel’s decision regarding an expungement request is not the final step in the process. A person seeking expungement must obtain a court order confirming an arbitration award for FINRA to expunge the customer dispute information from the CRD system. Accordingly, FINRA believes the word “recommend” more accurately describes the panel’s role in the expungement process. It has been FINRA’s longstanding practice to state in expungement awards that the panel “recommends” rather than “grant,” expungement. See also infra note 12, and accompanying text (stating that the proposed amendments to FINRA Rules 12805(c) and 13805(c) would also provide that the panel would “recommend” rather than “grant” expungement). See supra note 3.

12 FINRA Rule 2080 also requires that firms and brokers seeking a court order or confirmation of the arbitration award containing expungement name FINRA as a party, and provides that FINRA will challenge the request in court in appropriate circumstances. FINRA may, however, waive the requirement to name it as a party if a firm or broker requests a waiver and FINRA determines that the award containing expungement is based on affirmative judicial or arbitral findings that: (1) The claim, allegation or information is factually impossible or clearly erroneous; (2) the associated person was not involved in the alleged investment-related sales practice violation, forgery, theft, misappropriation or conversion of funds; or (3) the claim, allegation, or information is false. The arbitrators are further required to provide a brief written explanation of the reasons for recommending expungement. These circumstances.

FINRA may, however, waive the requirement to name it as a party if a firm or broker requests a waiver and FINRA determines that the award containing expungement is based on affirmative judicial or arbitral findings that: (1) The claim, allegation or information is factually impossible or clearly erroneous; (2) the associated person was not involved in the alleged investment-related sales practice violation, forgery, theft, misappropriation or conversion of funds; or (3) the claim, allegation, or information is false. The arbitrators are further required to provide a brief written explanation of the reasons for recommending expungement. These circumstances. The Panel’s decision regarding an expungement request is not the final step in the process. A person seeking expungement must obtain a court order confirming an arbitration award for FINRA to expunge the customer dispute information from the CRD system. Accordingly, FINRA believes the word “recommend” more accurately describes the panel’s role in the expungement process. It has been FINRA’s longstanding practice to state in expungement awards that the panel “recommends” rather than “grant,” expungement. See also infra note 12, and accompanying text (stating that the proposed amendments to FINRA Rules 12805(c) and 13805(c) would also provide that the panel would “recommend” rather than “grant” expungement).
dispute information arises from a customer arbitration or customer complaint that was disclosed on the broker’s CRD record a number of years prior to the request. \(^{16}\) Thus, during these expungement hearings, the panel may receive information only from the associated person requesting expungement.

Further, FINRA is concerned that an increasing number of straight-in requests are being heard by a single arbitrator instead of a three-person panel. \(^{17}\) FINRA believes that most expungement requests should be decided by a three-person panel. Expungement requests may be complex to resolve, particularly straight-in requests where customers typically do not participate in the expungement hearing. Thus, having three arbitrators available to see the requests, request evidence and to serve generally as fact-finders in the absence of customer input would help ensure that a complete factual record is created to support the arbitrators’ decision in such expungement hearings.

In addition, FINRA is concerned that some associated persons are making second requests to expunge the same customer dispute information that they previously requested be expunged by a court or another arbitration panel. For example, an associated person may have a CRD disclosure that resulted from a customer’s arbitration claim, but because the associated person is not named as a party to the customer arbitration (“unnamed person”), \(^{18}\) the associated person is not able to request expungement in the customer arbitration. \(^{19}\) When a firm asks, on-behalf-of the unnamed person, that the arbitrators recommend expungement, the unnamed person, as a non-party in the customer arbitration, may subsequently argue that he or she did not receive adequate notice of the expungement request or an opportunity to participate in the earlier proceeding. The unnamed person may then file a new claim to expunge the same disclosure that the firm requested on the unnamed person’s behalf, despite the fact that the panel denied the expungement request in the prior matter.

FINRA believes that re-filing an expungement request that has been denied by an arbitration panel undermines the integrity of the arbitration process and the information in the CRD system. Arbitration awards are final and binding on the parties. If an associated person seeks to challenge an arbitration award, the associated person can do so by filing a motion to vacate in court.

In addition, some associated persons make second requests for expungement after withdrawing or deciding not to pursue an expungement request made in a customer arbitration, believing that another panel who has not heard the merits of the claim may be more likely to recommend expungement. FINRA is concerned about this practice of “arbitrator shopping,” particularly when associated persons withdraw an original expungement request after the arbitration panel has been made aware of evidence that could result in the denial of the expungement request.

On December 6, 2017, FINRA published Notice 17–42\(^ {20}\) to seek comment on a variety of changes to the process of arbitrating expungement requests, including establishing a roster of arbitrators with additional training and specific backgrounds or experience from which a panel would be selected to decide an associated person’s request for expungement of customer dispute information. The arbitrators from this roster would decide straight-in requests. As discussed below in Item II.C., FINRA received 70 comment letters on Notice 17–42 that reflected a variety of perspectives and different suggestions regarding how to proceed. The proposed rule change is responsive to concerns raised by commenters and would include the following primary changes:

- **Expungement Requests in Customer Arbitrations**
  - An associated person named in a customer arbitration would be required to request expungement during the customer arbitration or forfeit the ability to request expungement of that same disclosure in any subsequent proceeding.
  - A named party from a customer arbitration would be permitted to request expungement during the customer arbitration on-behalf-of an unnamed person pursuant to specified conditions and limitations.

- **Expungement Requests Under the Industry Code**
  - All straight-in requests \(^{22}\) would be required to be filed under the Industry Code:
    - **Expungement Requests Under the Industry Code**
      - All straight-in requests \(^{22}\) would be required to be filed under the Industry Code.

16 Several questions on Forms U4 and U5 require associated persons to disclose certain investment-related, consumer-initiated (i) complaints and (ii) arbitrations and civil litigations, alleging sales practice violations. See Form U4, Question 14I, available at https://www.finra.org/sites/default/files/form-u4.pdf and Form U5, Question 7E, available at https://www.finra.org/sites/default/files/form-u5.pdf. These disclosures become part of the associated person’s CRD record and are made available on BrokerCheck.

17 An expungement request is a non-monetary or not specified claim. The Codes require that such claims are heard by a panel of three arbitrators, unless the parties agree in writing to one arbitrator. In addition, if a party requesting expungement adds a small monetary claim (of less than $100,000) to the expungement request, the Codes require that such claims are heard by one arbitrator. See FINRA Rules 12401 and 13401. FINRA has amended the Codes to apply minimum fees to expungement requests, whether the request is made as part of the customer arbitration or the associated person files an expungement request in a separate arbitration. The amendments also apply a minimum process fee and member surcharge to straight-in requests, as well as a minimum hearing session fee to expungement-only hearings. See Securities Exchange Act Release No. 89945 (May 26, 2020), 85 FR 31312 (June 1, 2020) (‘‘Order Approving File No. SR–FINRA–2020–005’’). See also Regulatory Notice 20–25 (July 2020) (announcing a September 14, 2020 effective date) at https://www.finra.org/rules-guidance/notices/20-25.

18 In 2009, the SEC approved amendments to Forms U4 and U5 to require, among other things, the reporting of allegations of sales practice violations made against unnamed persons. See Securities Exchange Act Release No. 59916 (May 11, 2009), 74 FR 21750 (May 20, 2009) (‘‘Order Approving File No. SR–FINRA–2009–008’’). Specifically, Forms U4 and U5 were amended to add questions to elicit whether the applicant or registered person, though not named as a respondent or defendant in a customer-initiated arbitration, was either mentioned in or could be reasonably identified from the body of the arbitration claim as a registered person who was involved in one or more of the alleged sales practice violations.

19 If a broker is not named as a party in the customer arbitration, brokers may seek to expunge customer dispute information by: (1) Asking a party to the arbitration, usually the firm, to request expungement on his or her behalf; (2) seeking to intervene in the customer arbitration; (3) initiating a new arbitration in which the unnamed person requests expungement and names the customer or firm as the respondent; or (4) going directly to court (without first going to arbitration).


21 Under the Codes, a “hearing” means the hearing on the merits of the arbitration. See FINRA Rules 12100(o) and 13100(o).

22 A straight-in request would include a request to expunge customer dispute information filed under the Industry Code: (1) By an associated
Code against the member firm at which the associated person was associated at the time the dispute arose and decided by a panel selected from a roster of arbitrators with enhanced experience and training ("Special Arbitrator Roster").

- If an associated person withdraws a straight-in request after a panel from the Special Arbitrator Roster is appointed, the case would be closed with prejudice.

  ➤ Special Arbitrator Roster

  - A three-person panel selected from the Special Arbitrator Roster would decide straight-in requests.
  - The parties would not be permitted to agree to fewer than three arbitrators from the Special Arbitrator Roster to decide straight-in requests.
  - Arbitrators on the Special Arbitrator Roster would be required to be public arbitrators who are eligible for the chairperson roster and who have fully met the following additional qualifications: (1) Evidenced successful completion of, and agreement with, enhanced expungement training provided by FINRA; and (2) service as an arbitrator through award on at least four customer-initiated arbitrations administered by FINRA or by another self-regulatory organization ("SRO") in which a hearing was held.
  - The Neutral List Selection System ("NLSS") would randomly select the three public chairpersons from the Special Arbitrator Roster to decide straight-in requests. The first arbitrator selected would be the chair of the panel. The parties would not be permitted to stipulate to the use of pre-selected arbitrators.
  - An associated person who files a straight-in request would not be permitted to strike any arbitrators selected by NLSS or stipulate to the arbitrator's removal, but would be permitted to challenge any arbitrator selected for cause. If an arbitrator is removed, NLSS would randomly select a replacement.

➤ Time Limitations on Requests for Expungement

For customer dispute information reported to the CRD system after the effective date of the proposed rule change, the proposal would provide that an associated person would be barred from requesting expungement if: (1) More than two years have elapsed since the close of the customer arbitration or civil litigation that gave rise to the customer dispute information; or (2) there was no customer arbitration or civil litigation involving the customer dispute information, and more than six years have elapsed since the date that the customer complaint was initially reported to the CRD system.

- For customer dispute information reported to the CRD system before the effective date of the proposed rule change, the proposal would require an associated person to request expungement as a straight-in request under the Industry Code: (1) Within two years of the effective date of the proposed rule change for disclosures that arose from a customer arbitration or civil litigation that closed on or prior to the effective date; and (2) within six years of the effective date of the proposed rule change for customer complaints initially reported to the CRD system on or prior to the effective date.

➤ Expungement Requests During a Simplified Arbitration

- If a party requests expungement during a simplified arbitration, the single arbitrator in the simplified arbitration would be required to decide the expungement request, regardless of how the simplified arbitration case closes (e.g., even if the case settles).
- If an associated person does not request expungement during the simplified arbitration, the request may be filed as a straight-in request under the Industry Code against the member firm at which the associated person was associated at the time the dispute arose, and be decided by a three-person panel randomly selected from the Special Arbitrator Roster.

➤ Expungement Hearings

- Establish procedural requirements that arbitrators and parties must follow for expungement hearings.

➤ State and Customer Notifications

- Establish requirements for notifying state securities regulators and customers of expungement requests.

Under the proposed rule change, an associated person would only be permitted to seek expungement of customer dispute information in the arbitration forum administered by FINRA by complying with the requirements of proposed Rules 12805 (expungement requests in a customer arbitration), 13805 (straight-in requests under the Industry Code) or 12800(d) (expungement requests in a simplified customer arbitration).

The proposed rule change, as revised in response to comments on Notice 17- 42, is set forth in further detail below.23

(II) Proposed Rule Change

The discussion below of the proposed rule change is divided into six areas: (A) Requests for expungement under the Customer Code; (B) straight-in requests under the Industry Code and the Special Arbitrator Roster; (C) limitations on expungement requests; (D) procedural requirements related to all expungement hearings; (E) notifications to customers and states regarding expungement requests; and (F) expungement requests during simplified customer arbitrations.

A. Requests for Expungement Under the Customer Code

FINRA Rule 12805 provides a list of requirements that arbitrators must meet before they may recommend expungement.24 The rule does not, however, provide guidance for associated persons on how and when they may request expungement during the customer arbitration, or on when arbitrators must make expungement determinations. The proposed rule change would amend FINRA Rule 12805 to set forth requirements for expungement requests filed by an associated person during a customer arbitration.

1. Expungement Requests During the Customer Arbitration

a. By a Respondent Named in a Customer Arbitration

Under current practice, an associated person who is named as a respondent in a customer arbitration ("named associated person") may request expungement at any time during the customer arbitration or separately from the customer arbitration in a straight-in request.25 If a named associated person

23 The proposed rule change would apply to all members, including members that are finding portals or have elected to be treated as capital acquisition brokers ("CABs"), given that the funding portal and CAB rule sets incorporate the impacted FINRA rules by reference.

24 FINRA Rule 12805 provides that a panel must comply with the following criteria before recommending expungement: (1) Hold a recorded hearing to decide the issue of expungement; (2) review settlement documents, and consider the amount of payments made to any party and any other terms and conditions of the settlement; (3) indicate in the award which of the grounds in FINRA Rule 2080 is the basis for expungement and provide a brief written explanation of the reasons for recommending expungement; and (4) assess all forum fees for hearing sessions in which the sole topic is the determination of the appropriateness of expungement against the parties requesting expungement. See also FINRA Rule 13805.

25 There are several ways in which a named associated person may request expungement during
requests expungement during the customer arbitration, does not withdraw the request and the case goes to hearing and closes by award, the panel in the customer arbitration will also decide the expungement request and include the decision as part of the customer’s award.\textsuperscript{26} If the customer arbitration does not close by award after a hearing (\textit{e.g.,} settles), and the associated person continues to pursue the expungement request, the panel from the customer arbitration may hold an expungement-only hearing as required by FINRA Rule 12805 to decide the expungement request.

Under the proposed rule change, if a named associated person seeks to request expungement of customer dispute information arising from the customer’s statement of claim, the named associated person must make the expungement request during the customer arbitration.\textsuperscript{27} As discussed below, the request would be subject to limitations on how and when the request may be made.\textsuperscript{28} In addition, the Director would be authorized to deny the forum to expungement requests during a customer arbitration that do not arise out of the customer arbitration.\textsuperscript{29} If the associated person does not request expungement during the customer arbitration, he or she would forfeit the opportunity to seek expungement of the same customer dispute information in any subsequent proceeding.\textsuperscript{30}

\textit{a customer arbitration.} The request may be included in the answer to the statement of claim that must be submitted within 45 days of receipt of the statement of claim, and may include other claims and remedies requested. See FINRA Rules 12303(a) and (b); see also FINRA Rules 13303(a) and (b). The expungement request may also be included in other pleadings (\textit{e.g.,} a counterclaim, a cross claim, or a third party claim) and must be filed with the Director of the Office of Dispute Resolution ("Director") through the Portal. See FINRA Rules 12100(x) and 12300(b). The associated person may also request at any time during the case (outside of a pleading) that the panel consider the person’s expungement request during the hearing. Under FINRA Rule 12503, such a request is treated like a motion, which gives the other parties an opportunity to object. If there is an objection, the panel must decide the motion pursuant to FINRA Rule 12503(d)(5). See also FINRA Rules 13503 and 13503(d)(5).

\textit{Under the Codes, a customer’s or claimant’s damage request determines whether a single arbitrator or a three-person panel will consider and decide an arbitration case. See FINRA Rules 12401 and 13401. For ease of reference, when discussing expungement requests during customer arbitrations under proposed Rule 12805, unless otherwise specified the rule filing uses the term “panel” to mean either a panel or single arbitrator.}

\textit{see supra note 25.}

\textit{26} See proposed Rule 12805(a)(1)(A).

\textit{27} See also infra Item II.A.1.(I)C.. “Limitations on Expungement Requests.”

\textit{28} See also proposed Rules 12203(b) and 12805(a).

\textit{29} As discussed above, the request would be subject to limitations on how and when the request may be made.

\textit{30} In addition, the Director would be authorized to deny the forum to expungement requests during a customer arbitration that do not arise out of the customer arbitration. If the associated person does not request expungement during the customer arbitration, he or she would forfeit the opportunity to seek expungement of the same customer dispute information in any subsequent proceeding.

\textit{FINRA is proposing to require that a named associated person request expungement during the customer arbitration because, if the arbitration closes by award after a hearing, the panel from the customer arbitration will be best situated to decide the related issue of expungement. Requiring the named associated person to request expungement in the customer arbitration increases the likelihood that a panel will have input from all parties and access to all of the evidence, testimony and other documents to make an informed decision on the expungement request. FINRA recognizes that this requirement could result in some named associated persons filing expungement requests to preserve their right to make a request, regardless of the potential outcome. FINRA believes that the potential costs that would be incurred by associated persons, arbitrators and the forum if named associated persons file expungement requests to preserve the ability to request expungement are appropriate given the potential benefit of having customer input and a complete factual record for the panel to decide an expungement request. In addition, certain aspects of the proposed rule change may limit the filing of requests without regard to the potential outcome. For example, under the proposed rule change, named associated persons would be permitted to request expungement no later than 30 days before the first scheduled hearing.\textsuperscript{31} This proposed amendment would provide the named associated person with a reasonable amount of time to consider, like the filing of a motion, whether to file the request because it could meet one or more of the FINRA Rule 2080(b)(1) grounds for expungement.\textsuperscript{32}

\texti{Method of Requesting Expungement}

The proposed rule change would limit how and when expungement requests may be made during the customer arbitration. Under the proposed rule change, if a named associated person requests expungement during the customer arbitration, the request must be included in the answer or a pleading requesting expungement.\textsuperscript{33} If the request is included in the answer, it must be filed within 45 days of receipt of the customer’s statement of claim in accordance with existing requirements under the Codes.\textsuperscript{34} If the named associated person requests expungement in a pleading requesting expungement, the request must be filed no later than 30 days before the first scheduled hearing begins.\textsuperscript{35} FINRA believes the proposed rule change would provide a reasonable amount of time for the requesting party to make an informed decision about whether to request expungement while also providing the parties with reasonable case-preparation time, since the expungement issues will overlap with the issues raised by the customer’s claim.

In addition, the proposed filing deadline would provide the Director a reasonable amount of time to notify state securities regulators of the expungement request.\textsuperscript{36} If a named associated person seeks to request expungement after the 30-day filing deadline, the panel would be required to decide whether to grant an extension and permit the request or whether to deny the request for expungement.\textsuperscript{37}

\textit{The proposed rule change would also require the party requesting expungement to explain whether expungement of the same customer dispute information was (i) previously requested and, if so (ii) how it was}

\textit{31} See proposed Rule 12805(a)(1)(C)(i). See also infra Item II.A.1.(I)E.3. “State Notification of Expungement Requests.”

\textit{32} See proposed Rule 12805(a)(1)(C); see also infra Item II.A.1.(I)C.. “Method of Requesting Expungement.”

\textit{33} In addition, FINRA notes that the SEC has approved changes to FINRA rules to apply minimum fees to expungement requests. See supra note 17.

\textit{34} See also Rule 12805(a)(1)(C)(i). See also supra note 17.

\textit{35} See proposed Rule 12805(a)(1)(C)(i)(b). An occurrence is a disclosure event that is reported to the CRD system via one or more Disclosure Reporting Pages. Each occurrence contains details regarding a specific disclosure event. An occurrence can have as many as three sources reporting the same event: Forms U4, U5 and U6.
decided.  This requirement would assist with implementation of the proposed prohibition on parties making second requests for expungement, discussed in more detail below. This proposed requirement is also consistent with language in the existing Guidance stating that arbitrators should ask a party requesting expungement whether an arbitration panel or a court previously denied expungement of the customer dispute information at issue and, if there was a prior denial, to deny the expungement request.

Under the proposed rule change, if an expungement request fails to include any of the proposed requirements for requesting expungement, the request would be considered deficient and would not be served unless the deficiency is corrected. These requirements would help ensure that FINRA, the panel and the parties understand who is requesting expungement and which disclosure is the subject of the request. Further, if the disclosure arose from a customer arbitration, the case name and docket number would provide the panel that is considering the expungement request with information about the dispute that gave rise to the disclosure that the party is seeking to expunge.

FINRA believes these proposed requirements for parties requesting expungement are necessary for the timely and orderly consideration of expungement requests as well as to maintain the integrity of the data in the CRD system.

b. Expungement Requests by a Party Named in the Customer Arbitration On-Behalf-Of an Unnamed Person

The Codes do not specifically address expungement requests by a party named in a customer arbitration on-behalf-of an unnamed person. Under current practice, a party to a customer arbitration may file an on-behalf-of request for expungement during the customer arbitration. If the party (typically, a firm) files the request and the customer arbitration closes by award after a hearing, the panel will decide the expungement request and include the decision in the award. If the customer arbitration does not close by award after a hearing (e.g., settles), either the requesting party or the unnamed person could ask the panel to consider and decide the expungement request before it disbands. In this circumstance, the panel from the customer arbitration will hold a separate expungement-only hearing to decide the expungement request.

The proposed rule change would codify the ability of a party in the customer arbitration to file an on-behalf-of request during a customer arbitration. Under the proposed rule change, a party to a customer arbitration may file an on-behalf-of request that seeks to expunge customer dispute information arising from the customer’s statement of claim, provided the request is eligible for arbitration under proposed Rule 12805. Filing an on-behalf-of request would be permissive, not mandatory. However, as discussed below, if the named party and the unnamed person agree to such a request, FINRA would require them to sign a form consenting to the on-behalf-of request which would help ensure that the unnamed person is fully aware of the request and that the firm is agreeing to represent the unnamed person for the purpose of requesting expungement during the customer arbitration.

The unnamed person would be required to consent to the on-behalf-of request in writing. In particular, the party filing an on-behalf-of request would be required to submit a signed form Requesting Expungement On Behalf of an Unnamed Person ("Form") and a statement requesting expungement with the Director.

The Form would provide that, if the Form would be submitted to the CRD system via a Form U4 or Form U5. Pursuant to FINRA Rule 1010, an associated person should be made aware of the filing of a Form U4 and any amendments thereto by the associated person’s member firm. In addition, Article V, Section 3 of the FINRA By-Laws of the Corporation requires that a member firm provide an associated person a copy of an amended Form U5, including certifying a customer complaint involving the associated person. FINRA also provides several methods for associating persons and former associated persons to check their record by accessing an Individual CRD Snapshot or online through BrokerCheck.

The proposed rule change would not require that an on-behalf-of request be included in an answer or pleading requesting expungement (although it could be), since the request seeks relief on-behalf-of a person who is not a party to the arbitration. However, the party making the request would be required to serve the request, which would include the Form, on all parties no later than 30 days before the first scheduled hearing.

FINRA believes that requiring submission of the Form would help address the issue of an unnamed person not being notified of the on-behalf-of request. As discussed above, FINRA is concerned that some associated persons are filing arbitration claims seeking expungement of the same customer dispute information that was the subject of a previous denial by a panel of an on-behalf-of request. By signing the Form, the unnamed person would be consenting to the on-behalf-of request and agreeing to be bound by the panel’s decision on the request. In addition, the Form would provide that, if the customer arbitration closes by award after a hearing, the unnamed person would be barred from filing a request for expungement for the same customer dispute information in a subsequent proceeding, and the unnamed person’s signature would serve as acknowledgement of this consequence.

ii. Required Contents of an On-Behalf-Of Expungement Request

Under the proposed rule change, an on-behalf-of request would be required to include the same elements as a request for expungement by a named associated person during a customer arbitration. Thus, the party requesting expungement on-behalf-of an unnamed person (typically, the firm) would be required to provide the applicable filing fee, the CRD number of the unnamed person, each CRD occurrence number that is the subject of the request and the expunged and the party requesting expungement on the unnamed person’s behalf must sign the Form.

The Form would be proposed Rule 12805(a)(2)(C)(iii). The 30-day deadline is the same as the proposed deadline for a named associated person to request expungement in a customer arbitration.

By signing the Form, the unnamed person would also be agreeing to maintain the confidentiality of documents and information from the customer arbitration to which the unnamed person is given access and to adhere to any confidentiality agreements or orders associated with the customer arbitration. See proposed Rule 12805(a)(2)(D). Failure of the unnamed person to comply with this provision could subject the unnamed person to a claim for damages by an aggrieved party.

See proposed Rule 12805(a)(1)(C)(iii); see also supra note 3. See proposed Rule 12805(a)(1)(C)(ii). The “Required Contents of an Expungement Request.”
case name and docket number that gave rise to the disclosure, if applicable. In addition, as discussed above, the party requesting expungement would be required to include the Form, signed by the unnamed person whose CRD record would be expunged and the party filing the request.

c. Deciding Expungement Requests During Customer Arbitrations

The proposed amendments would require that if there is a request for expungement by a named associated person or on-behalf-of an unnamed person during a customer arbitration, the panel from the customer arbitration must decide the expungement request if the customer arbitration closes by award after a hearing.54 If the customer arbitration closes other than by award (e.g., settles) or by award without a hearing, the panel would not consider the expungement request.55 Instead, the associated person would have the option of filing a request to expunge the same customer dispute information as a new claim under proposed Rule 13805 against the member firm at which he or she was associated at the time the customer dispute arose.56 A panel from the Special Arbitrator Roster would decide such an expungement request, as discussed in more detail below.57

i. Panel Decides the Expungement Request if the Customer’s Claim Closes by Award After a Hearing

Currently, if a named associated person requests expungement, or a party files an on-behalf-of request, and the customer’s claim closes by award after a hearing, the panel may consider and decide the expungement request during the customer arbitration and issue its decision in the award. If, however, the party requesting expungement does not raise the issue of expungement during the hearing, the panel will not decide the request and may deem it withdrawn without prejudice.54 In this instance, the associated person has the option to file the request again at a later date. Under the proposed rule change, if, during the customer arbitration, a named associated person requests expungement or a party files an on-behalf-of request, and the customer’s claim closes by award after a hearing, the panel in the customer arbitration would be required to consider and decide the request for expungement during the customer arbitration and issue a decision on the expungement request in the award.58 The panel would be required to decide the request even if the requesting party withdraws the request or fails to present a case in support of the request. In this instance, the panel must deny the expungement request with prejudice.59 This requirement would foreclose the ability of associated persons to withdraw expungement requests to avoid having their requests decided by the panel who heard the evidence on the customer’s arbitration claim, and then seeking to refile the request and receive a new list of arbitrators and a potentially more favorable decision.

ii. Panel Does Not Decide Expungement if the Customer’s Claim Closes Other Than by Award or by Award Without a Hearing

Currently, if a named associated person requests expungement or a party files an on-behalf-of request and the customer arbitration does not close by award after a hearing (e.g., settles) and the associated person or requesting party, if it is an on-behalf-of request, continues to pursue the expungement request, the panel from the customer arbitration will hold a separate expungement-only hearing to consider and decide the expungement request. If the named associated person or party requesting expungement does not request that the panel hold a separate, expungement-only hearing, the panel may deem the request withdrawn without prejudice, and the associated person has the option to file the request again at a later date.

The proposed rule change would provide that if, during a customer arbitration, a named associated person requests expungement or a party files an on-behalf-of request and the customer arbitration closes other than by award or by award without a hearing, the panel from the customer arbitration would not be permitted to decide the expungement request.60 Instead, the associated person would be required to seek expungement by filing a request to expunge the same customer dispute information as a straight-in request under proposed Rule 13805, where a panel from the Special Arbitrator Roster would decide the request.61

As discussed above, expungement requests may be complex to resolve, particularly straight-in requests where customers typically do not participate in the expungement hearing. Thus, having three arbitrators available to ask questions, request evidence and to serve generally as fact-finders in the absence of customer input would help ensure that a complete factual record is created to support the arbitrators’ decision in such expungement hearings.

FINRA believes this is the right approach because the panel selected by the parties in the customer arbitration has not heard the full merits of the case and, therefore, may not bring to bear any special insights in determining whether to recommend expungement. In addition, customers or their representative have little incentive to participate in an expungement hearing once their case has settled. Requiring that an associated person file the expungement request as a straight-in request under the Industry Code to be heard and decided by a three-person panel selected from the Special Arbitrator Roster would strengthen the expungement framework. As discussed in more detail below, this corps of specially trained arbitrators would follow the procedures set forth in proposed Rule 13805 and make a decision about whether FINRA Rule 2090(b)(1) grounds exist to recommend expungement, keeping in mind the importance of maintaining the integrity of information in the CRD system.

2. No Straight-In Requests Against Customers

The proposed amendments would prohibit an associated person from filing a straight-in request against a customer.62 Currently, straight-in requests are rarely filed against a customer.63 FINRA does not believe that

54 See proposed Rule 12805(a)(1)(D)(i) and (a)(2)(E)(i). 55 See proposed Rules 12805(a)(1)(D)(ii) and (a)(2)(E)(ii). 56 See supra note 54. Under the Codes, a “member” includes any broker or dealer admitted to membership in FINRA, whether or not the membership has been terminated, suspended, cancelled, revoked, the member has been expelled or barred from FINRA or the member is otherwise defunct. See FINRA Rules 12100(s) and 13100(q); see also Securities Exchange Act Release No. 88254 (February 20, 2020), 85 FR 11157 (February 26, 2020) (Order Approving File No. SR–FINRA–2019–027).
57 See infra Item II.A.1.(II)B.2., “Panel from the Special Arbitrator Roster Decides Requests Filed Under the Industry Code.”
58 See FINRA Rule 12702 and 13702.
59 See proposed Rules 12805(a)(1)(D)(i) and 12805(a)(2)(E)(i).
60 See proposed Rules 12805(a)(1)(D)(i) and 12805(a)(2)(E)(i).
62 See infra Item II.A.1.(II)B.2., “Panel from the Special Arbitrator Roster Decides Requests Filed Under the Industry Code.”
63 See proposed Rules 12805(a)(1)(D)(i) and 12805(a)(2)(E)(ii).
64 From January 2016 through June 2019, FINRA is able to identify 5,718 requests to expunge customer dispute information. Of those, 3,114 were
customers should be compelled to participate in a separate proceeding to decide an expungement request after the customer has resolved his or her arbitration claim or civil litigation, or submitted his or her customer complaint. Accordingly, the proposed amendments would prohibit an associated person from filing a straight-in request against a customer.

3. No Intervening in Customer Arbitrations To Request Expungement

The proposed amendments would also prohibit unnamed persons from intervening in a customer arbitration and requesting expungement. If the associated person is neither a party to the arbitration nor the subject of an on-behalf-of request by another party to the arbitration, the associated person should not be able to intervene in the customers’ arbitration to request expungement. In these circumstances, the associated person’s conduct is unlikely to be fully addressed by the parties during the customer arbitration, and FINRA does not believe that the customer should have the presentation of their case interrupted by an associated person’s intervention to request expungement. In addition, there have been instances in customer arbitrations in which the unnamed person learns that the customer’s arbitration case is nearing conclusion. The associated person (or his or her representative) then files a motion to intervene in the case to ask the panel to consider recommending expungement. As an unnamed person, the individual is not a party to the case and, therefore, has not made any arguments in support of the expungement request. Further, if the motion is granted, the parties to the case will be required to wait for a decision on the expungement request (which may necessitate another hearing) before their dispute is resolved, causing delay and additional cost to the parties.

Accordingly, under the proposed rule change, associated persons would be prohibited from intervening in a customer arbitration and requesting expungement. Instead, the unnamed person would have the option to file the request as a new claim under proposed Rule 13805, where a panel from the Special Arbitrator Roster would decide the request.

B. Straight-Requests and the Special Arbitrator Roster

Under the proposed rule change, all requests to expunge disclosures arising from customer complaints or civil litigations would be made as straight-in requests under proposed Rule 13805.67 In addition, an associated person could request expungement of customer dispute information arising from a customer arbitration under proposed Rule 13805 if: (1) The associated person is named in the arbitration or is the subject of an on-behalf-of request and the customer arbitration closes other than by award or by award without a hearing; or (2) the associated person is the subject of a customer arbitration, but is neither named in the arbitration nor the subject of an on-behalf-of request, and the customer arbitration closes for any reason. If an associated person requests expungement under proposed Rule 13805, a three-person panel selected from the Special Arbitrator Roster in accordance with proposed Rule 13806, would decide the expungement request.68

1. Filing a Straight-In Request Under the Industry Code

a. Applicability

Under the proposed rule change, an associated person requesting expungement of customer dispute information under the Industry Code must make a straight-in request by filing a statement of claim in accordance with FINRA Rule 13302 against a member firm at which he or she was associated at the time the customer dispute arose, unless the request is ineligible for arbitration under proposed Rule 13805(a)(2).69 Thus, the only way to request expungement of customer dispute information under the Industry Code would be to file the request under proposed Rule 13805.

The requirement that the associated person file the straight-in request against the member firm at which he or she was associated at the time the customer dispute arose would help ensure that there is a connection between the respondent firm and the subject of the expungement request. For example, the firm at which the person requesting expungement was associated at the time the dispute arose should have knowledge of the dispute and access to documents or other evidence relating to the dispute. In addition, the proposed requirement would help ensure that the panel from the Special Arbitrator Roster would be able to request evidence from a member firm with information that is relevant to the expungement request. If the requisite connection is not present, the Director would be authorized to deny the forum to the request.70

b. Required Contents of Straight-In Requests

The required contents of a straight-in request would be the same as those required for expungement requests filed under proposed Rule 12805.71 Thus, the associated person’s straight-in request would be required to contain the applicable filing fee;72 the CRD number of the party requesting expungement; each CRD occurrence number that is the subject of the request; the case name and docket number given to the disclosure, if applicable; and an explanation of whether expungement of the same customer dispute information was previously requested and, if so, how it was decided.73 In addition, as discussed below, the proposed rule change would impose limitations on when such requests may be made.74

2. Panel From the Special Arbitrator Roster Decides Requests Filed Under the Industry Code

If a straight-in request is filed in accordance with proposed Rule 13805, a three-person panel selected from the

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67 See proposed Rule 13203(b).
68 See supra Item II.A.1.([I]i)A.1.a.i., “Required Contents of an Expungement Request.”
69 FINRA would not assess a second filing fee when an associated person files a straight-in request if the associated person or the requesting party in the case of an on-behalf-of request, had previously paid the filing fee to request expungement of the same customer dispute information during a customer arbitration.
70 See proposed Rule 13805(a)(3).
71 See infra Item I.A.1.([I]i)E., “Limitations on Expungement Requests.” As discussed in more detail below in Item I.A.1.([I]i)E., the straight-in request would be ineligible for arbitration under the Industry Code if: (1) A panel held a hearing to consider the merits of the associated person’s request for expungement of the same customer dispute information; (2) a court previously denied the associated person’s request to expunge the same customer dispute information; (3) the customer arbitration, civil litigation or customer complaint that gave rise to the customer dispute information is not concluded; (4) more than two years has elapsed since the customer arbitration or civil litigation that gave rise to the customer dispute information has closed; or (5) there was no customer arbitration or civil litigation that gave rise to the customer dispute information and more than six years has elapsed since the date that the customer complaint was initially reported to the CRD system. See proposed Rule 13805(a)(2).
72 See proposed Rule 13805(a)(1).
73 See infra Item I.A.1.([I]i)B.2.a. and b. (discussing eligibility requirements for and composition of the Special Arbitrator Roster).
74 See supra Item II.B.2., “Economic Baseline.”
75 See proposed Rule 12805(a)(2).[E][iii].
76 See infra Item I.A.1.([I]i)B.2., “Panel from the Special Arbitrator Roster Decides Requests Filed Under the Industry Code.”
77 See infra Item I.A.1.([I]i)B.2.a. and b. (discussing eligibility requirements for and composition of the Special Arbitrator Roster).
78 See proposed Rule 13805(a)(1). FINRA Rule 13302 provides, in relevant part, that to initiate an arbitration, a claimant must file with the Director a signed and dated Submission Agreement, and a statement of claim specifying the relevant facts and remedies requested through the Party Portal.
Further, the public chairpersons must have evidenced successful completion of, and agreement with, enhanced expungement training provided by FINRA.\textsuperscript{81} FINRA currently provides an Expungement Training module for arbitrators.\textsuperscript{82} This training, however, would be expanded for arbitrators seeking to qualify for the Special Arbitrator Roster. This would allow FINRA to further emphasize, with the subset of arbitrators on the Special Arbitrator Roster, the unique, distinct role they play in deciding whether to recommend a request to expunge customer dispute information from a broker’s CRD record, and that expungement should be granted in limited circumstances and only if one or more of the grounds in FINRA Rule 2080(b)(1) is met.

Under the proposed amendments, arbitrators on the Special Arbitrator Roster would also be required to have served as an arbitrator through award on at least four customer-initiated arbitrations administered by FINRA or by another SRO in which a hearing was held.\textsuperscript{83} FINRA believes that if an arbitrator has served on four arbitrations through to award, it would indicate that the arbitrator has gained the knowledge and experience in the forum to conduct hearings.\textsuperscript{84}

b. Composition of the Panel

The proposed amendments would require that three randomly-selected arbitrators must complete the completer of, and agreement with, enhanced expungement training provided by FINRA.\textsuperscript{81} FINRA currently provides an Expungement Training module for arbitrators.\textsuperscript{82} This training, however, would be expanded for arbitrators seeking to qualify for the Special Arbitrator Roster. This would allow FINRA to further emphasize, with the subset of arbitrators on the Special Arbitrator Roster, the unique, distinct role they play in deciding whether to recommend a request to expunge customer dispute information from a broker’s CRD record, and that expungement should be granted in limited circumstances and only if one or more of the grounds in FINRA Rule 2080(b)(1) is met.

Under the proposed amendments, arbitrators on the Special Arbitrator Roster would also be required to have served as an arbitrator through award on at least four customer-initiated arbitrations administered by FINRA or by another SRO in which a hearing was held.\textsuperscript{83} FINRA believes that if an arbitrator has served on four arbitrations through to award, it would indicate that the arbitrator has gained the knowledge and experience in the forum to conduct hearings.\textsuperscript{84}

The proposed amendments would require that three randomly-selected arbitrators to decide straight-in requests.

a. Eligibility Requirements for the Special Arbitrator Roster

Arbitrators on the Special Arbitrator Roster would be public arbitrators who are eligible for the chairperson roster.\textsuperscript{77} Public arbitrators are not employed in the securities industry and do not devote 20 percent or more of their professional work to the securities industry or to parties in disputes concerning investment accounts or transactions or employment relationships within the financial industry.\textsuperscript{78} Arbitrators are eligible for the chairperson roster if they have completed chairperson training provided by FINRA and: (1) Have a law degree and are a member of a bar of at least one jurisdiction and have served as an arbitrator through award on at least one arbitration administered by an SRO in which hearings were held; or (2) have served as an arbitrator through award on at least three arbitrations administered by an SRO in which hearings were held.\textsuperscript{79} These requirements would help ensure that the persons conducting the expungement hearing are impartial and experienced in managing and conducting arbitration hearings in the forum.\textsuperscript{80}

\textsuperscript{75} See proposed Rule 13805(a)(4).
\textsuperscript{76} See supra note 75.
\textsuperscript{77} See proposed Rule 13806(b); see also FINRA Rule 12400(c).
\textsuperscript{78} See supra note 8.
\textsuperscript{79} See FINRA Rule 12400(c). For purposes of this proposed rule change, public arbitrators who are eligible for the chairperson roster would include those arbitrators who have met the chairperson eligibility requirements of FINRA Rule 12400(c), regardless of whether they have already served as a chair on an arbitration case.
\textsuperscript{80} The Task Force suggested that the arbitrators on its recommended special arbitration panel be chair-qualified, in part because of the training that

\textsuperscript{81} See proposed Rule 13806(b)(1).
\textsuperscript{82} See supra Item I.A.1.(I).C., “Concerns Regarding Expungement” (discussing the importance of having a three-person panel decide straight-in requests).
\textsuperscript{83} See proposed Rule 13806(b)(1). The first arbitrator selected would be the chair of the panel. See proposed Rule 13806(b)(3).
\textsuperscript{84} The parties also would not be permitted to stipulate to the use of pre-selected arbitrators (i.e., arbitrators that the parties find on their own to use in their cases). See proposed Rule 13806(b)(1).
\textsuperscript{85} See proposed Rule 13806(b)(4). In addition, before the first hearing session begins, the Director may remove an arbitrator for conflict of interest or bias, either upon request of a party or on the Director’s own initiative. See FINRA Rule 12407(a).
\textsuperscript{86} See proposed Rule 13806(b)(4); see also FINRA Rules 12402(g) and 12403(g).
\textsuperscript{87} See generally FINRA Rules 12402 and 12403.
\textsuperscript{88} See infra note 189.
\textsuperscript{89} Once the parties have ranked the arbitrators, the Director creates a combined ranked list of
straight-in request filed by an associated person against a firm may not be adversarial in nature. In addition, typically the customer or customer’s representative will not appear at the expungement hearing.

FINRA recognizes that the proposed arbitrator selection process for straight-in requests would limit the associated person and member firm’s input on arbitration selection. However, the arbitrators on the Special Arbitrator Roster would have the experience, qualifications and training necessary to conduct a fair and impartial expungement hearing in accordance with the proposed rules, and to render a recommendation based on a complete factual record developed during the expungement hearing. FINRA believes that the higher standards that the arbitrators must meet to serve on the Special Arbitrator Roster should mitigate the impact of the absence of party input on the selection of arbitrators. In addition, associated persons and member firms would still be permitted to challenge any arbitrator for cause.94

C. Limitations on Expungement Requests

Currently, Rules 12805 and 13805 do not address when a party would not be permitted to file an expungement request in the forum.95 The Guidance, however, describes several circumstances in which an expungement request should be ineligible for arbitration. The proposed rule change would incorporate the limitations contained in the Guidance as well as add time limits to when an associated person may file a straight-in request.

1. Limitations Applicable to Both Straight-In Requests and Expungement Requests During a Customer Arbitration

The Guidance provides that if a panel or a court has issued an award or decision denying an associated person’s expungement request, the associated person may not request expungement of the same customer dispute information in another arbitration. In particular, the Guidance states that arbitrators should ask a party requesting expungement whether an arbitration panel or a court previously denied expungement of the customer dispute information at issue and, if there has been a prior denial, the arbitration panel must deny the expungement request.96

The proposed rule change would codify the Guidance by providing that an associated person may not file a request for expungement of customer dispute information if (1) a panel held a hearing to consider the merits of the associated person’s expungement request for the same customer dispute information or (2) a court of competent jurisprudence previously denied the associated person’s request to expunge the same customer dispute information.97 These proposed amendments would prevent an associated person from forum shopping, or seeking to return to the arbitration forum administered by FINRA, to garner a favorable outcome on his or her expungement request.98

2. Limitations Applicable to Straight-In Requests Only

As discussed below, under the proposed amendments, three additional limitations would apply to straight-in requests.

i. No Straight-In Request if a Customer Arbitration Has Not Concluded

The Guidance provides that an associated person may not file a separate request for expungement of customer dispute information arising from a customer arbitration until the customer arbitration has concluded. The proposed rule change would codify and expand upon the Guidance by providing that an associated person may not file a straight-in request under proposed Rule 13805 if the customer arbitration, civil litigation or customer complaint that gave rise to the customer dispute information has not closed.99

The proposed rule change would prevent an associated person from obtaining a decision on an expungement request while the customer arbitration is still ongoing. This change would help ensure that a decision in the customer arbitration is issued before the decision on the expungement request and avoid the possibility of inconsistent awards. The proposed amendment would also help ensure that the arbitrators who will decide the straight-in request are able to consider the final factual record from the customer arbitration.

ii. Time Limits Applicable to Disclosures Arising After the Effective Date of the Proposed Rule Change

FINRA is aware that a number of expungement requests are filed many years after a customer arbitration closes or the reporting of a customer complaint in the CRD system.100 To encourage timelier filing of expungement requests, the proposed amendments would establish time limits for expungement requests that are specifically tied to the closure of customer arbitrations and civil litigations, or the reporting of customer complaints in the CRD system, as applicable.101 The proposed time limits should help encourage customer participation in expungement proceedings and help ensure that straight-in requests will not be brought before relevant evidence and testimony becomes stale or unavailable.102

a. Two Years From the Close of a Customer Arbitration or Civil Litigation

Under the proposed rule change, an associated person would be required to file a straight-in request within two years of the close of the customer arbitration or civil litigation that gave rise to the customer dispute information.103 A two-year period would provide a reasonable amount of time for associated persons and their firms to gather the documents, information and other resources required to file the expungement request. In addition, the two-year period would help ensure that the expungement hearing is held close enough in time to the customer arbitration, when information regarding the customer arbitration is available and in a timeframe that could increase the
likelihood for the customer to participate if he or she chooses to do so. The shorter timeframe, therefore, could provide panels with more complete factual records on which to base their expungement decisions. At the same time, it would allow the associated person time to determine whether to seek expungement by filing a straight-in request.

b. Six Years From the Date a Customer Complaint Is Reported to the CRD System

Under the proposed rule change, an associated person would be prohibited from filing a straight-in request to expunge a customer complaint where more than six years has elapsed since the customer complaint was initially reported to the CRD system and there was no customer arbitration or civil litigation that gave rise to the customer dispute information.104

Consistent with FINRA’s current eligibility rules,105 FINRA believes that six years from the date a customer complaint is initially reported to the CRD system should provide a reasonable amount of time for the associated person to bring an expungement claim. The six-year period would allow firms to complete their investigation of the customer complaint and close it in the CRD system; for the complaint to evolve, or not evolve, into an arbitration; and for the associated person to determine whether to proceed with a request to expunge the complaint. The proposed six-year time limit would also provide a reasonable time limit to encourage customer participation and help ensure the availability of evidence related to customer complaints.

iii. Time Limits Applicable to Disclosures Arising On or Prior to the Effective Date of the Proposed Rule Change

If the Commission approves the proposed rule change, the proposal would also establish time limits for requests to expunge customer dispute information arising from customer arbitrations and civil litigations that close, and for customer complaints that were initially reported to the CRD system, on or prior to the effective date of the proposed rule change.

Specifically, the proposed amendments would provide that if an expungement request is otherwise eligible under the six-year limitation period of FINRA Rule 13206(a), an associated person would be permitted to file a straight-in request under the Industry Code if: (1) The request for expungement is made within two years of the effective date of proposed rule change, and the disclosure to be expunged arises from a customer arbitration or civil litigation that closed on or prior to the effective date;106 or (2) the request for expungement is made within six years of the effective date of the proposed rule change, and the disclosure to be expunged arises from a customer complaint initially reported to the CRD system on or prior to its effective date.107

3. Director’s Authority To Deny the Forum

If an associated person files an expungement request that is ineligible for arbitration under proposed Rules 12805 and 13805, the proposed rule change would give the Director the express authority to deny the use of FINRA’s arbitration forum to decide the request.108 If the expungement request is ineligible for arbitration because a court or panel has decided previously an expungement request related to the same customer dispute information, the Director would deny the forum with prejudice as the request would be an attempt to receive a second decision on a request that had been decided previously on the merits. The Director would also deny the forum with prejudice if an expungement request is ineligible under the proposed time limitations.

If the request is ineligible because a customer arbitration that involves the same customer dispute information is not concluded, the Director would deny the forum without prejudice so that the associated person could file the request (or a party could file an on-behalf-of request) in the customer arbitration or as a straight-in request after the customer arbitration concludes.

D. Procedural Requirements Relating to All Expungement Hearings

The Codes currently provide a list of requirements panels must follow in order to decide an expungement request.109 In addition, the Guidance provides best practices that arbitrators should follow when deciding expungement requests. To guide further the arbitrators’ decision-making, the proposed rule change would expand the expungement hearing requirements currently in FINRA Rules 12805 and 13805 to incorporate the relevant provisions from the Guidance. The proposed amendments would apply to all expungement hearings.110

1. Recorded Hearing Sessions

The Codes require a panel that is deciding an expungement request to hold a recorded hearing session (by telephone or in person) regarding the appropriateness of expungement.111 Consistent with current practice, the proposed rule change would add the ability to hold a recorded hearing session by video conference.112 Further, the proposed rule change would clarify that a panel would not be limited in the number of hearing sessions it should hold to decide the expungement request.113

2. Associated Person’s Appearance

The proposed rule change would require the associated person who is seeking expungement of the customer dispute information to appear personally at the expungement hearing.114 A party requesting expungement on behalf of an unnamed person would also be required to appear at the hearing. The panel would determine whether an appearance should be by telephone, in person, or by video conference.

As the associated person is requesting the permanent removal of information from his or her CRD record, FINRA believes the associated person whose CRD record would be expunged must personally participate in the expungement hearing to respond to questions from the panel and those customers who choose to participate. Rather than restrict the method of appearance, FINRA is proposing to provide the panel with the authority to decide which method of appearance would be the most appropriate for the particular case. FINRA believes that

104 See proposed Rule 13805(a)(2)(A)(v).
105 See supra note 14.
106 See proposed Rule 13805(a)(2)(B)(i).
108 See proposed Rules 12203(b) and 13203(b).
109 See supra note 14.
110 See supra note 24.
providing flexibility as to the method of appearance would encourage appropriate fact-finding by the arbitrators and generally strengthen the process.

3. Customer’s Participation During the Expungement Hearing

The Guidance states that it is important to allow customers and their representatives to participate in the expungement hearing if they wish to do so.113 Specifically, the Guidance provides that arbitrators should:

- Allow the customers and their representatives to appear at the expungement hearing;
- Allow the customer to testify (telephonically, in person, or other method) at the expungement hearing;
- Allow the representative for the customer or a pro se customer to introduce documents and evidence at the expungement hearing;
- Allow the representative for the customer or a pro se customer to cross-examine the broker or other witnesses called by the party seeking expungement;
- Allow the representative for the customer or a pro se customer to present opening and closing arguments if the panel allows any party to present such arguments.

The proposed rule change would codify these provisions of the Guidance. The proposed rule change would make clear that all customers whose customer arbitrations, civil litigations and customer complaints gave rise to the customer dispute information that is a subject of the expungement request have a right to representation and are entitled to appear at the expungement hearing.114 The proposed rule change would provide that the customer can appear by telephone, in person, by video conference or other means convenient to the customer and customer's representative.117 By providing customers with options for how to participate in hearings, FINRA seeks to make it easier for customers to participate and, thereby, encourage customer participation. Customer participation during an expungement hearing provides the panel with important information and perspective that it might not otherwise receive.

In addition, the proposed rule change would provide that customers must be allowed to testify at the expungement hearing and be questioned by the customer's representative.119 If a customer testifies, the associated person or a party requesting expungement on-behalf-of an unnamed person would be allowed to cross-examine the customer.119 Similarly, the customer or customer's representative would be permitted to cross-examine the associated person or party requesting expungement on-behalf-of an unnamed person and any witnesses called by the associated person or party requesting expungement on-behalf-of an unnamed person during the expungement hearing.120 If the customer introduces any evidence at the expungement hearing, the associated person or party requesting expungement on-behalf-of an unnamed person could object to the introduction of the evidence, and the panel would decide any objections.121 The customer or customer's representative would also be permitted to present opening and closing arguments if the panel permits any party to present such arguments.122 FINRA believes the proposal strikes the right balance of allowing the customer to participate fully in the hearing and giving the associated person or party requesting expungement on-behalf-of an unnamed person the opportunity to substantiate arguments in support of the expungement request.

4. Panel Requests for Additional Documents or Evidence

Arbitrators on the panel do not conduct their own research when hearing an arbitration case; instead, they review the materials provided by the parties. If they need more information, they can request it from the parties.123 In deciding an expungement request, particularly in cases that settle before an evidentiary hearing or in cases where the customer does not participate in the expungement hearing, the arbitrator's role as fact-finder is critical. Given this significant role, arbitrators must ensure that they have all of the information necessary to make a fully-informed decision on the expungement request on the basis of a complete factual record. Thus, the proposed rule change would codify the ability of arbitrators to request from the associated person, or other party requesting expungement, any documentary, testimonial or other evidence that they deem relevant to the expungement request.124

5. Review of Settlement Documents

Current FINRA Rule 12805(b) provides that, in the event the parties from the customer arbitration settle their case, the panel considering the expungement request must review the settlement documents and consider the amount of payments made to any party and any other terms and conditions of the settlement.125 The proposed rule change would retain this requirement.126 In addition, the Guidance encourages arbitrators to inquire and fully consider whether a party conditioned a settlement of the arbitration upon agreement not to oppose the request for expungement in cases in which the customer does not participate in the expungement hearing or the requesting party states that a customer has indicated that he or she will not oppose the expungement request. The proposed rule change would codify this language in the Guidance.127 Conditioned settlements violate FINRA Rule 2081 and may be grounds to deny an expungement request.128

124 See supra note 123. The Guidance also suggests that arbitrators should ask the associated person seeking expungement or the party seeking expungement on an associated person's behalf to provide a current copy of the BrokerCheck report for the person whose record would be expunged, paying particular attention to the "Disclosure Events" section of the report. See supra note 3. FINRA continues to encourage arbitrators to request a current copy of the associated person's BrokerCheck report.

127 See proposed Rules 12805(c)(7) and 13805(c)(7).

128 FINRA Rule 2081 provides that no member firm or associated person shall condition or seek to condition settlement of a dispute with a customer on, or to otherwise compensate the customer for, the customer’s agreement to consent to, or not to oppose, the member’s or associated person’s request to expunge such customer dispute information from the CRD system. See also Prohibited Conditions Relating to Expungement of Customer Dispute Information.
6. Awards
Current FINRA Rules 12805(c) and 13805(c) require that the panel indicate in the arbitration award which of the FINRA Rule 2080 grounds for expungement serves as the basis for its expungement recommendation and provide a brief written explanation of the reasons for its finding that one or more FINRA Rule 2080 grounds for expungement applies to the facts of the case. The proposed rule change would retain this requirement, but would remove the word “brief” to indicate to the panel that it must provide enough detail in the award to explain its rationale for recommending expungement.132 As the Guidance suggests, the explanation must be complete and not solely a recitation of one of the FINRA Rule 2080 grounds or language provided in the expungement request.

In addition, the proposed rule change would incorporate language from the Guidance that the panel’s explanation should identify any specific documentary, testimonial or other evidence relied on in recommending expungement.130 The proposed rule change would also make clarifying revisions to FINRA Rules 12805(c) and 13805(c). The proposed amendments would indicate that the FINRA Rule 2080 grounds that the panel must indicate serve as the basis for the expungement order are the grounds found in paragraph (b)(1) of FINRA Rule 2080.131 The proposed amendments would also provide that the panel would “recommend” rather than “grant” expungement.132

7. Forum Fees
The proposed rule change would retain the current requirements in FINRA Rules 12805(d) and 13805(d) that addresses how forum fees are assessed in expungement hearings.133 Specifically, the panel must assess against the parties requesting expungement all forum fees for each hearing in which the sole topic is the determination of the appropriateness of expungement.

E. Notifications to Customers and States Regarding Expungement Requests
1. Associated Person Serves Customer With Statement of Claim
The Guidance suggests that when a straight-in request is filed against a firm, arbitrators order the associated person to provide a copy of the statement of claim to the customers involved in the customer arbitration that gave rise to the customer dispute information. This helps ensure that the customers know about the expungement request and have an opportunity to participate in the expungement hearing or provide a position in writing on the associated person’s request. The proposed rule change would codify this practice in the Industry Code by requiring that the associated person provide all customers whose customer arbitrations, civil litigations and customer complaints gave rise to the customer dispute information that is a subject of the expungement request with notice of the expiration request by serving a copy of the statement of claim requesting expungement.134 The panel would be authorized to decide whether extraordinary circumstances exist that make service on the customers impracticable.135

Given the associated person’s personal interest in obtaining expungement, FINRA believes that the panel should review all documents that the associated person used to inform the customers about the expungement request as well as any customer responses received. Accordingly, the proposed amendments would require the associated person to file with the panel all documents provided by the associated person to the customers, including proof of service, and any responses received by the associated person from a customer.136 The proposed requirement would help ensure that the associated person does not attempt to dissuade a customer from participating in the expungement hearing.

2. Notification to Customers of Expungement Hearing
To help ensure that the customer is notified about the expungement hearing, the proposed rule change would provide that the Director shall notify all customers whose customer arbitrations, civil litigations and customer complaints gave rise to the customer dispute information that is a subject of the expungement request, of the time, date and place of the expungement hearing using the customer’s current address provided by the party seeking expungement.137 The associated person would be required to provide a current address for the customer, or the expungement request would be considered deficient and would not be served.

3. State Notification of Expungement Requests
The proposed rule change would require FINRA to notify state securities regulators, in the manner determined by FINRA, of an expungement request within 30 days after receiving a complete request for expungement.138 The proposed amendments would help ensure that state securities regulators are timely notified of the expungement requests.139

F. Expungement Requests During Simplified Customer Arbitrations
Customer arbitrations involving $50,000 or less, called simplified arbitrations, are governed by FINRA Rule 12800. FINRA Rule 12800 provides customers with expedited procedures to make the FINRA forum economically feasible for these smaller claims. Simplified arbitrations are decided on the pleadings and other materials submitted by the parties, unless the customer requests a hearing.140 Further, a single arbitrator from the chairperson roster is appointed to consider and decide simplified arbitrations, unless the parties agree in writing otherwise.141

132 See proposed Rule 13805(b)(2). This requirement would apply to straight-in requests filed under the Industry Code; notice to customers would not be necessary for requests filed under proposed Rule 12805 of the Customer Code as the customer would be a named party.
133 See proposed Rules 12805(b)(2) and 13805(b)(3).
134 FINRA would make this notification in connection with expungement requests under the Customer and Industry Codes. Such notification could be achieved by notifying NASAA of the expungement requests.
135 See FINRA Rule 12800(a).
136 See FINRA Rule 12800(b). The parties could agree to have a three-person panel decide the simplified case. For ease of reference, when discussing expungement requests in simplified arbitrations under the proposed rule change, the rule filing uses the term “arbitrator,” unless
The customer who files a simplified arbitration determines how the claim will be decided. In particular, the customer has the option of having the case decided in one of three ways: (1) Without a hearing (referred to as “on the papers”), where the arbitrator decides the case on the pleadings or other materials; (2) in an “Option One” full hearing, in which prehearings and hearings on the merits take place pursuant to the regular provisions of the Code; or (3) in an “Option Two” special proceeding, whereby the parties present their case in a hearing to the arbitrator in a compressed timeframe, so that the hearings last no longer than one day.142

Currently, named associated persons and parties requesting expungement on-behalf-of unnamed persons request expungement during simplified arbitrations. FINRA Rule 12800 does not, however, expressly address how an expungement request should be filed or considered during a simplified arbitration. The proposed amendments would codify an associated person’s ability to request expungement when named as a respondent in a simplified arbitration, and for other parties to request expungement on-behalf-of an unnamed person. The proposed rule change would also establish procedures for requesting and considering expungement requests in simplified arbitrations that are consistent with the expedited nature of these proceedings.143

1. Requesting Expungement

The proposed rule change would permit a named associated person to request expungement, or a party to file an on-behalf-of request, during a simplified arbitration. Unlike in a non-simplified arbitration, if expungement is not requested during the simplified arbitration, the associated person would be permitted to request it as a straight-in request filed under the Industry Code.144

a. By a Named Associated Person During the Simplified Arbitration

Under the proposed rule change, an associated person named as a respondent in a simplified arbitration could request expungement during the arbitration of the customer dispute information arising from the customer’s statement of claim, provided the request is eligible for arbitration.145

If a named associated person requests expungement during a simplified arbitration, the proposed rule change would require the request to be filed in an answer or pleading requesting expungement and include the same information required as a request filed in a non-simplified arbitration.146

Because of the expedited nature of simplified arbitrations, if the named associated person requests expungement in a pleading other than answer, the request must be filed within 30 days after the date that FINRA notifies the associated person of arbitrator appointment,147 which is the last deadline provided to the parties in a simplified arbitration to submit any additional documents before the case is submitted to the arbitrator.148

To limit arbitrator shopping, the arbitrator would be required to decide an expungement request once it is filed by the associated person.149 If an associated person withdraws or does not pursue the request after filing, the arbitrator would be required to deny the request with prejudice so that it could not be re-filed.150

b. By a Party On-Behalf-Of an Unnamed Person

Under the proposed amendments, the requirements for a party to file an on-behalf-of request during a simplified arbitration would be the same as the requirements for a named associated person filing an expungement request during a simplified arbitration, with one

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142 See FINRA Rule 12800(c).
143 Under the proposed rule change, an associated person would not be permitted to request expungement in a simplified arbitration administered under the Industry Code, FINRA Rule 13800. All expungement requests under the Industry Code must be filed in accordance with proposed Rule 13805.
144 See Infra Item II.A.1.(II)A.1.c., “When No Expungement Request is Made in a Simplified Arbitration.”
145 See proposed Rule 12800(d)(1)(A). The limitations that apply to expungement requests filed by a named associated person under proposed Rule 12805(a)(1)(B) would apply to these requests. See supra Item II.A.1.(II)C., “Limitations on Expungement Requests.”
146 See proposed Rules 12800(d)(1)(B)(i) and 12805(a)(1)(C)(ii). Thus, the associated person’s expungement request would require to contain the applicable filing fee; the CRD number of the party requesting expungement; each CRD occurrence number that is the subject of the request; the case name and docket number that gave rise to the disclosure, if applicable; and an explanation of whether expungement of the same customer dispute information was previously requested and, if so, how it was decided.
147 FINRA would notify state securities regulators, in the manner determined by FINRA, of an expungement request within 30 days after receiving a complete expungement request. See proposed Rule 12800(f)(1).
148 See proposed Rule 12800(a)(1)(i)(ii). FINRA notifies the parties when an arbitrator has been appointed. FINRA informs the parties that they have 30 days from the date of notification to submit additional documents or other information before the case is submitted to the arbitrator.
149 See proposed Rule 12800(e)(1).
150 See proposed Rule 12800(d)(1)(C).
151 See proposed Rule 12800(d)(2). The request must also meet the same requirements as an on-behalf-of request filed under proposed Rule 12805(a)(2). See proposed Rules 12805(a)(1)(I)(ii), 12805(a)(2)(C)(ii) and 12805(a)(2)(D); see also supra Items II.A.1.(II)A.1.b., “Expungement Requests By a Party Named in the Customer Arbitration On-Behalf-Of an Unnamed Person.”
152 See proposed Rules 12800(e)(2), 12805 and 13806.
153 See proposed Rule 12805(a)(2); see also supra Item II.A.1.(II)C., “Limitations on Expungement Requests.”
the simplified arbitration case closes (e.g., even if the case settles).

Under the proposed rule change, how and when the expungement request is decided would depend on which option the customer selects to decide the simplified arbitration.

a. No Hearing or Option Two Special Proceeding

If the customer opts not to have a hearing or chooses an Option Two special proceeding, the arbitrator would decide the customer’s dispute first and issue an award. After the customer’s dispute is decided, the arbitrator must hold a separate expungement-only hearing to consider and decide the expungement request and issue a separate award.

The arbitrator would decide the customer’s dispute first and issue an award to minimize any delays in resolving the customer arbitration and any delays in potential recovery that a customer may be awarded. Further, because the customer arbitration may not be as fully developed when an “on the papers” or special proceeding is requested, the arbitrator must hold a separate expungement-only hearing to ensure that he or she has access to sufficient evidence to make a fully-informed decision on the expungement request. The Director would notify all customers whose simplified customer arbitrations and customer complaints gave rise to the customer dispute information that is a subject of the expungement request, of the time, date and place of the expungement hearing.

b. Option One Hearing

If the customer chooses to have a full “Option One” hearing on his or her claim and it closes by award, the arbitrator would be required to consider and decide the expungement request during the customer arbitration and include the decision in the award.

This process would be the same as deciding an expungement request during a non-simplified customer arbitration that closes by award after a hearing, where the customer’s claim and expungement request are addressed during the customer arbitration. As there would be a more complete factual record from the full hearing on the merits of the customer case, the arbitrator could decide the customer dispute and the expungement request after the hearing concludes.

If the customer arbitration closes other than by award or by award without a hearing, the arbitrator would be required to hold a separate expungement-only hearing to consider and decide the expungement request and issue the decision in an award. The arbitrator would need to conduct a separate expungement hearing to develop a complete factual record in order to make a fully-informed decision on the expungement request.

Given the generally less complex nature of simplified arbitrations, FINRA does not believe that it is necessary for a panel from the Special Arbitrator Roster to decide an expungement request if a simplified customer arbitration closes other than by award or by award without a hearing. However, if the Commission approves the proposed rule change, FINRA will continue to monitor expungement requests and decisions in simplified arbitrations to determine if such requests should be decided by the Special Arbitrator Roster, particularly if the customer chooses to have his or her case decided on the papers or in a special proceeding.

G. Non-Substantive Changes

FINRA is also proposing to amend the Codes to make non-substantive, technical changes to the rules impacted by the proposed rule change. For example, the proposed rule change would require the renumbering of paragraphs and the updating of cross-references in the rules impacted by the proposed rule change. In addition, the title of Part VIII of the Customer Code would be amended to add a reference to “Expungement” proceedings. Similarly, the title of Part VIII of the Industry Code would be amended to add a reference to “Expungement Proceedings” and “Promissory Note Proceedings.” FINRA believes the proposed changes to the titles would more accurately reflect the contents of Part VIII of the Customer and Industry Codes. FINRA is also proposing to re-number current FINRA Rule 13806 (Promissory Note Proceedings) as new FINRA Rule 13807, without substantive change to the current rule language.

If the Commission approves the proposed rule change, FINRA will announce the effective date of the proposed rule change in a Regulatory Notice to be published no later than 60 days following Commission approval. The effective date will be no later than 120 days following publication of the Regulatory Notice announcing Commission approval of the proposed rule change.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.

The proposed rule change seeks to balance the important investor protection objectives of maintaining the integrity and accuracy of the information in the CRD system and BrokerCheck with the interest of brokers and firms in the fairness and accuracy of the disclosures contained in the systems.

The proposed rule change will enhance the current expungement framework and improve the efficiency of the FINRA arbitration forum by codifying the Guidance as rules that arbitrators and parties must follow. In addition, when an associated person files a claim against a firm for the sole purpose of requesting expungement, these cases can be complex to resolve, particularly if the customer or customer’s representative does not participate in the hearing. Having three arbitrators available to ask questions, request evidence and generally to serve as fact-finders in the absence of customer input will help ensure that a complete factual record is created to support the arbitrators’ decision in such expungement hearings. In addition, the proposed rule change will help ensure that arbitrators who will decide these requests meet heightened qualifications and have completed enhanced expungement training. FINRA believes that by requiring a three-person panel from the Special Arbitrator Roster to decide expungement requests filed under the Industry Code, the proposed rule change will help ensure expungement is recommended in limited circumstances.

The proposed rule change will foreclose a practice that has emerged in the existing expungement process where parties seek expungement after a prior denial by a court or panel of a request.
to expunge the same customer dispute information, or where parties withdraw or do not pursue an expungement request and then make another request for expungement of the same customer dispute information. The proposed rule change imposes procedures and requirements around when and how a party may request expungement, and expressly provides that omission of certain of the requirements will make the expungement request deficient.

Further, the proposed rule change provides the Director with express authority to deny the forum if an expungement request is ineligible for arbitration under the proposed rules. Thus, FINRA believes the proposed rule change will add more transparency to the expungement process.

Moreover, the proposed rule change seeks to protect investors and the public interest by notifying customers of expungement requests filed under the Industry Code. Although a straight-in request will be filed against a firm, customers whose disputes are a subject of the request will be notified and encouraged to participate in the expungement hearing. Such notifications will make clear to arbitrators and parties the rights of customers who choose to participate in these hearings. The customers’ input will provide the panel with additional insight on the customer dispute and help create a complete factual record, which will result in more informed decisions on expungement requests. FINRA believes this enhancement, which will encourage and facilitate customer participation in expungement hearings, will help to maintain the integrity of the information in the CRD system.

Further, the process of requesting expungement during a simplified arbitration will be codified to help ensure that customers are aware of their rights under the process and how an expungement request will affect (and not affect) their arbitration claims. By expressly incorporating the practice of requesting expungement during simplified proceedings, the proposed amendments add consistency to the rules and provide more guidance to the arbitrators and the parties requesting expungement.

The proposed rule change will also help ensure that state securities regulators have knowledge of expungement requests by requiring notification to the states, in the manner determined by FINRA, after FINRA receives a complete expungement request. For these reasons, the proposed rule change represents a significant step towards addressing concerns with the current expungement framework. FINRA believes the proposed rule change will improve the expungement framework by incorporating the Guidance, establishing a Special Arbitrator Roster and addressing gaps that have emerged in the existing expungement framework. In addition, FINRA believes these changes will help to maintain the accuracy and integrity of the information in the CRD system and BrokerCheck, while also protecting brokers from the publication of false allegations against them.

B. Self-Regulatory Organization’s Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Economic Impact Assessment

FINRA has undertaken an economic impact assessment to analyze the regulatory need for the proposed rule change, its potential economic impacts, including anticipated costs, benefits and distributional and competitive effects, relative to the current baseline, and the alternatives FINRA considered in assessing how best to meet FINRA’s regulatory objectives.

1. Regulatory Need

The proposed rule change would address concerns relating to the expungement process that are not consistent with the regulatory intent to permit expungement in limited circumstances. The concerns include the potential impact of the absence of customers and their representatives from an expungement hearing which may result in the arbitrator or panel receiving information only from the associated person. The concerns also include associated persons having their straight-in requests heard by a single arbitrator instead of a three-person panel, and the selection of arbitrators to hear these requests. Lastly, the concerns include requests to expunge the same customer dispute information in multiple proceedings. The proposed rule change would also codify and expand upon the provisions of the Guidance to help ensure that arbitrators and parties are adhering to these procedures for all expungement requests, and to encourage and facilitate customer participation in expungement hearings.

2. Economic Baseline

The economic baseline for the proposed rule change includes the current provisions under the Codes that address the process for parties to seek expungement relief. In addition, because arbitrators are generally believed to be adhering to the best practices and recommendations that are a part of the Guidance, the economic baseline also includes the Guidance. The proposed rule change is expected to affect associated persons and other parties to expungement requests including member firms, customers and arbitrators. The proposed rule change may also affect users of customer dispute information contained in the CRD system and displayed through BrokerCheck.}

The customer dispute information contained in the CRD system is submitted by registered securities firms and regulatory authorities in response to questions on the uniform registration forms. The information can be valuable to current and prospective customers to learn about the conduct of associated persons. Current and prospective customers may not select or remain with an associated person or a member firm that employs an associated person with a record of customer disputes. Similarly, member firms and other companies in the financial services industry may use the information when making employment decisions. In this manner, the customer dispute information contained in the CRD system (and displayed through BrokerCheck) may positively or negatively affect the business and professional opportunities of associated persons. Where the information is reliable, it also provides for customer

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162 See supra note 3.

163 Users of customer dispute information include investors; members and other companies in the financial services industry; individuals registered as brokers or seeking employment in the brokerage industry; and FINRA, states and other regulators.

164 See supra note 5 and accompanying text for additional discussion of the uniform registration forms and the information contained in the CRD system. Some of the information may involve pending actions or allegations that have not been resolved or proven.


166 Customer dispute information submitted to the CRD system and displayed through BrokerCheck may have other uses. For example, investors may use the information when deciding with whom to do business. FINRA, states and other regulators also use the information to regulate brokers.
protections and information useful for member firms.

Any negative impact on the business and professional opportunities of associated persons may be appropriate and consistent with investor protection, such as when the customer dispute information has merit. Any such negative impact may be inappropriate, however, if, for example, the customer dispute information is factually impossible, clearly erroneous, or false. Regardless of the merit, associated persons have an incentive to remove customer dispute information from the CRD system and its public display through BrokerCheck.

An associated person, or a party on behalf-of an unnamed person, typically begins the process to remove customer dispute information from the CRD system by filing an expungement request in FINRA arbitration. FINRA is able to identify 6,928 requests to expunge customer dispute information in FINRA arbitration from January 2016 through December 2019 (the “sample period”). More than one expungement request can be made in a single arbitration, and multiple expungement requests may relate to the same arbitration, civil litigation or complaint if the dispute relates to more than one associated person.

Among the 6,928 expungement requests, 3,203 requests (46 percent) were made during a customer arbitration, and 3,725 requests (54 percent) were filed as a straight-in request.167 The 3,203 expungement requests made during a customer arbitration include 2,936 requests made during a non-simplified customer arbitration and 267 requests made during a simplified customer arbitration. The 3,725 requests to expunge customer dispute information disclosures filed as a straight-in request include 3,657 requests in arbitrations filed solely against a member firm or against a member firm and a customer, and 68 requests in arbitrations filed solely against a customer. In the 3,203 expungement requests made during a customer arbitration, the associated person was a named party in 1,504 of the requests (47 percent), and an unnamed party in 1,699 of the requests (53 percent).

Among the expungement requests during the sample period, FINRA is able to identify 82 requests to expunge the same customer dispute information in a subsequent arbitration.168 For purposes of this analysis, FINRA limited the identification of additional expungement requests to those requests where both the initial request and the subsequent request were made during the sample period. Additional subsequent expungement requests may have been filed during the sample period if the initial expungement request was made prior to the sample period (i.e., before January 2016). The 82 requests to expunge the same customer dispute information in a subsequent arbitration can, therefore, be considered a lower bound for the number of these requests during the sample period. The proposed rule change would foreclose associated persons from filing additional requests.

As of December 2019, 5,159 of the 6,928 expungement requests were made in an arbitration that closed. Among the 5,159 expungement requests, 2,255 requests (44 percent) were made during a customer arbitration and 2,904 requests (56 percent) were filed as a straight-in request. The 2,255 expungement requests made during a customer arbitration include 2,015 requests made during a non-simplified customer arbitration and 240 requests made during a simplified customer arbitration. The 2,904 requests filed as a straight-in request include 2,838 requests in arbitrations filed solely against a member firm or a member firm and a customer, and 66 requests in arbitrations filed solely against a customer. Under the proposed rule change, an associated person would be prohibited from filing a straight-in request against a customer.

An arbitrator or panel made a decision in arbitrations relating to 3,722 of the 5,159 requests in arbitrations that closed, and made no decision in arbitrations relating to the remaining 1,437 requests. A single arbitrator made a decision in arbitrations relating to 2,692 of the 3,722 requests, and a two- or three-person panel made a decision in arbitrations relating to the remaining 1,030 requests. For the customer arbitrations, the decision by an arbitrator or panel may relate to the arbitration, an expungement request, or both. For the straight-in requests, the decision would relate to the expungement request only.

In arbitrations where no decision on the merits of the customer case or an expungement request was made, the requests were either not eligible (as determined by the arbitrator or panel), withdrawn, or otherwise not pursued by the associated person or party that filed the request. As detailed in the next paragraph, the percentage of expungement requests that are recommended is higher when the arbitrator or panel receives information only from the associated person or other party requesting expungement. The arbitrator or panel is likely to receive information only from the party requesting expungement when (1) the customer arbitration does not close by award after a hearing [e.g., settles], or (2) an associated person files a straight-in request against a member firm. In both circumstances, the customer and his or her representative have little incentive to participate in an expungement hearing.

Among the 3,722 expungement requests in arbitrations where an arbitrator or panel made a decision, 2,874 resulted in an arbitrator or panel recommending expungement (77 percent). Among the 3,722 expungement requests, 976 requests were made during a non-simplified or simplified customer arbitration, and 2,746 requests were filed as a straight-in request. An arbitrator or panel recommended expungement in response to 595 of the 976 requests (61 percent) made during a customer arbitration. This includes 168 of the 369 requests (46 percent) made during a customer arbitration that closed by award after a hearing, and 427 of the 607 expungement requests (70 percent) made during a customer arbitration that closed by award without a hearing or other than by award. An arbitrator or panel recommended expungement in 2,279 of the 2,746 requests filed as a straight-in request (83 percent).169
A recommendation for expungement in FINRA arbitration is not the final step in the expungement process. If the arbitrator or panel recommends expungement, then the firm or associated person must confirm the arbitration award in a court of competent jurisdiction and serve the confirmed award on FINRA. As of July 2020, FINRA had removed 2,641 customer dispute information disclosures from the CRD system from the possible 2,874 requests (92 percent) in which an arbitrator or panel recommended expungement. Firms or associated persons may have not yet sought or obtained a court order for the remaining disputes.

Approximately one-third of the 2,641 customer dispute information disclosures (965, or 37 percent) that were expunged were submitted to the CRD system from 2014 to 2019. The 965 customer dispute information disclosures reflect three percent of the total number of customer dispute information disclosures submitted to the CRD system during this period of time (approximately 37,000). The remaining 1,676 customer dispute information disclosures were submitted to the CRD system prior to 2014. The number of customer dispute information disclosures expunged during the sample period that were submitted to the CRD system prior to 2014 suggests that associated persons may yet still expunge customer dispute information disclosures submitted to the CRD system during or prior to the sample period. The three percent of expunged customer dispute information disclosures should therefore be considered a lower bound for the rate at which customer dispute information disclosures are expunged.

A firm or associated person can also initiate a proceeding directly in a court of competent jurisdiction without first going through any arbitration proceeding. From January 2016 through December 2019, the expungement of 138 customer dispute information disclosures were sought directly in court. As of July 2020, court proceedings had concluded for 118 of those disclosures and proceedings remained ongoing for 20 disclosures. Among the 118 disclosures for which the court proceeding had concluded, 86 disclosures were expunged by a court and 32 disclosures were not ordered to be expunged. FINRA will challenge these requests in court in appropriate circumstances.

3. Economic Impact

A. Overview

The proposed rule change would codify the best practices described in the Guidance. The best practices include the prohibition on the filing of an expungement request if (1) an arbitration panel or court of competent jurisdiction previously denied a request to expunge the same customer dispute information, or (2) the customer dispute information arises from a customer's arbitration that has not concluded. Based on FINRA staff observations, arbitrators are generally believed to be adhering to these best practices and, therefore, codifying them should not result in new material economic impacts. Codifying the best practices in the Guidance should, however, clarify among parties how the practices should be applied, including what is permitted during the expungement hearing and the responsibilities of the parties and the arbitrator or panel when expungement is requested. Codifying the Guidance may also help inform customers more generally of the practices that the forum has implemented to encourage and facilitate customer participation in expungement hearings. In addition, parties may incur fewer costs from the codification of the practices, including the costs from actions or decisions (e.g., requesting expungement of customer dispute information that was previously denied in another arbitration or court) that would be denied by an arbitration panel pursuant to the Guidance.

The proposed rule change would also introduce other changes to the Codes that expand upon or that are not a part of the Guidance. In particular, the proposed rule change would restrict when an associated person is permitted to request expungement in FINRA arbitration. The proposed rule change would also require an arbitrator or panel from a customer arbitration that closes by award after a hearing, from a simplified customer arbitration, or a panel from the Special Arbitrator Roster to decide an expungement request. Finally, the proposed rule change would address the participation by associated persons and customers in expungement hearings. These changes may result in new material economic benefits and costs. These economic effects are discussed in further detail below.

B. Expungement Requests During Customer Arbitrations

The proposed rule change would set forth requirements for expungement requests during customer arbitrations. The proposed rule change would establish different requirements for non-simplified customer arbitrations and simplified customer arbitrations, and for an associated person named or unnamed to a (non-simplified or simplified) customer arbitration.

i. Expungement Requests by Named Associated Persons During Non-Simplified Customer Arbitrations

The proposed rule change would require an associated person named in a non-simplified customer arbitration to request expungement during the customer arbitration regarding the conduct that gave rise to the arbitration. Otherwise, the associated person would forfeit the opportunity to seek expungement of the same customer dispute information in any subsequent proceeding. The arbitrator or panel from a non-simplified customer arbitration would decide an expungement request if the arbitration closes by award after a hearing. The proposed rule change would help ensure that, if possible, the arbitrator or panel from a non-simplified customer arbitration, with input from all parties and access to all evidence, testimony and other documents, would decide an expungement request. These arbitrators or panels would be best situated to decide the related issue of expungement, and thereby help ensure that expungement recommendations and the customer dispute information contained in the CRD system and displayed through BrokerCheck reflect the conduct of associated persons.

An associated person named in a non-simplified customer arbitration may lose the ability to request expungement of the customer dispute information arising from the arbitration. A named associated person who does not request expungement during a non-simplified customer arbitration (or within the required time) would lose the ability to seek expungement relief. Because the named associated person may lose the ability to assess information that arises as a part of arbitration before they are required to request expungement,
associated persons may incur costs to preserve their right to request expungement by filing a request with or without the expectation that the arbitrator or panel would recommend expungement. FINRA believes, however, that the proposed rule change would mitigate these potential costs by providing associated persons a reasonable amount of time (i.e., within 45 days of receipt of the customer’s statement of claim if the request is included in an answer, or 30 days before the first scheduled hearing begins if the request is included in a pleading) during the arbitration to consider whether to file a request. Parties may also incur other, indirect costs if, for example, the deadline to request expungement during a non-simplified customer arbitration causes them to incur costs to expedite the filing of the expungement request or constrains their ability to engage in other activities (i.e., incur opportunity costs).

ii. Expungement Requests During a Non-Simplified Customer Arbitration That Close Other Than by Award or by Award Without a Hearing

Associated persons who request expungement during a non-simplified customer arbitration (either as a named party or as an unnamed party that consents to an on-behalf-of request) that closes other than by award or by award without a hearing (and would have otherwise had their expungement request decided as part of the customer arbitration) would incur additional costs to file a straight-in request.\(^{174}\) Associated persons may incur delays in receiving a decision on the request, and may incur additional legal fees and forum fees to resolve the straight-in request. The member firms with which the associated persons were associated at the time the customer dispute arose would also incur additional legal and forum fees. These costs would be imposed by the proposed rule change if the expungement requests would have otherwise been decided as part of the non-simplified customer arbitration. These costs would not be imposed by the proposed rule change, however, if regardless of the proposed rule change associated persons would have filed a straight-in request after the close of the non-simplified customer arbitration.

The additional costs for an associated person to resolve a straight-in request after the close of a non-simplified customer arbitration (that closes other than by award or by award without a hearing) may reduce the likelihood that the parties settle a customer arbitration.\(^{175}\) In particular, the associated person may factor the cost to resolve a separate straight-in request into the decision regarding whether to settle the arbitration or have the case decided by the arbitrator or panel to the arbitration. In addition, even if the parties continue to settle the dispute, the associated person may subtract the cost to resolve a separate straight-in request from the potential settlement amount.

An associated person (or a party on behalf of an associated person) who files a straight-in request would incur the minimum hearing session fee of $1,125 for each session the panel conducts to resolve the expungement request.\(^{176}\) The member firm at which the broker was associated at the time the customer dispute arose would also be assessed a minimum surcharge fee of $1,900 and a minimum process fee of $3,750. The fees associated with non-monetary claims would help ensure that costs to the forum for administering expungement requests are allocated as intended to the party or parties requesting expungement and, as applicable, the member firms at which the broker was associated at the time the customer dispute arose.

iii. Expungement Requests by Unnamed Persons in Non-Simplified Customer Arbitrations and by Named and Unnamed Persons in Simplified Customer Arbitrations

The proposed rule change would not require an unnamed person in a non-simplified customer arbitration, an associated person named in a simplified customer arbitration, or an unnamed person in a simplified customer arbitration to request expungement of the customer dispute information during the customer arbitration. Instead, similar to today, these associated persons may wait until after the customer arbitration has concluded to request expungement as a straight-in request.\(^{177}\) The option to wait until after the customer arbitration has concluded to request expungement is not a benefit created by the proposed rule change, but is instead currently permitted under the Codes. FINRA believes that an associated person who is not named in a non-simplified customer arbitration, or an associated person who is either named or not named in a simplified customer arbitration, should be able to seek expungement as a straight-in request and have their request decided by a panel from the Special Arbitrator Roster.

Associated persons who are not required and choose not to request expungement during the customer arbitration may also incur additional costs. Any incremental costs from not filing an expungement request during a customer arbitration, however, are not imposed by the proposed rule change. Instead, they are borne at the discretion of the parties who make the determination of when to request expungement, and are similar to the costs they would incur under the Codes today.

iv. Time Limit for Requesting Expungement in Simplified and Non-Simplified Customer Arbitrations

A named associated person or a party on-behalf-of an unnamed person would be required to request expungement in a simplified customer arbitration within 30 days of the date that FINRA provides notice of arbitrator appointment.\(^{178}\) A named associated person or a party requesting expungement on-behalf-of an unnamed person in a non-simplified customer arbitration would be required to request expungement no later than 30 days before the first scheduled hearing.\(^{179}\)

\(^{174}\) Associated persons who would otherwise request expungement as a counterclaim during an industry arbitration, which is rare, or who would otherwise intervene in a customer arbitration and have an expungement request decided during the arbitration, would instead be required to file a straight-in request under proposed Rule 13805. These associated persons and member firms with which the associated persons were associated would incur similar costs.

\(^{175}\) FINRA notes, however, that the determination regarding whether to settle a customer arbitration can depend on a number of factors, including the parties’ respective estimates of the additional costs they would incur to continue the customer arbitration, the value that the associated person places on expungement, the associated person’s estimate of the likelihood that he or she could obtain expungement in the customer case compared to in a straight-in request and the costs that they estimate the associated person would incur to pursue the straight-in request.

\(^{176}\) The associated person would not, however, incur an additional filing fee to file the straight-in expungement request. See infra Item II.C.8.

\(^{177}\) This requirement would help ensure that the panel from the Special Arbitrator Roster is aware of the outcome of the arbitration when deciding the request.

\(^{178}\) The proposed rule change would require that if the named associated person or party on-behalf-of an unnamed person requests expungement in a pleading other than an answer, the request must be filed within 30 days after the date FINRA provides the associated person with notice of arbitrator appointment, which is the last deadline provided to the parties in a simplified arbitration to submit additional documents before the case is submitted to the arbitrator. See proposed Rules 120806[d](1)(B)(i) and 120806[d](2)(B)(ii). See proposed Rules 12805(a)(1)(C)(i) and 12805(a)(2)(C)(iii). The proposed rule change also provides that FINRA would notify state securities regulators, in the manner determined by FINRA, of an expungement request within 30 days of receiving
Associated persons who do not request expungement within these time limits may incur additional costs that may include costs arising from delays in receiving a decision on the request and legal and forum fees. The member firms with which the brokers were associated at the time the customer dispute arose would also incur additional legal and forum fees. These costs would be imposed by the proposed rule change.

C. Time Limits for Filing Straight-In Requests

The proposed rule change would also set forth requirements for an associated person to file a straight-in request. For customer dispute information reported to the CRD system after the effective date of the proposed rule change, the proposed rule change would require an associated person to file a straight-in request within two years of a customer arbitration or civil litigation closing, or, if no customer arbitration or civil litigation, within six years from the initial reporting of the customer complaint to the CRD system.180

The proposed rule change would also require a two-year time limit for requests to expunge customer dispute information that arose from a customer arbitration or civil litigation that closed on or prior to the effective date of the proposed rule change or a six-year time limit to request expungement of customer dispute information arising from a customer complaint initially reported to the CRD system on or prior to the effective date of the proposed rule change.181 These time limits would begin from the effective date of the proposed rule change.

Arbitrators on the Special Arbitrator Roster would have the experience, qualifications and training necessary to decide straight-in requests. These time limits may increase customer participation in the proceedings and the likelihood that the panel from the Special Arbitrator Roster receives the relevant evidence and testimony to decide an expungement request. The time limits would help ensure that the expungement hearing is held close in time to the customer arbitration or civil litigation, or the events that led to the customer dispute information disclosure, and foreclose the option of an associated person to choose the timing of a straight-in request to potentially reduce the likelihood of customer participation. Similar to other amendments proposed herein, an increase in customer participation may provide a panel from the Special Arbitrator Roster with additional information to decide an expungement request and help ensure the accuracy of the customer dispute information contained in the CRD system and displayed through BrokerCheck.

These time limits, however, may constrain an associated person from filing a straight-in request.182 Associated persons who would otherwise delay the filing of a straight-in request may incur additional costs to file a straight-in request within the required time limits (e.g., opportunity costs, as described above). These time limits may also constrain an associated person from filing more than one expungement request in the same straight-in request. For example, associated persons may lose the ability to delay the filing of a straight-in request to expunge a complaint from a particular customer until other customers make additional complaints. If the filing of the straight-in request to expunge the complaint of the first customer would be time barred. Instead, an associated person may be required (as a result of the time limits) to file more than one straight-in request.

Associated persons who are restricted from including more than one request to expunge customer dispute information in the same straight-in request would incur additional legal and forum fees for each straight-in request or not seek expungement for all of the disclosures. The member firm at which the associated person was associated at the time the customer dispute arose would incur additional legal and forum fees if the associated person were to file multiple, separate straight-in requests.

D. Time Limits for Straight-In Requests—Quantitative Description

As discussed as part of the Economic Baseline, 3,725 expungement requests were filed as straight-in requests during the sample period. The following estimates demonstrate that the majority of these straight-in requests would not have been permitted under the proposed time limits, and associated persons may not have been able to include more than one expungement request in the same straight-in request. The estimates, however, do not take into account the potential change in the behavior of associated persons; associated persons would have incentive under the proposed amendments to file the straight-in requests within the time limits or otherwise lose the ability to make or file a request.183

Among the 3,725 expungement requests filed as a straight-in request, 1,140 requests followed a (non-simplified or simplified) customer arbitration (of the same underlying dispute). Two-hundred ninety of the 1,140 requests (25 percent) were filed as a straight-in request within the two-year time limit and would have been permitted under the proposed rule change. The remaining 850 requests (75 percent) were filed as a straight-in request after the two-year time limit and would not have been permitted. The median time from the close of the customer arbitration to the filing of the straight-in request was six years.

The 3,725 expungement requests filed as a straight-in request also include 2,585 requests that did not follow a (non-simplified or simplified) customer arbitration (of the same underlying dispute). Among the 2,585 requests, 813 requests (31 percent) were filed as a straight-in request within six years from the initial reporting of the disclosure to the CRD system and would have been permitted under the proposed rule change. The remaining 1,772 requests (69 percent) were filed as a straight-in request after the six-year time limit and would not have been permitted.

As discussed above, more than one expungement request can be made in a single arbitration, and the time limits may limit the ability of an associated person to include multiple expungement requests in the same straight-in request. The 3,725 expungement requests filed as a straight-in request relate to 1,778 arbitrations. Associated persons included more than one request to expunge customer dispute information in 810 of the 1,778 arbitrations. Under the proposed time limits, associated persons would not have been able to include all expungement requests in at least 225 of the 810 arbitrations.

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182 If the Commission approves the proposed rule change, FINRA expects that a number of associated persons would file a straight-in request to expunge customer dispute information reported to the CRD system prior to or soon after the effective date of the proposed rule change to help ensure that they are not constrained from seeking expungement because of the proposed time limitations.
183 The following estimates also do not take into account the number of straight-in requests of customer dispute information arising from a previous (non-simplified or simplified) customer arbitration which, under the proposed rule change, may have been decided as part of the customer arbitration.
E. Arbitrators or Panels Deciding Expungement Requests

The proposed rule change would require that the arbitrator or panel from a non-simplified customer arbitration decide expungement requests during the arbitration if the arbitration closes by award after a hearing. In addition, the proposed rule change would require the arbitrator from a simplified customer arbitration to decide expungement requests if there is a full hearing, or in a separate expungement-only hearing after the simplified arbitration closes if the arbitration is decided “on the papers” or in a special proceeding.

The proposed rule change would also require a randomly selected panel from the Special Arbitrator Roster to decide straight-in requests.

The proposed rule change is not structured to increase or decrease the likelihood that an arbitrator or panel recommends expungement in any individual hearing except as it relates to the merits of the request. The proposed rule change is structured, however, to place an arbitrator or panel in a better position to determine whether to recommend expungement of customer dispute information, and thereby help ensure the accuracy of the customer dispute information contained in the CRD system and displayed through BrokerCheck. Under the proposed rule change and in general, the arbitrator or panel that decides a request would either hear the full merits of the customer case or have additional training and qualifications when they are likely to receive information only from the party requesting expungement. In addition, panels from the Special Arbitrator Roster would be able to request evidence from the member firm at which the associated person was associated at the time the customer dispute arose.

The proposed rule change is also structured to reduce the potential influence of associated persons and member firms on the selection of the arbitrator or panel that decides an expungement request. First, a panel from the Special Arbitrator Roster would be randomly selected to decide a straight-in request, thereby decreasing the extent to which an associated person and member firm with which the associated person was associated at the time the customer dispute arose may together select arbitrators who are more likely to recommend expungement.

Second, the proposed rule change would foreclose the option for an associated person to withdraw a request and seek expungement of the same customer dispute information in a subsequent arbitration. Associated persons may exercise this option if they believe that they have a higher probability of obtaining an expungement recommendation with a different arbitrator or panel in another arbitration, and in particular if the associated person files a straight-in request against the member firm with which the broker was associated at the time the customer dispute arose. To the extent that the associated person and his or her employer’s interests are aligned and both seek to increase the likelihood that expungement is recommended, they would together be expected to select arbitrators who may be more likely to recommend expungement.

Though these proposed amendments are consistent with the regulatory intent to permit expungement in limited circumstances, it may decrease the likelihood that associated persons are able to obtain an award recommending expungement.

In general, under the proposed rule change, a three-person panel would consider and decide expungement requests during non-simplified customer arbitrations that close by award after a hearing and straight-in requests. Expungement decisions by a three-person panel may differ from expungement decisions by a single arbitrator. In addition, the decisions may differ depending on the arbitrators selected and the interaction among the arbitrators when deciding an expungement request. The extent to which a three-person panel would decide an expungement request differently than a single arbitrator, however, is not known. As discussed above, expungement requests may be complex to resolve, particularly straight-in requests where customers typically do not participate in the expungement hearing. Thus, having three arbitrators available to ask questions, request evidence and to serve generally as fact-finders in the absence of customer input would help ensure that a complete factual record is created to support the arbitrators’ decision in such expungement hearings.

F. Arbitrators or Panels Deciding Expungement Requests—Quantitative Description

As discussed as part of the Economic Baseline, 5,159 of the 6,928 expungement requests sought during the sample period were filed in an arbitration that closed. Among the 5,159 expungement requests, 4,521 requests (88 percent) would have required a panel from the Special Arbitrator Roster. The 4,521 requests include 2,456 expungement requests made during a non-simplified customer arbitration that closed by award without a hearing or other than by award, and 2,065 requests that were filed as a straight-in request but did not relate to a previous (non-simplified or simplified) customer arbitration.

An arbitrator or panel from a (non-simplified or simplified) customer arbitration would have been required to decide 590 of the 5,159 expungement requests (11 percent). The 590 expungement requests include 292 requests made during a non-simplified customer arbitration that closed by award after a hearing and straight-in requests. Expungement decisions by a three-person panel may differ from expungement decisions by a single arbitrator. In addition, the decisions may differ depending on the arbitrators selected and the interaction among the arbitrators when deciding an expungement request. The extent to which a three-person panel would decide an expungement request differently than a single arbitrator, however, is not known. As discussed above, expungement requests may be complex to resolve, particularly straight-in requests where customers typically do not participate in the expungement hearing. Thus, having three arbitrators available to ask questions, request evidence and to serve generally as fact-finders in the absence of customer input would help ensure that a complete factual record is created to support the arbitrators’ decision in such expungement hearings.

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award after a hearing. 240 expungement requests made during a simplified customer arbitration, and 58 requests filed as a straight-in request to expunge customer dispute information arising from a previous non-simplified customer arbitration that closed by award after a hearing.

Finally, a panel from the Special Arbitrator Roster, or an arbitrator from a simplified customer arbitration, would have been required to decide the remaining 48 arbitration requests that relate to customer dispute information arising from a previous simplified customer arbitration. The arbitrator or panel that would have decided the request is dependent on whether an associated person, or a party on-behalf of an associated person, would have requested expungement during the simplified arbitration.

G. Participation in Expungement Hearings

The proposed rule change would require an associated person to appear personally at an expungement hearing.191 This requirement would provide the arbitrator or panel the opportunity to ask questions of an associated person to better assess his or her credibility. An associated person would be permitted to cross-examine and seek information from customers who testify.192 This may provide associated persons with the opportunity to substantiate their arguments in support of their expungement request. Associated persons may incur additional costs to appear at an expungement hearing. The additional costs may depend on the method of appearance (i.e., by telephone, videoconference, or in person), which, under the proposed rule change, would be determined by the arbitrator or panel. For example, associated persons who would otherwise not appear in person may incur additional costs under the proposed rule change if they are so required. The additional costs include the time and expense to appear, and other direct and indirect costs (e.g., opportunity costs) associated with the associated person’s appearance.

The proposed rule change would also help encourage customer participation in an expungement hearing. As noted above, the proposed rule change would require that a named associated person request expungement during a non-simplified customer arbitration and that the arbitrator or panel decide the expungement request if the arbitration closes by award after a hearing. In addition, an expungement request during a non-simplified customer arbitration would be considered and decided by the arbitrator or panel from that arbitration.

Further, the proposed time limits for filing straight-in requests may increase customer participation during these arbitrations. The proposed rule change would also provide customers the option to appear at an expungement hearing using whichever method is convenient for them. The proposed rule change would also codify elements of the guidance that permit the customer to testify, cross-examine the associated person and other witnesses, present evidence at the hearing and make opening and closing arguments.193

H. Impact on Business and Professional Opportunities

As a result of the proposed rule change, associated persons may determine that the additional costs to seek expungement relief are higher than the anticipated benefits. In addition, although the proposed rule change is intended to help ensure arbitrators recommend expungement when appropriate as it relates to the merits of the request, an arbitrator or panel may be less likely to recommend expungement depending on the information that becomes available for the reasons described above. This may cause associated persons not to seek expungement where expungement is likely (or unlikely) to be recommended.

Associated persons who no longer seek, or are not able to expunge customer dispute information from the CRD system and its display through BrokerCheck, or are delayed in doing so, may experience a loss of business and professional opportunities. The loss of business and professional opportunities by one associated person, however, may be the gain of another. Associated persons who may benefit in this regard include those who still determine that the additional costs to seek expungement relief under the proposed rule change is less than the anticipated benefits and continue to seek expungement of customer dispute information, and other associated persons who do not have similar disclosures.

A firm or associated person can also initiate an expungement proceeding directly in a court of competent jurisdiction without first going through any arbitration proceeding. The proposed rule change may incent firms or associated persons to initiate an expungement proceeding directly in a court of competent jurisdiction without first going through any arbitration proceeding. For some firms and associated persons, the anticipated costs to first go through arbitration may be greater than the similar costs to proceed directly in a court of competent jurisdiction. Firms and associated persons who would otherwise first go through arbitration as a result of the proposed rule change may incur additional costs to seek expungement relief.

The number of firms or associated persons who would instead initiate an expungement proceeding directly in a court of competent jurisdiction is dependent not only on the additional costs under the proposed rule change, but the costs a firm or associated person would expect to incur in the different forums to initiate an expungement proceeding. This information is generally not available, and accordingly the potential effect of the proposed rule change on direct-to-court expungement requests is uncertain.

I. Other Economic Effects

Finally, the proposed rule change may have other marginal economic effects. First, the prohibition of a subsequent expungement request would decrease the potential inefficient allocation of resources resulting from a subsequent request that would have resulted in the same decision (i.e., denial) as the first. The resources of the forum allocated to the additional expungement request could instead be used for other claims or requests that were not previously adjudicated or for other purposes.194

Second, the proposed rule change may increase the efficiency of the forum by requiring that a party provide certain information when filing an expungement request. The information includes identification of the customer dispute information that is the subject of the request, and whether expungement of the same customer dispute information was previously requested.

193 Other amendments to the proposed rule change would also help encourage customer participation. For example, the proposed rule change would allow customers to be represented at an expungement hearing and thereby mitigate any potential concern they may have regarding a direct confrontation with the associated person. In addition, the proposed rule change provides that FINRA would notify the customer of the time and place of the expungement hearing. Customers would still retain the option to participate in the expungement hearing or provide their position on the expungement request in writing. The costs to participate would therefore be borne at the customers’ discretion.

194 The resources relate to the specific costs to administer the claim, as well as the overall attendant costs to administer the forum.
and, if so, how it was decided. This would increase the efficiency of the forum by enabling FINRA to identify and track a request through the expungement process, and by alerting arbitrators and FINRA to another expungement request of the same customer dispute information. The efficiency of the forum would also increase by requiring an unnamed person to consent to an on-behalf-of expungement request in writing. This would help ensure that an unnamed person is aware of the request and prevent another expungement request by the unnamed person of the same customer dispute information.

In addition, the proposed rule change may affect the value of the customer dispute information to describe the conduct of associated persons. The change in the value of the information depends on the merit of the disclosures that would have otherwise been expunged. The merit of these disclosures also depends on many factors which are difficult to predict. These factors include the incentive of parties to file an expungement request under the proposed rule change, the decisions by the arbitrator or panel to recommend expungement dependent on the information that is available, and the merit of the customer dispute information that would have otherwise been sought to be expunged.

As stated above, the proposed rule change is not structured to increase or decrease the likelihood that an arbitrator or panel recommends expungement in any individual hearing except as it relates to the merits of the request. The proposed rule change may, however, reduce the incentive for an associated person to request expungement even when warranted. The effect of the proposed rule change on the extent to which the customer dispute information available in the CRD system (and its public display through BrokerCheck) accurately describes the conduct of associated persons is, therefore, uncertain.

4. Alternatives Considered

Alternatives to the proposed rule change include amendments that were proposed in Notice 17–42. Notice 17–42 proposed to restrict when a party can file or serve an expungement request during a customer arbitration to 60 days before the first hearing session begins. Although 60 days would provide a customer with more time to address an expungement request, 60 days may further restrict a party from seeking expungement during a customer arbitration relative to the 30 days before the first scheduled hearing begins in the proposed rule change. FINRA believes that the proposed 30-day period would provide customers with enough time to address an expungement request, and FINRA with sufficient time to notify the states of the request. FINRA also believes that 30 days would reduce the potential that parties would lose their ability to file an expungement request during an arbitration.

Notice 17–42 also proposed that an arbitrator or panel find that the customer dispute information has “no investor protection or regulatory value,” and that there must be a unanimous rather than a majority decision by a panel to recommend expungement. These proposed amendments may increase the difficulty for an associated person to receive an expungement recommendation, and thereby deter an associated person from seeking expungement. After considering the comments, FINRA has determined not to propose that the panel must find “no investor protection or regulatory value” to recommend expungement. FINRA agrees with some commenters that the standard may, if codified into rule language, create confusion among arbitrators and the potential for inconsistent application among different arbitrators and panels.

A majority decision is also consistent with what is required for other decisions in customer and industry arbitrations. FINRA also believes that the overall proposal, coupled with the existing standards in FINRA Rule 2080, would be sufficient to help preserve in the CRD system information that is valuable to investors and regulators, while allowing associated persons to remove information that is inaccurate.

Another alternative to the proposed rule change includes different time limits for an associated person to file a straight-in request. Although shorter (longer) time limits may increase (decrease) customer participation in the proceedings and the likelihood that the panel from the Special Arbitrator Roster receives the relevant evidence and testimony to decide an expungement request, shorter (longer) time limits may further (less) constrain an associated person from filing a straight-in request or including more than one expungement request in the same straight-in request. FINRA believes that the time limits proposed herein would facilitate customer participation but also provide associated persons sufficient opportunity to file a straight-in request.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

In December 2017, FINRA published Notice 17–42, requesting comment on proposed amendments to the expungement process including establishing a roster of arbitrators with additional training and specific backgrounds or experience from which a panel would be selected to decide an associated person’s request for expungement of customer dispute information. The arbitrators from this roster would decide expungement requests where the customer arbitration is not resolved on the merits or the associated person files a straight-in request to expunge customer dispute information. FINRA received 70 comments in response to Notice 17–42.

A copy of Notice 17–42 is attached [sic] as Exhibit 2a. A list of comment letters received in response to Notice 17–42 is attached [sic] as Exhibit 2b and copies of the comment letters are attached [sic] as Exhibit 2c.

In general, individual commenters supported some aspects of the proposal and raised concerns with others. A summary of the comments and FINRA’s responses are discussed below.

1. Requirement To Request Expungement During a Customer Arbitration

In Notice 17–42, FINRA proposed that an associated person who is named as a party in a customer arbitration must request expungement during the arbitration or be prohibited from seeking to expunge the customer dispute information arising from the customer’s statement of claim during any subsequent proceeding under the Codes. NASAA and PIABA supported the proposed limitation. NASAA stated that the limitation would help ensure timelier expungement requests and help avoid requests made years after the underlying customer arbitration has closed. PIABA stated that it did not believe that requiring associated persons to request expungement during the customer arbitration would result in more expungement requests because the

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195 FINRA notes that in its Order approving NASD Rule 2130 (now FINRA Rule 2080), which describes the current findings that arbitrators must make to recommend expungement, the SEC stated that “it believes the proposal strikes the appropriate balance between permitting members and associated persons to remove information from the CRD system that holds no regulatory value, while at the same time preserving information on the CRD system that is valuable to investors and regulators.” See Securities Exchange Act Release No. 48933 (December 16, 2003) 68 FR 74667, 74672 (December 24, 2003) (Order Approving File No. SR–NASD–2002–164).

196 All references to commenters are to the comment letters as listed in Exhibit 2b.
rule proposal contained “heightened standards applicable to expungement requests” and a “clear process for requesting expungement following the close of the customer case,” which may cause “associated persons [to] be more deliberate in making expungement requests.”

Some commenters opposed the limitation for a variety of reasons. \(^{197}\) Cornell stated that it “could lead associated persons to request expungement in every dispute in order to preserve the right to request expungement.” Keesal stated that these additional expungement requests could result in increased expenses to associated persons and member firms and “could impede the goals of protecting investors and ensuring that FINRA arbitration remains an expedient and cost-effective forum.” Herskovits expressed a concern that an associated person “may be unaware of the important rights he is waiving by failing to file a request for expungement in the underlying arbitration.” Saretzky, responding to FINRA’s concern that customers and documents may be unavailable when an associated person files a separate expungement request years after the customer arbitration closed, stated that customers can be located through counsel or internet searches, and that securities industry rules mandate the retention of important customer and account records for several years. JonesBell and Behr stated that the requirement to request expungement during that arbitration or during any hearing. One commenter, Cornell, stated that this change would require that an associated person to enter an appearance in response to the complaint. In addition, FINRA notes that if the named associated person requests expungement, under the proposed rule change, the associated person would be required to appear at the expungement hearing.

The proposed amendments would also provide a detailed framework governing the expungement process, which should help ensure that both associated persons and customers are aware of their rights. FINRA acknowledges commenters’ concerns that the proposed limitation could potentially result in an increase in the number of expungement requests and their associated costs. To address this concern, as well as the related concern that the requirement could result in expungement requests by associated persons simply to preserve their right to request expungement, FINRA has modified the proposed rule to allow the associated person to make the request 30 days before the hearing in the customer arbitration. \(^{199}\) This should provide sufficient time during the customer arbitration for the associated person to evaluate whether an expungement request is warranted and help avoid unnecessary expungement requests.

2. Deadline To File Expungement Request During a Customer Arbitration

In Notice 17–42, FINRA proposed that an expungement request made in a pleading during a customer arbitration must be made no later than 60 days before the first hearing session begins. Three commenters opposed the proposal, stating that the 60-day filing deadline was an impractical or unnecessary restriction that could cause an associated person to miss the deadline and, therefore, an opportunity to file a request. \(^{200}\) These commenters suggested that the proposal retain the status quo, which allows an associated person to request expungement up to and during any hearing. One commenter, Keesal, supported a deadline of 60 days before the first scheduled hearing date, provided however, that the associated person “has appeared in [the] Underlying Customer Case.” Keesal stated that this would “ensure[ ] that all participants” were “on notice of the issues to be addressed and determined at the evidentiary hearing.” SIFMA stated that the proposed requirement “to file for expungement 60 days prior to the first scheduled hearing date” was impractical and would require the payment of expungement fees even though a large portion of cases settle within 60 days of the hearing.

After considering the comments, FINRA does not believe that it is necessary to require a 60-day filing deadline. Instead, the proposed rule change would require that an expungement request be filed no later than 30 days before the first scheduled hearing. \(^{201}\) This should provide the parties with sufficient case preparation time, as the expungement issues will overlap with the issues raised by the customer’s claim. If a named associated person seeks to request expungement after the 30-day filing deadline, the panel would be required to decide whether to grant an extension and permit the request. \(^{202}\) The purpose of the deadline is to provide the parties other than the associated person with sufficient notice that expungement will be addressed at the hearing.

In addition, FINRA has determined that requiring the party to request expungement at least 30 days before the first “hearing session,” which is typically the initial pre-hearing conference (“IPHC”) rather than the first hearing on the merits, may not provide the requesting party with sufficient time to make an informed decision about whether to request expungement. \(^{203}\) Therefore, FINRA has modified the proposal to require that an expungement request must be made 30 days before the first scheduled “hearing” begins to provide time for the requesting party to make a better-informed decision. \(^{204}\)

3. Panel From the Customer Arbitration

Decides Expungement Requests Where the Customer Arbitration Closes by Award After a Hearing

In Notice 17–42, FINRA proposed that if the customer arbitration closes by award, the panel from the customer arbitration would consider and decide the expungement request during the customer arbitration.

Some commenters disagreed with this aspect of the proposal and suggested

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\(^{197}\) See Behr, Cornell, Herskovits, JonesBell, Keesal and Saretzky.

\(^{198}\) See supra Item II.B.3.D., “Time Limits for Straight-in Requests—Quantitative Description.”

\(^{199}\) See supra Item II.A.1.[II.A.1.ii.a.i.,”Method of Requesting Expungement.”

\(^{200}\) See Behr, JonesBell and SIPMA.

\(^{201}\) See supra Item II.A.1.[II.A.1.ii.a.i.,”Method of Requesting Expungement.”

\(^{202}\) See supra note 37.

\(^{203}\) The term “hearing session” means any meeting between the parties and arbitrator(s) of four hours or less, including a hearing or a prehearing conference. See FINRA Rules 12100(p) and 13100(p). The IPHC is scheduled after the panel is appointed. During the IPHC, the panel will set discovery, briefing, and motions deadlines, schedule subsequent hearing sessions, and address other preliminary matters. The parties may agree, however, to forgo the IPHC. See generally FINRA Rules 12500 and 13500.

\(^{204}\) Under the Codes, a “hearing” means a hearing on the merits. See supra note 21.
that a panel selected from the Special Arbitrator Roster should decide all expungement requests, even if the customer arbitration was decided by an award.\textsuperscript{205} For example, PIABA stated that a panel from the Special Arbitrator Roster should decide the expungement request separate from the customer’s claim because the “decision a panel is asked to make with respect to expungement is different than deciding whether or not to find liability on a customer claim” and because it is “unfair to require a customer to participate in potentially lengthy expungement hearing that they did not ask for.” Grebenik stated that the expungement request should be evaluated separately by an independent panel because the arbitrator may “have bias” and “has heard comments and issues from the customer [about] the actual claim.” AdvisorLaw stated that all expungement requests should receive the “same level of review and consideration by a specially trained arbitration panel.”

Cornell expressed a concern that the proposed requirement could “transform hearings designed to determine the merits of a customer dispute into lengthy expungement hearings.” Cornell proposed, as an alternative, that the same panel from the customer arbitration make the expungement determination, but do so in a separate proceeding to avoid inconveniencing the customer.

Keesal questioned whether the proposed requirement that the panel from the customer arbitration decide the expungement request if the customer arbitration “closes by award” would require the panel to decide an expungement request if the cases closes as a result of an order dismissing the case.

In response to the comments, FINRA is clarifying that the panel from the customer arbitration would be required to decide the expungement request and include its decision in the award if the arbitration “closes by award after a hearing” instead of where the arbitration “closes by award.” FINRA believes that where the panel from the customer arbitration has heard the parties’ presentation of the evidence about the customer’s claim, that same panel is best situated to decide the expungement request. In addition, it would generally be more efficient and less costly for the panel from the customer arbitration to decide the expungement request in these circumstances. Although FINRA Rule 2080(b)(1) requires the panel to make a separate, different determination than its determination on the merits of the customer’s claim, the evidence offered with respect to both determinations should generally overlap. Accordingly, FINRA does not believe that it would overly burden the parties if, when the customer arbitration closes by award after a hearing, the panel must also decide the expungement request in addition to the merits of the customer’s claim.

4. Qualifications of Arbitrators on the Special Arbitrator Roster

In Notice 17–42, FINRA proposed that to qualify for the Special Arbitrator Roster, a public chairperson would be required to: (i) Have completed enhanced expungement training; (ii) be admitted to the practice of law in at least one jurisdiction; and (iii) have five years’ experience in litigation, federal or state securities litigation, administrative law, service as a securities regulator or service as a judge. Commenters generally supported the proposed requirements,\textsuperscript{206} but were split on whether the members of the Special Arbitrator Roster should be required to be attorneys.\textsuperscript{207} One commenter, Black, did not oppose the proposed qualifications but suggested that they would likely result in fewer eligible arbitrators for straight-in requests. PIABA stated that the Special Arbitrator Roster should be made up of attorneys because it would be difficult for FINRA, in some areas of the country, to alternatively fill the Special Arbitrator Roster with local chair-qualified arbitrators that had served on three arbitrations through award. PIABA also stated that arbitrators with legal training may be better equipped to make the distinction between the FINRA Rule 2080 grounds for expungement and deciding the merits of the underlying claim. Keeseal, in contrast, stated that there was no showing non-lawyers to decide straight-in requests made during the customer arbitration, but not brought as a stand-alone claim.

Some commenters also expressed concerns that the arbitrators on the Special Arbitrator Roster were not required to have securities industry experience.\textsuperscript{208} FSI stated that without this background “it may be difficult to appreciate whether information has regulatory significance or investor protection value.” AdvisorLaw stated that “[r]equiring all expungement arbitrators to have a minimum of five years’ experience with the financial services industry [would be] appropriate considering the complexity of expungement requests in cases involving customer dispute information.” In contrast, Public Citizen suggested that at least one FINRA employee who meets the requirements of the Special Arbitrator Roster be a member of every three-person panel that considers an expungement request.

After considering the comments, FINRA has determined not to propose requiring that the members of the Special Arbitrator Roster be attorneys; instead, they would be required to be public arbitrators who have evidenced successful completion of, and agreement with, enhanced expungement training, and have served as an arbitrator through award on at least four customer-initiated arbitrations.\textsuperscript{209} FINRA believes that the non-lawyers on its roster who meet these qualifications and complete enhanced expungement training should be appropriately knowledgeable and experienced to decide straight-in requests. The requirement that the arbitrators on the Special Arbitrator Roster be public arbitrators should help ensure that the arbitrators are free of bias. The requirement that they have served on four cases through to award would help ensure that the members of the Special Arbitrator Roster have the necessary knowledge and experience to conduct hearings in the forum.

\textsuperscript{205} See AdvisorLaw, Georgia State, Grebenik, PIABA, St. John’s, Tinkleberg and UNLV. In addition, St. John’s “strongly agree[d] with requiring associated or unnamed persons to wait until the conclusion of a customer’s case to file an expungement request.”

\textsuperscript{206} See, e.g., SIFMA (supporting the proposal, and stating that more highly qualified and trained arbitrators should lead to more efficient and fair process); NASAA (for the proposal, and stating that the extent to which the panels truly appreciate the nuanced regulatory issues related to expungement largely depended on the content and effectiveness of the proposed enhanced expungement training).

\textsuperscript{207} See AdvisorLaw, FSI, Gooch, Keesel, Osiason, Rodriguez and White (all opposing the requirement that members of the Special Arbitrator Roster be attorneys); But cf. Cornell, Georgia State, NASAA, PIABA, Schlein, SIFMA, St. John’s and Tinkleberg (all supporting the requirement).

\textsuperscript{208} See AdvisorLaw, Behr, FSI and JonesBell. Behr and JonesBell also criticized the proposal as allowing claimants’ attorneys “whose business is the ligation of customer complaints” to serve on the Special Arbitrator Roster. FINRA notes, however, that the proposal requires that arbitrators on the Special Arbitrator Roster be public arbitrators, and that FINRA’s definition of public arbitrators excludes, among other persons, those who devote 20 percent or more of their professional time to representing parties in disputes concerning investment accounts or transactions, or employment relationships within the financial industry. See FINRA Rules 12100(aa) and 13100(k); see also supra note 8.

\textsuperscript{209} See proposed Rule 13806(b)(2)(B). In addition, to qualify for the Special Arbitrator Roster, arbitrators must be chairpersons and, therefore, will have completed the training that arbitrators must complete before they can be added to the chairperson roster. See also supra note 80.
Although FINRA believes that a sufficient number of arbitrators on its roster would meet these additional qualifications, if the Commission approves the proposed rule change, FINRA would engage in efforts to recruit arbitrators for the Special Arbitrator Roster. FINRA notes that its Office of Dispute Resolution has embarked on an aggressive campaign to recruit new arbitrators, with a particular focus on adding arbitrators from diverse backgrounds, professions and geographical locations.\footnote{See Our Commitment to Achieving Arbitrator and Mediator Diversity at FINRA, https://www.finra.org/ arbitration-mediation/our-commitment-achieving-arbitrator-and-mediator-diversity-finra.} FINRA’s commitment and focus on this critical initiative have resulted in increases in under-represented categories of arbitrators.\footnote{See supra note 210.} FINRA believes its continued commitment to this important initiative will help the forum improve the quality, depth and diversity of its public chairperson roster.

5. Special Arbitrator Roster Decides Expungement Requests if the Customer Arbitration Closes Other Than by Award or by Award Without a Hearing

In Notice 17–42, FINRA proposed that if the customer arbitration closes other than by award (e.g., the parties settle the arbitration), the panel in that arbitration would not decide the associated person’s expungement request. Instead, the associated person would be permitted to file an expungement request as a new claim under the Industry Code against the member firm at which he or she was associated at the time of the events giving rise to the customer dispute.

The SEC Investor Advocate supported the proposal because FINRA’s data showed that where the arbitration case was not decided on the merits, the expungement rate was “simply too high for an extraordinary remedy.”\footnote{See supra Item II.A.1.[II]B.2.b., “Straight-in Requests and the Special Arbitrator Roster, Composition of the Panel.”} (emphasis in original). NASAA also supported the proposal, stating that “post-settlement expungement hearings often consist of a one-sided presentation of the facts” because “investors and their counsel have little incentive to participate after the customer’s concerns have been resolved.”\footnote{See Behr, Herskovits, JonesBell, Saretksy and SIFMA. Herskovits also stated that “[financial advisers] will respond to the proposed rule by filing a counterclaim or cross claim for expungement in the customer arbitration, thus preventing the customer arbitration from closing before a hearing is held on expungement or the [financial advisors’] other claims for relief.” FINRA notes, however, that under the proposed rule change, a request for expungement relief would not prevent a customer arbitration from closing.}

Some commenters disagreed with the proposal to require the associated person to file a new arbitration under the Industry Code if the customer arbitration closes other than by award, as inefficient or burdensome on associated persons.\footnote{See supra note 213.} As an alternative, FINRA suggested that the panel from the customer arbitration decide the request; but, to address FINRA’s concern for greater training and increased qualifications for those arbitrators determining expungement, FINRA suggested that the proposed rule change require that at least one arbitrator on every three-person panel be selected from the Special Arbitrator Roster at the inception of each customer arbitration.

Saretksy stated that associated persons should be able to name the customer, and that the “minor inconvenience” to the customer was outweighed by the harm to the associated person. PIABA stated that it would be “inappropriate” to name customers. St. John’s “support[ed] allowing the proposed expungement process to proceed without the customer having to be named a party to the request.”

Schlein expressed concerns that a former employing member firm may have “little or no economic incentive to cooperate in an expungement proceeding,” and that it “would also be difficult for the panel to elicit potentially relevant facts” where the “economic and reputational interests of the associated person and the employer are aligned.” Schlein also stated that an “aggrieved customer has no economic incentive to participate in an expungement proceeding that occurs only after the underlying case has concluded.” Schlein also expressed concern that expungement requests would be referred to the Special Arbitrator Roster even if the matter settled on the eve of hearing, when it may be more efficient and promote investor protection to require the existing panel to hear the expungement request. Schlein stated that “FINRA could ameliorate the possibility that a panel might receive one-sided information” by (i) providing the expungement panel with significant filings from the underlying customer dispute, (ii) permitting the panel to review the parties’ settlement papers and (iii) giving the associated person, firm, and the customer the right to provide the panel with transcripts of the underlying customer proceeding.

FINRA believes that where there has not been a hearing on the merits of the customer’s claim, the members of the Special Arbitrator Roster, who would be public chairpersons who have served on at least four customer arbitrations in which a hearing was held and received enhanced expungement training, would be better situated to decide expungement requests than the panel from the customer arbitration. FINRA does not believe that requiring the associated person to file a new arbitration under the Industry Code would unduly burden the associated person—instead of presenting evidence related to the expungement request to the arbitrators in the customer arbitration in a separate expungement hearing, they would instead present the evidence supporting the expungement request to a panel randomly selected from the Special Arbitrator Roster.

FINRA shares commenters’ concerns that the factual record could be less well-developed where a straight-in request is filed against a member firm and the associated person or member firm’s interests are aligned, or where the customer does not participate. FINRA does not believe, however, that the customer should be named as a respondent or be required to participate in an expungement proceeding after the customer’s claim has been resolved (e.g., after the claim is settled). Instead, the proposed rule change addresses concerns that straight-in requests filed against the member firm may be non-adversarial or lack customer participation by, among other things (i) requiring that straight-in requests be decided by three randomly selected public chairpersons with enhanced training and experience,\footnote{See supra Item II.A.1.[II]B.2.b., “Straight-in Requests and the Special Arbitrator Roster, Composition of the Panel.”} (ii) requiring the panel to review the settlement documents,\footnote{See proposed Rules 12805(c)(7) and 13805(c)(7).} (iii) granting the panel the explicit authority to request from the associated person, the member firm at which he or she was associated at the time the customer dispute arose or other party requesting expungement, any documentary, testimonial or other evidence that it deems relevant to the expungement request,\footnote{See proposed Rules 12805(c)(6) and 13805(c)(6).} and (iv) including provisions to encourage and facilitate customer participation in expungement hearings.\footnote{See supra Item II.A.1.[II]D.3., “Customer’s Participation during the Expungement Hearing.”}

In response to commenters’ concerns, FINRA has modified the language in the proposed rule change to require that a straight-in request be filed against the
member firm at which he or she was associated “at the time the customer dispute arose,” consistent with the language used in other FINRA rules, instead of “at the time of the events giving rise to the customer dispute.” 217

6. Three Randomly Selected Arbitrators Decide Straight-In Requests

In Notice 17–42, FINRA proposed that the NLSS would randomly select three public chairpersons to serve on the Special Arbitrator Roster who would decide the request for expungement, and that the first arbitrator selected would be the chairperson. The parties would not be permitted to agree to fewer than three arbitrators or to the use of pre-selected arbitrators. The associated person seeking expungement would not be permitted to strike any arbitrators, but would be able to challenge a selected arbitrator for cause.

PIABA and AdvisorLaw supported the proposed random selection of three arbitrators. PIABA stated that the random selection of three arbitrators would “reduce the risk of arbitrators being concerned about ruling against an associated person for fear they may not be selected for another panel.”

Other commenters opposed the proposed rule change. SIFMA expressed concerns that not permitting parties to rank and strike arbitrators would remove the parties’ involvement and input.218 SIFMA also stated that there was no compelling need to use three rather than a single arbitrator, and that the proposal would increase the financial burden on registered representatives seeking expungement. Walter stated that a single FINRA-qualified arbitrator with the special qualifications would be “more than qualified to make a determination as to expungement” and that “[h]aving to coordinate the schedules of three arbitrators will delay the processing and will impose unnecessarily high additional costs on all parties involved.” 219 Tinklenberg opposed the three-person panel requirement because of the associated costs. Baritz stated that the three-person panel requirement would increase expenses to associated persons and the “time necessary to rank and choose a panel,” and “significantly delay the process.”

Kessal opposed the random selection of three arbitrators as unfair to associated persons, and suggested that FINRA “randomly select a minimum of 12 proposed arbitrators to serve on an expungement case, from which the associated person and anyone else involved in the case can rank and strike the proposed panelists.” FINRA notes that since straight-in requests may be complex, may not be actively opposed by another party and the customer or customer’s representative typically does not appear at the hearing, having three arbitrators from the Special Arbitrator Roster available to ask questions and request evidence would help ensure that a complete factual record is developed to support the arbitrators’ decision. In addition, FINRA believes that requiring two out of three randomly selected public chairpersons with enhanced training and qualifications to agree that expungement is appropriate in straight-in requests should help FINRA maintain the integrity of its CRD records and ensure that expungement is recommended in limited circumstances and only when one of the FINRA Rule 20800(b)(1) grounds applies.

FINRA does not believe that selecting three rather than one arbitrator would overly burden the parties during the proceeding or result in undue delay. As the parties would not be permitted to rank or strike these arbitrators, this should shorten the average length of the proceeding.220 In addition, pursuant to FINRA Rule 13403, FINRA would send the lists generated by the NLSS to all parties at the same time, within approximately 30 days after the last answer is due, regardless of the parties’ agreement to extend any answer due date.

FINRA recognizes that the proposed random arbitrator selection process would limit party input on arbitrator selection. However, the arbitrators on the Special Arbitrator Roster would have the experience, qualifications and training necessary to conduct a fair and impartial expungement hearing in accordance with the proposed rules, and to render a recommendation based on a complete factual record developed during the expungement hearing.

217 See, e.g., FINRA Rules 12901(a)(1)(C) and 13903(b); see also Kessal.

218 SIFMA also proposed that “to preserve arbitrator neutrality and foster greater transparency,” FINRA make publicly available all training Arbitrators’ communications with arbitrators regarding expungement, and documents related to the addition, removal or exclusion of any arbitrators from the roster. FINRA notes that making such communications and documents publicly available could have a chilling effect on arbitrator recruitment and communications. FINRA does, however, make expungement training materials publicly available. See supra note 82.

219 See also Saretsky.

220 Under the Codes, the lists of ranked arbitrators must be completed and returned to the Director no more than 20 days after the date the Director sends the lists to the parties. See, e.g., FINRA Rules 12403(c)(3) and 13404. However, the parties may agree to extend the due date. See FINRA Rules 12105 and 13105.

221 See proposed Rule 13806(b)(4).

222 See NASAA, PIABA, The SEC Investor Advocate, St. John’s and UNLV.

223 See also UNLV.

224 See Behr, JonesBell and Kessal.
expungement request, regardless of how the simplified arbitration case closes (e.g., even if the case settles), FINRA believes that it is appropriate for the single arbitrator in a simplified arbitration case to decide expungement requests, regardless of how the underlying case closes, due to the lower monetary requirement and generally less complex nature of these cases. To address concerns that customers should not be required to participate in a hearing addressing expungement requests in simplified arbitrations, the proposed rule change would require arbitrators to hold a separate expungement-only hearing after the customer’s dispute is decided to consider the expungement request if the customer elects to have his or her claim decided on the papers or through an Option Two special proceeding. The arbitrator would be required to issue a subsequent, separate award in connection with the expungement-only hearing.

8. Fees That Parties Will Incur To File a New Claim Under the Industry Code To Request Expungement

Some commenters expressed concerns that if an associated person were required to file a separate claim under the Industry Code to request expungement after the customer arbitration closes other than by award, the member firm and associated person would be assessed the filing fee, member surcharge and process fees twice, in both the underlying customer arbitration and the separate straight-in request. SIFMA stated that this could increase the costs of expungement and have the “indirect effect of increasing the costs of settlement, potentially discouraging settlement in smaller cases due to the increased costs associated with expungement.”

FINRA believes that it is appropriate to assess the member surcharge and process fee for straight-in requests because they are separate arbitrations before a separate panel of specially trained arbitrators. The member firm, having not previously paid a member surcharge and process fee for the expungement request, would be assessed these fees when and if a straight-in request is filed. FINRA would not, however, assess a second filing fee when an associated person files a straight-in request if the associated person, or the requesting party if it is an on-behalf-of request, has previously paid the filing fee to request expungement of the same customer dispute information during a customer arbitration.

9. Arbitrators “Recommend” Rather Than “Grant” Expungement

In Notice 17–42, FINRA requested comment on whether to revise FINRA Rule 12805 and 13805 to state that the panel may “recommend” rather than “grant” expungement if the FINRA Rule 2080 standards are satisfied. Several commenters approved the revision as a clarifying change that would more accurately reflect the panel’s role in the expungement process. For example, PIABA stated that after the panel recommends expungement, under FINRA Rule 2080 the member or associated person “must obtain an order from a court of competent jurisdiction confirming the arbitration award containing expungement relief.”

FINRA believes that “recommend” more accurately captures the panel’s authority in the expungement process. Pursuant to FINRA Rule 2080, FINRA will only expunge customer dispute information after a court of competent jurisdiction enters an order approving it to do so. Accordingly, the proposed rule change would change the word “grant” to “recommend” in proposed Rules 12805 and 13805.

10. Unanimity of Decision

In Notice 17–42, FINRA proposed that to recommend expungement, a three-person panel of arbitrators would be required to agree unanimously to recommend expungement. Some commenters opposed the unanimity requirement as making it too difficult to obtain expungement or because it was inconsistent with the ability of a customer to prevail by a majority decision. SIFMA, for example, stated that the unanimity requirement would “impinge upon the fundamental fairness of the expungement process in providing an effective balance to the allegation-based complaint reporting regime and will have a significant impact on registered representatives’ ability to protect their livelihoods and reputations.”

Other commenters supported requiring a unanimous decision to recommend expungement. For example, PIABA stated that the unanimity requirement would help ensure that expungement was an extraordinary remedy that is only granted when it has no meaningful investor protection or regulatory value. The SEC Investor Advocate stated that the requirement would provide greater “assurance that only meritorious complaints are expuned,” and expressed hope “that this requirement will encourage brokers to only seek expungement when the underlying customer dispute information is meritorious.”

After considering the comments, FINRA has determined to allow arbitrators to recommend expungement through a majority decision, consistent with what is required for other decisions in customer and industry arbitrations. FINRA believes that requiring a majority of arbitrators to agree that expungement is appropriate should be sufficient to help preserve in the CRD system information that is valuable to investors and regulators, while allowing associated persons a reasonable mechanism to remove information that is inaccurate. FINRA notes, however, that if the SEC approves the proposed rule change, FINRA will continue to monitor the expungement process to determine if additional changes are needed.

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225 See proposed Rule 12800(e)(1).
226 See proposed Rule 12800(e)(1)(A).
227 See supra note 10.
228 See AdvisorLaw, Behr, Goccek, Hagenstein, Higgenbotham, Janney, JonesBell, Keesal, Leven, Mahoney, Saretsky, SIFMA, Smart, Speicher, Tinklenberg and White.
229 See also Wellington.
230 See supra note 10.
231 See AdvisorLaw, Behr, Goccek, Hagenstein, Higgenbotham, Janney, JonesBell, Keesal, Leven, Mahoney, Saretsky, SIFMA, Smart, Speicher, Tinklenberg and White.
11. No Investor Protection or Regulatory Value

In Notice 17–42, FINRA proposed to require that a panel find that customer dispute information has “no investor protection or regulatory value” to recommend expungement. Several commenters opposed the requirement.234 For example, Herskovits stated that the standard was vague and opened the possibility of inconsistent rulings among different panels. FSI stated that the proposal was “confusing as it is difficult to imagine a scenario where information that is false, clearly erroneous, factually impossible or did not involve the advisor, would have regulatory or investor protection value.”

SIFMA stated that the requirement was redundant and rigid of the current high standards in FINRA Rule 2080(b)(1), may have the effect of discouraging meritorious expungement claims, was already incorporated into the Guidance and would transform the traditional role of arbitrators as fact-finders and require them to make a policy determination in each case. Keesal stated that the change would unnecessarily complicate the expungement process to the detriment of associated persons with no corresponding investor protection value. Saretsky proposed that arbitrators instead be required to find that the customer dispute had no “reasonable” investor protection or regulatory value.

NASAA expressed a concern with the proposal because it would allow arbitrators, rather than regulators, to make the finding. The SEC Investor Advocate expressed the same concern, and suggested that FINRA provide a framework on how the standard should be interpreted and applied to avoid disparate interpretations and outcomes. Schloesser stated that arbitrators “should receive supplemental training on the proposed new standard,” and that FINRA should also “offer training or instructional materials to judges” who will be required to confirm an expungement award.

Other commenters supported the requirement.235 For example, PIABA suggested that arbitrators should be required to make the finding because in practice arbitration panels “often believe that the Rule 2080 standards are easily met” and “do not grasp the fact that” a claim may not be factually impossible or false even though a customer has not met his or her burden of proof for purposes of establishing liability or rebutting an affirmative defense. St. John’s stated that the proposed requirement would “help strengthen investor protection by improving confidence in the accuracy of the CRD system and BrokerCheck.”

Cornell stated that the requirement would allow the panel to look beyond the claim and at the associated person’s record as a whole, including other customer dispute information, which would protect public investors. Liebrader stated that “[t]oo many legitimate claims disappear from public view in the largely uncontested expungement arena.”

After considering the comments, FINRA has determined not to propose that the panel must find “no investor protection or regulatory value” to recommend expungement. FINRA agrees with some commenters that the standard may, if codified into rule language, create confusion among arbitrators and the potential for inconsistent application among different arbitrators and panels.236 FINRA also believes that the overall proposal, coupled with the existing standards in FINRA Rule 2080, would be sufficient to help preserve in the CRD system information that is valuable to investors and regulators, while allowing associated persons to remove information that is inaccurate.

12. Panel Must Identify One of the FINRA Rule 2080(b)(1) Grounds for Expungement

In Notice 17–42, FINRA clarified in proposed Rules 12805 and 13805 that the FINRA Rule 2080 grounds for expungement that the panel must identify to recommend expungement are the grounds stated in paragraph (b)(1) of FINRA Rule 2080. In response to Notice 17–42, PIABA supported clarifying “that an arbitration panel may not recommend expungement on grounds other than those set forth in Rule 2080.” Keesal, however, viewed FINRA’s proposal as “remov[ing] the arbitrator’s ability to grant expungement relief based on judicial or arbitral findings other than those listed in Rule 2080(b)(1).” 237

FINRA notes that in its Order approving NASD Rule 2310 (now FINRA Rule 2080), which describes the current findings that arbitrators must make to recommend expungement, the SEC stated that “it believes the proposal strikes the appropriate balance between permitting members and associated persons to remove information from the CRD system that holds no regulatory value, while at the same time preserving information on the CRD system that is valuable to investors and regulators.” See Securities Exchange Act Release No. 48933 (December 16, 2003) 68 FR 74667, 74672 (December 24, 2003) (Order Approving File No. SR–NASD–2002–166).

234 See Baritz, FSI, Goczek, Herskovits, Janney, Keesal, Saretsky, SIFMA and White.
235 See Cornell, Liebrader, PIABA, St. John’s and UNLV.
236 See also Baritz, compare SIFMA (stating that “FINRA already imposes high standards in order for arbitrators to recommend expungement.”) and that “FINRA Rule 2080(b)(1) requires a finding either that: (i) the claim or allegation is factually impossible or clearly erroneous; (ii) the registered person was not involved in the alleged sales practice violation, forgery, theft, misappropriation or conversion of funds, or (iii) the claim, allegation, or information is false”).
237 See Regulatory Notice 08–79 (December 2008) (stating that “[t]he arbitration panel must indicate which of the grounds for expungement under Rule 2080(b)(1)(A)-(C) serve as the basis for their expungement order, and provide a brief written explanation of the reasons for ordering expungement.”).
238 See Proposed Rules 12805(c)(8) and 13805(c)(8).
239 See AdvisorLaw, Barber, Baritz, Behr, Brookes, FSI, Glenn, Grebenik, Herskovits, Higgenbotham, JonesBell, Keesal, Leven, Saretsky, SIFMA, Smart, Speicher, Stephens and Walter.
that would become ineligible if the rule proposals were implemented.” 241 JonesBell and Behr stated that an associated person may be unaware that a member firm “has reported a customer complaint on his or her CRD.” 242 FSI stated that associated persons should have three years to file expulsion requests to provide them with time to assess how the information will impact their business, which may not be immediately apparent. Keesal stated that because customers may wait up to six years to file an arbitration claim under FINRA Rule 12206 after making a customer complaint, the proposed time limits would be unfair and would increase the frequency of requests, as the associated person would have to make a second expungement request if the customer complaint was later the subject of an arbitration claim. Saretksy stated that the time restriction was unnecessary because arbitrators are “free to weigh the evidentiary value (if any) of an associated person’s undue delay.” Herskovits stated that FINRA’s concern about document retention was “misplaced” because SEC and FINRA rules “generally mandate the preservation of most records for 3 to 6 years (and many firms preserve documents for longer periods of time).” Grebenik expressed concerns with the proposed time limits because there were “thousands of advisors who have customer disputes and do not know about the expungement process.”

Other commenters supported the time limits. 243 For example, UNLV stated that the proposed time limit would ensure “that relevant evidence is available and increases investors’ ability to participate.” In response to other commenters’ suggestion that brokers may not be aware of a customer complaint, Cornell stated that “public investors should not be penalized for the failure of firms to implement streamlined notification and recordkeeping procedures,” and that “it is not too much to ask that the associated person follow up as to disposition by the firm.”

PIABA “strongly support[ed] a definite cut-off date for requests for expungement,” and stated that a customer is “far more likely to participate in an expungement hearing when it takes place in close proximity to the resolution of the underlying arbitration proceeding.” PIABA also stated that a more stringent time limit would lead to higher quality evidence, which becomes less reliable and available with the passage of time. PIABA stated that when the arbitration results in an award, a shorter timeframe of 90 days is preferable because significant time will already have passed from the filing of the customer’s arbitration claim, and because 90 days matches the deadline to file a motion to vacate an arbitration award under the Federal Arbitration Act. PIABA also stated that, because member firms and associated persons control the date that information is reported in the CRD system, the time limit for customer complaints should run from the sooner of the date the firm initially reported the complaint in the CRD system or a month after the associated person receives notice of the complaint.

After considering the comments, FINRA believes that adjustments to the originally proposed time limitations are warranted to provide sufficient time for associated persons to determine whether to seek expungement of customer dispute information. Accordingly, FINRA has revised the proposal to provide for a two-year period to file an expungement request when a customer arbitration or civil litigation that gives rise to customer dispute information closes. 244 The two-year period would help ensure that the expungement hearing is held close in time to the customer arbitration or civil litigation, when information regarding the customer arbitration is available and in a timeframe that would increase the likelihood for the customer to participate if he or she chooses to do so. At the same time, it would allow the associated person time to determine whether to seek expungement.

For customer complaints where no customer arbitration or civil litigation gave rise to the customer dispute information, the proposed rule change would provide for six years from the date that the complaint was initially reported to the CRD system for the associated person to file the expungement request. 245 Six years would allow firms time to complete investigations of customer complaints and close them in the CRD system and for the complaints to evolve, or not evolve, into an arbitration. Thus, the revised proposal would help avoid unnecessary duplicative requests to expunge customer complaints that subsequently evolve into arbitrations or civil litigations, while providing reasonable time limits to encourage customer participation and help ensure the availability of evidence. The proposed six-year time limitation is also consistent with FINRA’s general eligibility rule, which provides that no claim shall be eligible for submission to arbitration under the Code where six years have elapsed from the occurrence or event giving rise to the claim. 246 The proposed rule change makes similar revisions to the time limits described in Notice 17-42 to seek to expunge customer dispute information that arose prior to the effective date of the proposed rule change. For customer dispute information arising from customer arbitrations or civil litigations that closed on or prior to the effective date of the proposed rule change, the expungement request would be required to be made within two years of the effective date of the proposed rule change. 247 For customer complaints initially reported to the CRD system on or prior to the effective date of the proposed rule change, where no customer arbitration or civil litigation gave rise to the customer dispute information, the expungement request would be required to be made within six years of the effective date of the proposed rule change. 248

14. Effect of Withdrawal of Expungement Request

In Notice 17-42, FINRA proposed that if the associated person withdraws an expungement request after the panel is appointed in a straight-in request, the case would be closed with prejudice, unless the panel decides otherwise. AdvisorLaw supported the proposal, stating that it would “create safeguards, and prevent an associated person from simply withdrawing their case and refiling in hopes of drawing a more favorable pool of randomly selected arbitrators.”

Under the proposed rule change, for expungement requests during customer arbitrations and straight-in requests, if the associated person withdraws or does not pursue the expungement request (or the party, with the written consent of the unnamed person, withdraws or does not pursue the request), the panel would be required to deny the expungement request with prejudice. 249 These requirements would foreclose the ability of associated persons withdrawing expungement requests to avoid having

241 See also AdvisorLaw (stating that providing six months where the customer arbitration closes on or prior to the effective date of the proposed rule change was unfair and creates an unjustifiable distinction between cases that close prior to the rules and those that close after).
242 See supra note 48.
243 See Cornell, Georgia State, PIABA, Public Citizen and Schlein.
244 See proposed Rule 13805(a)(2)(A)(iv).
245 See proposed Rule 13805(a)(2)(A)(iv).
246 See supra note 14.
247 See proposed Rule 13805(a)(2)(B)(i).
249 See proposed Rules 12205(a)(1)(D)(i), 12805(a)(2)(E)(i) and 12805(a)(4).
their requests decided by the panel, and then seeking to re-file the request and receive a new list of arbitrators and a potentially more favorable panel and decision."

15. Associated Person’s Appearance Required at the Expungement Hearing

In Notice 17–42, FINRA proposed that an associated person seeking to have his or her CRD record expunged would be required to appear at the expungement hearing either in person or by video conference. Five commenters supported the proposal, stating generally that this would allow the arbitrators to better assess the associated person’s demeanor and credibility. 250 UNLV also stated that requiring videoconferencing would carry minimal costs given its widespread availability at FINRA’s regional offices and other venues. NASAA stated that the broker should be required to appear in-person, “given the extraordinary relief the broker is seeking.” Georgia State also supported requiring an associated person to appear in person at the hearing, and stated that appearance by video conference should only “be permitted, if at all, in those simplified cases where a hearing did not take place.”

Six commenters preferred to allow the associated person to appear by telephone. 251 SIFMA, for example, stated that there appeared to be no basis for allowing customers, but not associated persons, to appear by telephone, and that the proposal would “greatly increase the cost of expungement through attendant travel costs and loss of productivity.” Three commenters stated that the arbitrators should decide the method of appearance. 252 White, for example, stated that telephonic testimony “might be acceptable in limited circumstances,” and suggested that “arbitrators can make this determination and the Rule should not limit their flexibility to do so.”

After considering the comments, the proposed rule change would allow the panel to determine the method of appearance by the associated person—by telephone, in person or by video conference. 253 As the associated person is requesting the permanent removal of information from his or her CRD record, FINRA believes the associated person should personally participate in the expungement hearing to respond to questions from the panel and those customers who choose to participate. Rather than restrict the method of appearance, the panel would have the authority to decide which method of appearance would be the most appropriate for the particular case. 254 FINRA believes that providing flexibility as to the method of appearance would encourage appropriate fact-finding by the arbitrators and generally strengthen the process.

16. Customer Notification

In Notice 17–42, FINRA proposed that when an expungement request is filed separately from the customer arbitration, FINRA would notify the parties from the customer arbitration or the customer who initiated the complaint that is the subject of the request about the expungement request. PIABA supported the proposed customer notification requirement. Georgia State recommended “additional notifications to the investor about the expungement hearing.”

The proposed rule change modifies the proposal in Notice 17–42 to add an additional notification to help ensure that customers receive timely notice of both the expungement request and the expungement hearing. The associated person would be required to serve all customers whose customer arbitrations, civil litigations and customer complaints gave rise to customer dispute information that is a subject of the expungement request with notice of the request by serving on the customers a copy of the statement of claim requesting expungement before the first scheduled hearing session is held. 255 The Director would then notify the customers of the time, date and place of the expungement hearing using the customers’ current address provided by the party seeking expungement. 256

17. Customer Participation During the Expungement Hearing

In Notice 17–42, FINRA proposed that, consistent with the Guidance, all customers in the customer arbitration or who filed a customer complaint would be entitled to appear at the expungement hearing. At the customer’s option, the customer could appear by telephone.

In response to Notice 17–42, PIABA and The SEC Investor Advocate stated that FINRA should codify all of the customer rights provided in the Guidance, including, for example, allowing the customer or their counsel to introduce documents and other evidence and to cross-examine the broker or other witnesses called by the broker seeking expungement. 257 FINRA agrees that the customer rights contained in the Guidance should be codified, as reflected in the proposed rule change. 258 In addition to incorporating the customer rights contained in the Guidance, the proposed rule change also clarifies that the customer may be represented and states that the customer may appear at the expungement hearing by telephone, in person, or by video conference. In addition, if a customer testifies, the associated person or other person requesting expungement would be allowed to cross-examine the customer. If the customer introduces any evidence at the expungement hearing, the associated person or party requesting expungement could object to the introduction of the evidence, and the panel would decide any objections. The proposed rule change would allow and encourage customers to participate fully in the expungement hearing, including providing the associated person with a reasonable opportunity to rebut evidence introduced by the customer. 259

18. State Notification

In response to Notice 17–42, NASAA requested “earlier notices to state regulators of an expungement request to better facilitate regulator involvement where appropriate.” 260 The proposed rule change provides that FINRA would notify state securities regulators, in the manner determined by FINRA, of the associated person’s expungement request within 30 days after receiving a complete request for expungement, so that the states are timely notified of the request. 261

19. Unnamed Persons

In Notice 17–42, FINRA proposed to codify the ability of a party in a customer arbitration to request expungement on behalf of an unnamed person. AdvisorLaw stated that it opposed the practice and suggested that FINRA prohibit it entirely as there

250 See Black, Carruso, Cornell, PIABA and UNLV.
251 See Baritz, Coccek, Grebenik, Keesal, SIFMA and Tinkenberg.
252 See AdvisorLaw, Robbins and White.
253 See proposed Rules 12805(c)(2) and 13805(c)(2).
254 See supra note 253.
255 See proposed Rule 13805(b)(1)(A); see also supra note 134.
256 See proposed Rule 13805(b)(2); see also supra note 137.
257 See also St. John’s.
258 See proposed Rules 12805(c) and 13805(c).
259 In response to the Notice 17–42, White stated that if the customer chooses to object to the expungement request, “it would be helpful if it was mandated that the customer participate in the hearing or file a substantive statement or brief opposing expungement.” Schlein stated that FINRA should consider requiring the associated person to “bear the cost of the customer’s attendance if the customer wishes to participate in person.” FINRA believes that these requirements would be unduly burdensome and, therefore, has determined not to propose them as requirements.
260 See also The SEC Investor Advocate.
261 See proposed Rules 12805(b) and 13805(b)(3).
would be an “inherent conflict” of interest for the firm’s counsel because the interest of the member (who is the counsel’s client) and the associated person rarely align. AdvisorLaw also suggested that the associated person’s consent may be compromised “in the likely scenario where the member firm is providing financial assistance for the legal representation, as the associated person may agree under financial duress.” NASAA supported codifying the practice, but noted that it would “require cooperation between firms and their associated persons” and that FINRA would have to develop “robust, mandated notification procedures.”

FINRA notes that under the proposed rule change, filing an on-behalf-of request would be permissible, not mandatory. In addition, FINRA would require the party and the unnamed person to sign a form consenting to the arbitration purposes of requesting expungement. The proposed amendments would not prevent an unnamed associated from filing an arbitration claim seeking expungement against a member firm for the sole purpose of seeking expungement of a customer complaint and have the request decided by the Special Arbitrator Roster. In response to Notice 17–42, NASAA stated that it objected to “expanding the scope of Rule 2080 to apply to all information related to non-arbitrated customer complaints.”

NASAA stated that today, the expungement process is used to expunge customer complaints that are not the subject of arbitration, but believed that this practice was “beyond the scope originally intended with the rules” and that codification would further embed a flawed process that does not afford regulators the ability to preserve information already considered to have regulatory value and provide investor protection. The SEC Investor Advocate also indicated that it did not believe that “now is the time to expand the Rule 2080 expungement process to claims that do not result in arbitration,” and that it would “prefer to see the results of the new process before introducing an entirely new class of complaints to the mix.”

FINRA notes that customer complaints have always been within the contemplated scope of FINRA Rule 2080. In proposing and adopting predecessor NASD Rule 2130, and in proposing to adopt FINRA Rule 2080 without material change, FINRA defined “customer dispute information” as including “customer complaints, arbitration claims, and court filings made by customers, and the arbitration awards or court judgments that may result from those claims or filings.”

The proposed amendments would continue to allow associated persons to file a claim in arbitration against a member firm for the sole purpose of seeking expungement of a customer complaint that is reported in the CRD system.

21. Application of Expungement Framework to Customer Complaints

In Notice 17–42, FINRA proposed to allow an associated person to file an arbitration against a member firm for the sole purpose of seeking expungement of a customer complaint and have the request decided by the Special Arbitrator Roster. In response to Notice 17–42, NASAA stated that it objected to “expanding the scope of Rule 2080 to apply to all information related to non-arbitrated customer complaints.”

NASAA stated that today, the expungement process is used to expunge customer complaints that are not the subject of arbitration, but believed that this practice was “beyond the scope originally intended with the rules” and that codification would further embed a flawed process that does not afford regulators the ability to preserve information already considered to have regulatory value and provide investor protection. The SEC Investor Advocate also indicated that it did not believe that “now is the time to expand the Rule 2080 expungement process to claims that do not result in arbitration,” and that it would “prefer to see the results of the new process before introducing an entirely new class of complaints to the mix.”

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The proposed amendments would continue to allow associated persons to file a claim in arbitration against a member firm for the sole purpose of seeking expungement of a customer complaint that is reported in the CRD system.

22. Other General Comments in Response to Notice 17–42

A. Personal Experiences With the Expungement Process

Some commenters opposed the proposal as set forth in Notice 17–42 because of their experiences with what they considered to be meritless customer arbitration claims. In addition, a number of commenters described their personal experiences with the customer complaint and expungement process or generally criticized the current process and the proposed rule change as unfair. FINRA acknowledges and appreciates the commenters’ concerns and has considered them in connection with the proposed rule change as a whole.

B. General Perspectives on the Proposed Rule Change

Some commenters also offered more general perspectives on the rule proposal as set forth in Notice 17–42. The SEC Investor Advocate, while generally supporting the proposed rule change, expressed a concern that the proposed amendments may cause brokers to seek to avoid the FINRA Rule 2080 process entirely, and instead request expungement directly in a court of competent jurisdiction.

FINRA notes that today, a broker can seek expungement by going through the FINRA arbitration process or by going directly to court. SIFMA stated that FINRA already has in place a robust set of rules and expanded guidance to safeguard the expungement process, and that there did not appear to be any empirical justification for the additional regulations contained in the proposal, such as that expungements are too numerous or are being improperly granted.

PIABA stated that FINRA should only promulgate rules that facilitate removal of customer dispute information from the CRD system in the most extraordinary of circumstances. NASAA supported the proposal as an “important first step” that “add[ed] beneficial requirements and limitations related to the procedure of expungement.”

FINRA appreciates the commenters’ differing perspectives. FINRA’s review suggests that the percentage of expungement requests that are...
recommended is higher when the arbitrator or panel receives information only from the associated person or other party requesting expungement.\textsuperscript{270} FINRA believes that the expungement process that would be established by the proposed rule change would help ensure that expungement is recommended in limited circumstances, while providing associated persons with a reasonable framework to seek expungement of information on their CRD records by establishing one or more of the grounds set forth in FINRA Rule 2080(b)(1).

C. Alternatives to the CRD Disclosure and Expungement Framework

Several commenters suggested alternatives to the current CRD disclosure and expungement framework.\textsuperscript{271} For example, Mahoney stated that where an arbitration panel renders an award denying a customer’s claims against an associated person, “the associated person should automatically have their CRD record expunged of all references to the complaint.” Mahoney also stated that FINRA should not subject associated persons who are not named in a customer complaint, but were determined by member firms to have been involved in the sales practice violation(s), to disclosure and expungement standards that “create an unprecedented rebuttable presumption of liability.”\textsuperscript{272} In contrast, St. John’s suggested that associated persons be prohibited from seeking expungement if there has been a finding of liability in the arbitration.

PIABA stated that although it supported the proposed rule change, expungement requests would be best handled separate from the arbitration and determined by FINRA itself rather than arbitrators. NASAA proposed further reform to the expungement process built around several principles including, for example, increased regulatory participation that allows for a regulatory determination regarding the merits of the expungement request.

FINRA appreciates the commenters’ suggestions. As indicated by the proposed rule change, FINRA believes that revising the current expungement process as set forth in the proposed rule change, particularly the establishment of a panel of arbitrators randomly selected from the Special Arbitrator Roster to consider and decide straight-

\textsuperscript{270}See supra Item II.B.2., “Economic Baseline.”
\textsuperscript{271}See Barber, Baumgardner, Burrill, Butt, Chepucavug, Commonwealth, Harmon, Harris, Mahoney, Penzell, PIABA, Stewart, Tinkenberg and Wellington.
\textsuperscript{272}See also FSI.
• Send an email to rule-comments@sec.gov. Please include File Number SR–FINRA–2020–030 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–FINRA–2020–030. 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 such filing also will be available for inspection and copying at the principal office of FINRA. 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–FINRA–2020–030 and should be submitted on or before October 22, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.277

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2020–21660 Filed 9–30–20; 8:45 am]

BILLING CODE 8011–01–P

Executive Order 13951—An America-First Healthcare Plan
Executive Order 13951 of September 24, 2020

An America-First Healthcare Plan

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. Purpose. Since January 20, 2017, my Administration has been committed to the goal of bringing great healthcare to the American people and putting patients first. To that end, my Administration has taken monumental steps to improve the efficiency and quality of healthcare in the United States.

(a) My Administration has been committed to restoring choice and control to the American patient. On December 22, 2017, I signed into law the repeal of the burdensome individual-mandate penalty, liberating millions of low-income Americans from a tax that penalized them for not purchasing health-insurance coverage they did not want or could not afford. Through Executive Order 13813 of October 12, 2017 (Promoting Healthcare Choice and Competition Across the United States), my Administration has expanded coverage options for millions of Americans in several ways. My Administration increased the availability of renewable short-term, limited-duration healthcare plans, providing options that are up to 60 percent cheaper than the least expensive alternatives under the Patient Protection and Affordable Care Act (ACA) and are projected to cover 500,000 individuals who would otherwise be uninsured. My Administration expanded health reimbursement arrangements, which have been projected by the Department of the Treasury to reach 800,000 businesses and over 11 million employees and to expand coverage to more than 800,000 individuals who would otherwise be uninsured. My Administration also issued a rule to increase the availability of association health plans for small businesses, which, upon implementation of the rule, are projected to cover up to 400,000 previously uninsured individuals for an average 30 percent less cost.

As set forth in the Economic Report of the President (February 2020), my Administration's expansion of health savings accounts will further help millions of Americans pay for health expenditures by allowing them to save more of their own money free from Federal taxation, and will especially help Americans with chronic conditions who now have more flexibility to enroll in plans that fit their complicated care needs and can be paired with a tax-advantaged account.

At the beginning of the current COVID-19 pandemic, my Administration acted to dramatically increase the accessibility and availability of telehealth services for Medicare beneficiaries, enabling millions of individuals to use these services. Pursuant to Executive Order 13941 of August 3, 2020 (Improving Rural Health and Telehealth Access), the Secretary of Health and Human Services will make permanent many of the new policies that improve the accessibility and availability of telehealth services. In addition, pursuant to that order, the Secretary of Health and Human Services and the Secretary of Agriculture will develop and implement a strategy to improve the physical and communications healthcare infrastructure available to rural Americans.

Through our State Relief and Empowerment Waivers, my Administration has given States additional health-insurance flexibility, which has expanded health-insurance coverage options for consumers and lowered costs for patients. These waivers allow States to move away from the ACA’s rigid
structure and are estimated to have lowered premiums by approximately 11 percent in Wisconsin, 20 percent in Minnesota, and 43 percent in Maryland. Due to actions my Administration took, like the State Relief and Empowerment Waivers, after years of dwindling choices and escalating prices, plan options for consumers increased and for 2019, for the first time ever, benchmark premiums actually decreased on Healthcare.gov. For 2020, the average benchmark premium dropped by nearly 4 percent.

After the prior Administration spent tens of billions of dollars creating electronic health records systems unable to accurately or effectively record and communicate patient data, my Administration has paved the way for a new wave of innovation to allow patients to safely send their own medical records to care providers of their choosing. My Patients over Paperwork initiative has cut red tape for doctors and nurses so they can spend more time with their patients, which the Centers for Medicare and Medicaid Services (CMS) within the Department of Health and Human Services (HHS) has estimated to save over 40 million hours of wasted time for providers and suppliers between 2017 and 2021.

(b) My Administration has been ceaseless in its efforts to lower costs to make healthcare more affordable for American patients.

Under my tenure, prescription drugs saw their largest annual price decrease in nearly half a century. For three consecutive years, we have approved a record number of generic drugs. The Council of Economic Advisers has estimated that these approvals saved patients $26 billion in the first 18 months of my Administration alone. As part of the Further Consolidated Appropriations Act, 2020, I signed into law the Creating and Restoring Equal Access to Equivalent Samples Act, which will pave the way for even more generic drugs and is projected to save taxpayers $3.3 billion from 2019 to 2029.

CMS has acted to offer Medicare beneficiaries prescription drug plans with the option of insulin capped at $35 in out-of-pocket expenses for a 30-day supply. We are also reducing Government payments to overcharging hospitals participating in the 340B Drug Pricing Program by instead paying rates that more accurately reflect the hospitals’ acquisition costs, which CMS estimated would save Medicare beneficiaries $320 million on copayments for drugs alone.

As a result of Executive Order 13937 of July 24, 2020 (Access to Affordable Life-Saving Medications), low-income Americans who receive care from a federally qualified health center will have access to insulin and injectable epinephrine at prices lower than ever before. Under Executive Order 13938 of July 24, 2020 (Increasing Drug Importation to Lower Prices for American Patients), my Administration will be the first to complete a rulemaking to authorize the safe importation of certain lower-cost prescription drugs from Canada. Pursuant to Executive Order 13939 of July 24, 2020 (Lowering Prices for Patients by Eliminating Kickbacks to Middlemen), my Administration is taking action to eliminate wasteful payments to middlemen by passing drug discounts through to patients at the pharmacy counter without increasing premiums for beneficiaries or cost to Federal taxpayers. And my Administration is taking action to ensure that Medicare patients receive the lowest price that drug companies offer comparable foreign nations through Executive Order 13948 of September 13, 2020 (Lowering Drug Prices by Putting America First).

As part of the Further Consolidated Appropriations Act, 2020, I also signed into law the repeal of the medical device tax, the annual fee on health-insurance providers, and the “Cadillac” tax on certain employer-sponsored health insurance, which threatened to dramatically increase the cost of healthcare for working families.

My Administration is transforming the black-box hospital and insurance pricing systems to be transparent about price and quality. Regardless of health-insurance coverage, two-thirds of adults in America still worry about the threat of unexpected medical bills. This fear is the result of a system
under which individuals and employers are unable to see how insurance companies, pharmacy benefit managers, insurance brokers, and providers are or will be paid. One major culprit is the practice of “surprise billing,” in which a patient receives unexpected bills at highly inflated prices from providers who are not part of the patient’s insurance network, even if the patient was treated at a hospital that was part of the patient’s network. Patients can receive these bills despite having no opportunity to select around an out-of-network provider in advance.

On May 9, 2019, I announced four principles to guide congressional efforts to prohibit exorbitant bills resulting from patients’ accidentally or unknowingly receiving services from out-of-network physicians. Unfortunately, the Congress has failed to act, and patients remain vulnerable to surprise billing.

In the absence of congressional action, my Administration has already taken strong and decisive action to make healthcare prices more transparent. On June 24, 2019, I signed Executive Order 13877 (Improving Price and Quality Transparency in American Healthcare to Put Patients First), directing certain agencies—for the first time ever—to make sure patients have access to meaningful price and quality information prior to the delivery of care. Beginning January 1, 2021, hospitals will be required to publish their real price for every service, and publicly display in a consumer-friendly, easy-to-understand format the prices of at least 300 different common services that are able to be shopped for in advance.

We have also taken some concrete steps to eliminate surprise out-of-network bills. For example, on April 10, 2020, my Administration required providers to certify, as a condition of receiving supplemental COVID–19 funding, that they would not seek to collect out-of-pocket expenses from a patient for treatment related to COVID–19 in an amount greater than what the patient would have otherwise been required to pay for care by an in-network provider. These initiatives have made important progress, although additional efforts are necessary.

Not all hospitals allow for surprise bills. But many do. Unfortunately, surprise billing has become sufficiently pervasive that the fear of receiving a surprise bill may dissuade patients from seeking appropriate care. And research suggests a correlation between hospitals that frequently allow surprise billing and increases in hospital admissions and imaging procedures, putting patients at risk of receiving unnecessary services, which can lead to physical harm and threatens the long-term financial sustainability of Medicare.

Efforts to limit surprise billing and increase the number of providers participating in the same insurance network as the hospital in which they work would correspondingly streamline the ability of patients to receive care and reduce time spent on billing disputes.

On May 15, 2020, HHS released the Health Quality Roadmap to empower patients to make fully informed decisions about their healthcare by facilitating the availability of appropriate and meaningful price and quality information. These transformative actions will arm patients with the tools to be active and effective shoppers for healthcare services, enabling them to identify high-value providers and services, and ultimately place downward pressure on prices.

My Administration has cracked down on waste, fraud, and abuse that direct valuable taxpayer resources away from those who need them most. My Administration implemented a “site neutral” payment system between hospital outpatient departments and physicians’ offices, to ensure Medicare beneficiaries are charged the same price for the same service regardless of where it takes place, which CMS estimates will save them approximately $160 million in co-payments for 2020. We also changed the rules to enable Government watchdogs to proactively identify and stop perpetrators of fraud before money goes out the door.

(c) My Administration has been dedicated to providing better care for all Americans.
This includes a steadfast commitment to always protecting individuals with pre-existing conditions and ensuring they have access to the high-quality healthcare they deserve. No American should have to risk going without health insurance based on a health history that he or she cannot change. In an attempt to justify the ACA, the previous Administration claimed that, absent action by the Congress, up to 129 million (later updated to 133 million) non-elderly people with what it described as pre-existing conditions were in danger of being denied health-insurance coverage. According to the previous Administration, however, only 2.7 percent of such individuals actually gained access to health insurance through the ACA, given existing laws and programs already in place to cover them. For example, the Health Insurance Portability and Accountability Act of 1996 has long protected individuals with pre-existing conditions, including individuals covered by group health plans and individuals who had such coverage but lost it.

The ACA produced multiple other failures. The average insurance premium in the individual market more than doubled from 2013 to 2017, and those who have not received generous Federal subsidies have struggled to maintain coverage. For those who have managed to maintain coverage, many have experienced a substantial rise in deductibles, limited choice of insurers, and limited provider networks that exclude their doctors and the facilities best suited to care for them.

Additionally, approximately 30 million Americans remain uninsured, notwithstanding the previous Administration’s promises that the ACA would address this intractable problem. On top of these disappointing results, Federal taxpayers and, unfortunately, future generations of American workers, have been left with an enormous bill. The ACA’s Medicaid expansion and subsidies for the individual market are projected by the Congressional Budget Office to cost more than $1.8 trillion over the next decade.

The ACA is neither the best nor the only way to ensure that Americans who suffer from pre-existing conditions have access to health-insurance coverage. I have agreed with the States challenging the ACA, who have won in the Federal district court and court of appeals, that the ACA, as amended, exceeds the power of the Congress. The ACA was flawed from its inception and should be struck down. However, access to health insurance despite underlying health conditions should be maintained, even if the Supreme Court invalidates the unconstitutional, and largely harmful, ACA.

My Administration has always been committed to ensuring that patients with pre-existing conditions can obtain affordable healthcare, to lowering healthcare costs, to improving quality of care, and to enabling individuals to choose the healthcare that meets their needs. For example, when the COVID–19 pandemic hit, my Administration implemented a program to provide any individual without health-insurance coverage access to necessary COVID–19-related testing and treatment.

My commitment to improving care across our country expands vastly beyond the rules governing health insurance. On July 10, 2019, I signed Executive Order 13879 (Advancing American Kidney Health) to improve care for the hundreds of thousands of Americans suffering from end-stage renal disease. Pursuant to that order, my Administration launched a program to encourage home dialysis and promote transplants for patients, and expects to enroll approximately 120,000 Medicare beneficiaries with end-stage renal disease in the program. We also have removed financial barriers to living organ donation by adding additional financial support for living donors, such as by reimbursing expenses for lost wages, child care, and elder care. HHS, together with the American Society of Nephrology, issued two phases of awards through KidneyX’s Redesign Dialysis Price Competition to work toward the creation of an artificial kidney.

My Administration has taken unprecedented action to improve the quality of and access to care for individuals with HIV, as part of our goal of ending the epidemic of HIV in the United States by 2030. HHS has awarded
at least $226 million to expand access to HIV care, treatment, medication, and prevention services, focused on 48 counties, Washington, DC, and San Juan, Puerto Rico, where more than 50 percent of new HIV diagnoses occurred in 2016 and 2017, as well as seven States with a substantial rural HIV rate. We secured a historic donation of a groundbreaking HIV preventive medication that is available at no cost to eligible patients.

My Administration has started a transformation in healthcare in rural America. This includes a new effort, pursuant to my directive in Executive Order 13941, to support small hospitals and health clinics in rural communities in transitioning from volume-based Medicare and Medicaid reimbursement, which has failed rural communities that struggle with a lack of patient volume, and toward value-based payment mechanisms that are tailored to meet the needs of their communities. We updated Medicare payment policies to address a problem in the program’s payment calculation that has historically disadvantaged rural hospitals, and released a Rural Action Plan to incorporate recommendations from experts and leaders across the Federal Government. We have also dedicated a special focus on improving care offered through the Indian Health Service (IHS) within HHS, including by creating the Office of Quality, implementing an increase in annual funding for IHS by $243 million from 2019 to 2020, and expanding nationwide IHS’s successful Alaska Community Health Aide Program.

My Administration has additionally demonstrated an incredible dedication to protecting and improving care for those most in need, including senior citizens, those with substance use disorders, and those to whom our Nation owes the greatest debt: our veterans.

I have protected the viability of the Medicare program. For example, on February 9, 2018, I signed into law the repeal of the Independent Payment Advisory Board, which would have been a group of unelected bureaucrats created by the ACA, designed to be insulated from the will of America’s elected leaders for the purpose of cutting the spending of this important program. On October 3, 2019, I signed Executive Order 13890 (Protecting and Improving Medicare for Our Nation’s Seniors), to modernize the Medicare program and continue its viability. According to CMS estimates, seniors have saved $2.65 billion in lower Medicare premiums under my Administration while benefiting from more choices. For example, the average monthly Medicare Advantage premium has declined an estimated 28 percent since 2017, and Medicare Advantage has included about 1,200 more plan options since 2018. New Medicare Advantage supplemental benefits have helped seniors stay safe in their homes, improved respite care for caregivers, and provided transportation, more in-home support services and assistance, and non-opioid pain management alternatives like therapeutic massages. Medicare Part D premiums are at their lowest level in their history, with the average basic premium declining 13.5 percent since 2016.

My Administration has directed unprecedented attention on the substance use disorder epidemic, with a focus on reducing overdose deaths from prescription opioids and the deadly synthetic opioid fentanyl. On October 24, 2018, I signed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, enabling the expenditure of billions of dollars of funding for important programs to support prevention and recovery. My Administration has provided approximately $22.5 billion from 2017 to 2020 to address the opioid crisis and improve access to prevention, treatment, and recovery services. We saw a 34 percent decrease in total opioids dispensed monthly by pharmacies between 2017 and 2019, an approximate increase of 64 percent in the number of Americans who receive medication-assisted treatment for opioid use disorder since 2016, and a 484 percent increase in naloxone prescriptions since 2017. Data show that drug overdose deaths fell nationwide for the first time in decades between 2017 and 2018, with many of the hardest-hit States leading the way.
Improving care for our Nation’s veterans has been a priority since the beginning of my Administration. On June 6, 2018, I signed the VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018, which authorized billions of dollars to improve options for veterans to receive care outside of Department of Veterans Affairs (VA) healthcare providers. Since taking effect, the VA estimates that more than 2.4 million veterans have benefited from more than 6.5 million referrals to the 725,000 private healthcare providers with which the VA is now working. On June 23, 2017, I signed the Department of Veterans Affairs Accountability and Whistleblower Protection Act of 2017 to hold our civil servants accountable for maintaining the best quality of care possible for our Nation’s veterans by giving the Secretary of Veterans Affairs more power to discipline employees and shorten an appeals process that can last years. On March 5, 2019, I signed Executive Order 13861 (National Roadmap to Empower Veterans and End Suicide) to ensure that the Federal Government leads a collective effort to prevent suicide among our veterans.

I have used scientific research to focus on areas most pressing for the health of Americans. On September 19, 2019, I signed Executive Order 13887 (Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health), recognizing the threat that pandemic influenza continues to represent and putting forward a plan to prepare for future influenza pandemics. To modernize influenza vaccines and promote national security and public health, HHS issued a 6-year, $226 million contract to retain and increase capacity to produce recombinant influenza vaccine domestically, and the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health within HHS, initiated the Collaborative Influenza Vaccine Innovation Centers program.

Investments my Administration has made in scientific research will help tackle some of our most pressing medical challenges and pay dividends for generations to come. This includes working to increase funding for Alzheimer’s disease research by billions of dollars since 2017 and a plan to invest more than $500 million over the next decade to improve pediatric cancer research. On December 18, 2018, I signed the Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act of 2018 to provide support for research into sickle cell disease, which disproportionately impacts African Americans and Hispanics, and to authorize programs relating to sickle cell disease surveillance, prevention, and treatment.

On May 30, 2018, I signed the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, which gives terminally ill patients the right to access certain treatments without being blocked by onerous Federal regulations.

In response to the COVID–19 pandemic, my Administration launched Operation Warp Speed, a groundbreaking effort of the Federal Government to engage with the private sector to quickly develop and deliver safe and effective vaccines, therapeutics, and diagnostics for COVID–19. On August 6, 2020, I signed Executive Order 13944 (Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States), to protect Americans through reduced dependence on foreign manufacturers for essential medicines and other items and to strengthen the Nation’s Public Health Industrial Base.

Taken together, these extraordinary reforms constitute an ongoing effort to improve American healthcare by putting patients first and delivering continuous innovation. And this effort will continue to succeed because of my Administration’s commitment to delivering great healthcare with more choices, better care, and lower costs for all Americans.

Sec. 2. Policy. It has been and will continue to be the policy of the United States to give Americans seeking healthcare more choice, lower costs, and
better care and to ensure that Americans with pre-existing conditions can obtain the insurance of their choice at affordable rates.

**Sec. 3. Giving Americans More Choice in Healthcare.** The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall maintain and build upon existing actions to expand access to and options for affordable healthcare.

**Sec. 4. Lowering Healthcare Costs for Americans.** (a) The Secretary of Health and Human Services, in coordination with the Commissioner of Food and Drugs, shall maintain and build upon existing actions to expand access to affordable medicines, including accelerating the approvals of new generic and biosimilar drugs and facilitating the safe importation of affordable prescription drugs from abroad.

(b) The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall maintain and build upon existing actions to ensure consumers have access to meaningful price and quality information prior to the delivery of care.

(i) Recognizing that both chambers of the Congress have made substantial progress towards a solution to end surprise billing, the Secretary of Health and Human Services shall work with the Congress to reach a legislative solution by December 31, 2020.

(ii) In the event a legislative solution is not reached by December 31, 2020, the Secretary of Health and Human Services shall take administrative action to prevent a patient from receiving a bill for out-of-pocket expenses that the patient could not have reasonably foreseen.

(iii) Within 180 days of the date of this order, the Secretary of Health and Human Services shall update the Medicare.gov Hospital Compare website to inform beneficiaries of hospital billing quality, including:

(A) whether the hospital is in compliance with the Hospital Price Transparency Final Rule, as amended (84 Fed. Reg. 65524), effective January 1, 2021;

(B) whether, upon discharge, the hospital provides patients with a receipt that includes a list of itemized services received during a hospital stay; and

(C) how often the hospital pursues legal action against patients, including to garnish wages, to place a lien on a patient’s home, or to withdraw money from a patient’s income tax refund.

(c) The Secretary of Health and Human Services, in coordination with the Administrator of CMS, shall maintain and build upon existing actions to reduce waste, fraud, and abuse in the healthcare system.

**Sec. 5. Providing Better Care to Americans.** (a) The Secretary of Health and Human Services and the Secretary of Veterans Affairs shall maintain and build upon existing actions to improve quality in the delivery of care for veterans.

(b) The Secretary of Health and Human Services shall continue to promote medical innovations to find novel and improved treatments for COVID–19, Alzheimer’s disease, sickle cell disease, pediatric cancer, and other conditions threatening the well-being of Americans.

**Sec. 6. General Provisions.** (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

THE WHITE HOUSE,
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Federal Register
Vol. 85, No. 191
Thursday, October 1, 2020

CUSTOMER SERVICE AND INFORMATION

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TABLE OF EFFECTIVE DATES AND TIME PERIODS—OCTOBER 2020

This table is used by the Office of the Federal Register to compute certain dates, such as effective dates and comment deadlines, which appear in agency documents. In computing these dates, the day after publication is counted as the first day. When a date falls on a weekend or holiday, the next Federal business day is used. (See 1 CFR 18.17)

A new table will be published in the first issue of each month.

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