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GOVERNMENT ACCOUNTABILITY OFFICE

4 CFR Part 21

Government Accountability Office, Administrative Practice and Procedure, Bid Protest Regulations, Government Contracts

AGENCY: Government Accountability Office.

ACTION: Final rule.

SUMMARY: This document amends the Government Accountability Office's (GAO) Bid Protest Regulations, promulgated in accordance with the Competition in Contracting Act of 1984 (CICA), to implement the requirements in sec. 1501 of the Consolidated Appropriations Act for Fiscal Year 2014, which was enacted on January 14, 2014. These amendments implement the legislation's direction to establish and operate an electronic filing and document dissemination system for the filing of bid protests with GAO. The amendments also include administrative changes to reflect current practice, to streamline the bid protest process, and to make clerical corrections.

DATES: This rule is effective: May 1, 2018.

FOR FURTHER INFORMATION CONTACT: Ralph O. White (Managing Associate General Counsel, *whitero@gao.gov*), Kenneth E. Patton (Managing Associate General Counsel, *pattonk@gao.gov*) or Jonathan L. Kang (Senior Attorney, *kangj@gao.gov*).

SUPPLEMENTARY INFORMATION:

Background

On April 16, 2016, GAO published a proposed rule (81 FR 22197) to amend its Bid Protest Regulations. The supplementary information included with the proposed rule explained that the proposed revisions to GAO's Bid Protest Regulations were promulgated in accordance with CICA, as the result of a statutory requirement imposed by the Consolidated Appropriations Act for 2014, Public Law 113–76, 128 Stat. 5 (Jan. 14, 2014). Section 1501 of this act directs GAO to establish and operate an electronic filing and document dissemination system, ''under which, in accordance with procedures prescribed by the Comptroller General—(A) a person filing a protest under this subchapter may file the protest through electronic means; and (B) all documents and information required with respect to the protest may be disseminated and made available to the parties to the protest through electronic means.'' Public Law 113–76, div. I, title I, sec. 1501, 128 Stat. 5, 433–34 (Jan. 17, 2014). The proposed rule advised that GAO was developing the system, which is called the Electronic Protest Docketing System (EPDS). As of the effective date of this final rule, EPDS will be the sole means for filing a bid protest at GAO (with the exception of protests containing classified information) and will enable parties to a bid protest and GAO to file and receive documents. Additional guidance for the use of EPDS is provided by GAO in the EPDS Instructions, which are available at *https://epds.gao.gov/login.*

In addition to directing GAO to establish and operate an electronic filing and document dissemination system, sec. 1501 of the Consolidated Appropriations Act for 2014 authorizes GAO to ''require each person who files a protest under this subchapter to pay a fee to support the establishment and operation of the electronic system under this subsection.'' Public Law 113–76, div. I, title I, sec. 1501, 128 Stat. 5, 434 (Jan. 17, 2014). The proposed rule advised that GAO will require persons filing a protest to pay a fee to file a protest through EPDS, and that GAO anticipates that the fee will be $350. Additional guidance regarding procedures for payment of the fee is available in the EPDS Instructions.

Finally, the proposed rule addressed other administrative changes to reflect current practice and to streamline the bid protest process.

Summary of Comments

GAO received a total of 34 timely comments by the closing date of May 16, 2016. GAO received 6 comments from federal agencies; 11 comments from businesses (including 2 comments from the same business on different dates), all of which were identified as small businesses; 2 comments from professional associations; 3 comments from law firms and consulting firms; and 12 comments from individuals or anonymous commentators. In adopting this final rule, GAO has carefully considered all comments received.

Electronic Protest Docketing System (EPDS)

Request for More Details

Seven commentators requested additional information as to how EPDS will function. For example, the commentators asked for information concerning how the implementation of EPDS will occur, how to pay the fee, how documents will be uploaded and distributed through EPDS, how agencies will be notified by GAO of the filing of a protest, and the security provisions for EPDS.

GAO response: The purpose of the proposed revisions to our regulations is to implement sec. 1501 of the Consolidated Appropriations Act for Fiscal Year 2014 and to make certain administrative changes to reflect current practice and to streamline the bid protest process. GAO has issued guidance regarding EPDS, including the transition to EPDS, at *https://epds.gao.gov/login.* Additional information regarding the procedures for using EPDS is available in the EPDS Instructions.

Classified Documents

GAO proposed to revise redesignated paragraph (g) of 4 CFR 21.1 to clarify how a document is ''filed'' under GAO's Bid Protest Regulations by specifying that EPDS will be the sole method for filing a document with GAO for a bid protest—with the exception of protests containing classified material, as explained in a sentence added to the revised paragraph (h) of 4 CFR 21.1. The revisions throughout this final rule reflect that all filings are presumed to be made through EPDS (with the exception of protests containing classified material), which will enable the parties and GAO to file and receive documents.

Two commentators suggested that the proposed rule at paragraph (h) of 4 CFR 21.1, which states that classified documents ''may not'' be filed through EPDS, should be revised to use more expressly prohibitive language.

GAO response: GAO agrees with the suggestion and will revise our regulations to state that documents with classified material ''shall not'' be filed through EPDS.

One commentator requested that GAO clarify that the prohibition on filing documents containing ''classified'' material does not refer to proprietary or source-selection sensitive information.

GAO response: GAO does not believe that the rule requires clarification, but affirms here that the term ''classified'' refers to information deemed classified by a United States government agency for national security reasons, and not to information that is proprietary or source-selection sensitive.

One commentator requested that we revise the rules to provide for alternative filing procedures for documents that contain classified material.

GAO response: As discussed above, the EPDS Instructions provide guidance regarding the use of EPDS. Consistent with current practice, the EPDS Instructions direct parties to contact GAO for guidance in filing documents that contain classified material.

Exclusive Use of EPDS

One commentator opposed the proposed rule in redesignated paragraph (g) of 4 CFR 21.1 that EPDS will be the sole means for filing documents in a bid protest. The commentator expressed concern that some documents may be unsuitable due to size or other formatting issues for electronic submission.

GAO response: GAO confirms that EPDS will be the sole means for filing documents in connection with a protest, with two exceptions: (1) Documents containing classified material, and (2) documents that, for reasons of size or format, are not suitable for filing through EPDS. The EPDS Instructions address the process for filing these two categories of documents.

Additional Corrections

The final rule makes additional minor corrections to paragraphs (c), (f), and (h) of 4 CFR 21.3 to reflect that documents must be filed through EPDS.

Filing Fee for Bid Protests

The proposed rule advised that GAO anticipates requiring persons filing a protest to pay a fee to file a protest through EPDS, which, as discussed above, will be the sole means for filing a bid protest at GAO. GAO advised that the anticipated fee will be $350. The EPDS Instructions address how persons filing a protest must pay the fee, and the circumstances under which the fee will apply. A fee will be required for filing a protest. At this time, additional fees will not be required for supplemental protests, requests for reconsideration, requests for recommendation for reimbursement of costs, or requests for recommendation on the amount of costs.

Support and Opposition to the Fee

GAO received six comments in favor of the proposed fee.

Five commentators advocated for a higher fee. One commentator proposed requiring an additional, potentially higher fee for each supplemental protest, because, in the commentator's view, protesters routinely supplement their protests with more arguments in an attempt to circumvent timeliness or engage in ''gamesmanship.'' One commentator proposed requiring protesters to file fees based on a graduated scale to discourage what the commentator viewed as ''serial'' or frequent protesters. Under the proposed graduated scale, a protester would be required to file higher fees if it files multiple protests during the course of a year, *e.g.,* a base fee for the first five protests, twice the base fee for more than five but less than eight protests, and four times the base fee for more than eight protests.

One commentator suggested that a fee of up to $1,000 would be appropriate, and that the overall goal of the fee should be the reduction of GAO's caseload, which would in turn permit GAO to issue decisions in fewer days. The same commentator suggested that a fee that was based on a percentage of the value of the procurement could be appropriate.

One commentator supported the fee and expressed the view that a fee could discourage ''frivolous'' protests.

Fifteen commentators opposed the proposed fee. All of the commentators opposed to the fee recommended that GAO either establish a lower fee for small businesses or waive the fee for small businesses.

Fourteen commentators opposed the fee on the basis that the fee creates a barrier to filing protests for small businesses, some of which stated that they lack the resources to pay the fee. In particular, one commentator argued that a $350 fee would make a protest economically infeasible for small businesses seeking the award of very small contracts.

Two commentators argued that because GAO is funded through appropriated funds a separate fee for bid protests is not warranted.

One commentator argued that a fee is not justified because GAO's bid protest forum is not staffed by judges, and that a fee should not be imposed in a manner similar to that imposed by a court. Another commentator argued that a fee is not justified because GAO does not have the same authority to enforce its decisions as a court.

One commentator argued that the fee is an attempt by GAO to discourage bid protests and thereby limit oversight over improper contracting actions by agencies. The commentator opposed the fee based on what the commentator views as GAO's failure to be an effective forum for the resolution of protests concerning small businesses, veteran-owned small businesses, and service-disabled veteran-owned small businesses. The commentator also opposed the fee on the basis that GAO failed to conduct adequate outreach to service-disabled veteran-owned small businesses—in particular, the commentator.

One commentator, while not expressly opposed to the fee, proposed a periodic reassessment of the fee to consider its impact on small business.

GAO response: GAO has considered all of the comments submitted regarding the proposed fee for filing a protest through EPDS. Additionally, GAO solicited views concerning the proposed fee from a number of business groups and associations that represent small businesses, including veteran-owned businesses, women-owned businesses, and minority-owned businesses. Further, although GAO is not subject to the Administrative Procedures Act, GAO voluntarily issued the proposed rule (81 FR 22197, Apr. 16, 2016) and invited comments.

As discussed in the proposed rule, sec. 1501 of the Consolidated Appropriations Act for 2014 directs GAO to establish and operate an electronic filing and document dissemination system, and authorizes GAO to ''require each person who files a protest under this subchapter to pay a fee to support the establishment and operation of the electronic system under this subsection.'' Public Law 113–76, div. I, title I, sec. 1501, 128 Stat. 5, 434 (Jan. 17, 2014). GAO derived the $350 fee using a methodology that took into account development costs for EPDS, estimates of hosting and maintenance costs, estimates of future bid protest filings, and a recovery period for development costs of approximately seven years.

GAO does not intend for the fee to discourage or reduce the number of protests. Rather, the proposed fee will cover the costs of establishing and operating EPDS. GAO does not agree with the proposals to charge a fee that

is higher than necessary to address the costs of EPDS or for the purpose of discouraging protests. With regard to a lower fee or fee waiver for small businesses, GAO has concluded that the anticipated fee of $350 is appropriate given the costs of the system. Additionally, GAO has concluded that the interest of administrative efficiency supports imposition of a uniform fee for all protests.

GAO will monitor the fee to ensure that it is properly calibrated to recover the costs of establishing and maintaining the system. Any adjustment to the fee based on the review will reflect changes in the costs of EPDS, as is consistent with the statutory direction.

Other Comments on the Fee

In addition to the comments regarding the requirement for a fee and the amount of the fee, GAO received six additional comments.

One commentator proposed that the requirement to pay a fee be expressly incorporated into 4 CFR 21.1, and that the regulation specify that failure to pay the fee will result in dismissal of a protest.

GAO response: GAO believes that the proposed rule makes clear that filing protests through EPDS is mandatory, other than classified protests, and GAO has advised that filing a protest through EPDS will require a fee. The EPDS Instructions provide additional guidance for the use of EPDS. GAO confirms that EPDS will not permit the filing of a protest without confirmation of payment. GAO also confirms that the filing of classified protests will also require payment of a fee.

Three commentators recommended that protesters be automatically refunded or reimbursed the fee if GAO sustains a protest.

GAO response: GAO does not agree that the fee should be automatically reimbursed by GAO if a protest is sustained. Instead, paragraph (d) of 4 CFR 21.8 provides that, if GAO sustains a protest, GAO may recommend that the agency reimburse the protester's costs of pursuing its protest. Additionally, paragraph (e) of 4 CFR 21.8 provides that, where an agency takes corrective action in response to a protest, the protester may request that GAO recommend that the agency reimburse the protester's costs of pursuing its protest. Fees will be reimbursable costs of pursuing a protest in the event GAO recommends that the agency reimburse protest costs.

Two commentators proposed that protesters be automatically refunded or reimbursed the fee if an agency takes corrective action in response to a protest.

GAO response: GAO does not agree that the fee should be automatically reimbursed by GAO if an agency takes corrective action in response to a protest. Instead, paragraph (e) of 4 CFR 21.8 provides that, if an agency decides to take corrective action in response to a protest, the protester may request that GAO recommend that the agency reimburse the protester's costs of pursuing the protest. Fees will be reimbursable costs of pursuing a protest in the event GAO recommends that the agency reimburse protest costs.

Filing a Protest

One commentator asked whether, in light of the requirement to file all documents with GAO through EPDS, protesters will continue to be required to provide a copy of the protest to the contracting officer, as required by paragraph (e) of 4 CFR 21.1.

GAO response: GAO did not revise the requirement to provide a copy of the protest to the contracting officer, as required by paragraph (e) of 4 CFR 21.1. GAO believes that this requirement, which is separate from the requirement to file documents with GAO through EPDS, remains an important requirement so that contracting officers are provided prompt notice of protests, which enables them to meet their obligations to notify interested parties, as required by Federal Acquisition Regulation section 33.104(a)(2) and paragraph (a) of 4 CFR 21.3.

One commentator requested that redacted versions of protests should be posted in EPDS in a manner that is available to the public.

GAO response: EPDS does not allow access to documents, redacted or otherwise, to non-parties.

Time for Filing

GAO proposed to revise paragraph (a) of 4 CFR 21.2 to clarify that where a basis for challenging a solicitation becomes known after the solicitation's closing date, but the solicitation does not establish a new closing date, the protest must be filed within 10 days of when the protester knew or should have known of that basis—regardless of whether the time period for filing other protest claims was ''tolled'' because a required debriefing had been requested. The revision was proposed to address a conflict as to which of our timeliness rules—21.2(a)(1) or 21.2(a)(2)—takes precedence where a solicitation impropriety becomes apparent after proposals have been submitted, but there is no opportunity to submit revised proposals. Our Office addressed this issue in two decisions: *Protect the Force, Inc.—Reconsideration,* B–411897.3, Sept. 30, 2015, 2015 CPD ¶ 306, and *Armorworks Enterprises, LLC,* B–400394, B–400394.2, Sept. 23, 2008, 2008 CPD ¶ 176. The revision as proposed makes 4 CFR 21.2(a)(2) consistent with the policy outlined in those decisions.

One commentator opposed the proposed revision to paragraph (a)(2) of 4 CFR 21.2 and argued that the policy established in the two decisions should be reversed. The commentator argued that allowing protests concerning this type of solicitation impropriety to be ''tolled'' until after a required and requested debriefing has been provided would avoid the possibility of a protester with ''mixed'' protest claims (*i.e.,* claims of an alleged solicitation impropriety as well as claims concerning the source selection) from being required to file two separate protests.

GAO response: GAO believes the revision is necessary to reflect our decisions and to avoid the conflict in the current rules. As an initial matter, the circumstance described by the commentator arises in exceedingly few protests. In any event, and as discussed in the two decisions that address this issue, there is sound policy underlying the proposed revision. Namely, the revision advances the principle that allegations of solicitation improprieties should be resolved as early as possible in the procurement process in order to promote fairness and efficiency. Further, adopting the policy advocated by the commentator could result in protesters and agencies unnecessarily expending time and resources on actions—such as preparing a protest concerning a source selection decision, in the protester's case, and preparing and providing debriefings, in the agency's case—in instances where there is merit in the allegation regarding the solicitation impropriety. For these reasons, we decline to eliminate the revision as requested by the commentator.

Communication Among Parties

GAO proposed to revise paragraph (a) of 4 CFR 21.3 to require that parties to a protest provide copies of all protest communications ''to the agency and to other participating parties'' either through EPDS or email.

Three commentators expressed concern that the proposed revision would require parties to copy all other parties on all exchanges concerning the protest, including strategy or settlement communications.

GAO response: The proposed revision to paragraph (a) of 4 CFR 21.3 was not intended to prohibit the parties from engaging in communications that do not involve GAO, or communications between some, but not all parties. Rather, the rule was intended to update the current rule to include EPDS. The current rule requires all parties to be copied on all protest communications, which, in practice, means that when a party communicates with GAO, it must copy the other parties. To avoid confusion, GAO will revise the final rule to provide that parties must copy all other parties on communications with GAO.

Two commentators requested clarification as to how GAO will communicate with parties after the implementation of EPDS.

GAO response: As discussed above, the EPDS Instructions provide guidance regarding the use of EPDS. EPDS will provide email notification to parties of communications by GAO to the parties transmitted through EPDS. GAO also anticipates that some communications to the parties will continue to be made through email and telephone, as appropriate.

Additional Documents

GAO proposed to revise paragraph (c) of 4 CFR 21.3 to clarify that if the fifth day for filing the agency's required response to a protester's request for documents falls on a weekend or federal holiday, the response shall be filed on the last business day that precedes the weekend or federal holiday.

Calculating the Due Date

One commentator expressed support for the revision to paragraph (c) because it avoids a potential ambiguity as to the due date for the agency's response.

One commentator objected to the revision to paragraph (c) because it results in less time for agencies to prepare their responses to document requests and allows protesters more time to object to an agency's list of documents to be filed.

GAO response: GAO believes that a revision to the date for the agency's response is required due to a potential ambiguity when the due date falls on a weekend or federal holiday. The resolution of the ambiguity necessarily results in either a longer or shorter time for agencies to respond. GAO concludes that a potentially shorter time for the agency's response, and potentially longer time for the protester to identify concerns or objections regarding the agency's response, is consistent with our statutory obligation to resolve protests within 100 days.

Filing Before the Due Date

One commentator suggested that the requirement to file an agency's response ''on the last business day . . .'', should be revised to require filing ''by the last business day . . .'', to reflect an agency may file its response earlier.

GAO response: GAO agrees that the use of the term ''by,'' rather than ''on'' is appropriate and will revise paragraph (c) of 4 CFR 21.3 in the final rule to reflect this change.

Submission of the Agency Report

One commentator expressed the view that paragraph (d) of 4 CFR 21.3, which requires the agency report to ''include'' a contracting officer's statement, inadvertently suggests that the memorandum of law is part of the contracting officer's statement.

GAO response: Although this language was not proposed for revision, and does not appear to have caused confusion for agencies in the preparation of their agency reports, GAO agrees that placing the phrase ''including a best estimate of the contract value'' in parentheses avoids any implication that the contracting officer is responsible for preparing a memorandum of law. This revision is reflected in the final rule.

One commentator objected to the revision to paragraph (d) of 4 CFR 21.3, which currently requires the agency report to include a copy of the protest. The commentator argued that the protest is a relevant document that should be included in the report.

GAO response: We believe that inclusion of a copy of the protest is no longer required because this document will already have been filed through EPDS. This revision is reflected in the final rule.

Protective Orders

Filing Redactions

GAO proposed to redesignate paragraph (b) of 4 CFR 21.4 as paragraph (c), redesignate paragraph (c) as paragraph (d), redesignate paragraph (d) as paragraph (e), and add a new paragraph (b). New paragraph (b) provides that when parties file documents that are covered by a protective order, the parties must provide copies of proposed redacted versions of the document to the other parties within 1 day after the protected version is filed. Proposed redacted versions of documents should not be filed through EPDS; rather, the party responsible for preparing the proposed redacted version of the document should provide the document to the other parties by email or facsimile. New paragraph (b) provides that, where appropriate, the exhibits to the agency report or other documents may be proposed for redaction in their entirety. Additionally, new paragraph (b) provides that the party that files the protected document must file through EPDS within 5 days a final, agreed-to redacted version of the document. New paragraph (b) also directs the parties to seek GAO's resolution of any disputes concerning redacted documents.

Five commentators expressed concern that requirements to prepare and review proposed and final redacted versions of documents will place a burden on parties because of the resources required to prepare and approve the redactions. One commentator argued that a requirement to prepare redacted versions of all documents filed under a protective order would be inconsistent with GAO's statutory mandate under CICA to provide for the inexpensive resolution of bid protests.

Two commentators expressed the view that the ''current practice'' for parties filing protected documents is for the parties to negotiate among themselves as to which documents should remain under the protective order in their entirety and which documents should be redacted for release outside the protective order. These commentators suggested that the proposed rule in new paragraph (b) be revised to allow the parties ''flexibility'' in deciding which documents to redact. One commentator expressed concern that the requirement that the agency prepare redacted versions that inform pro se parties will be burdensome. Another commentator expressed specific concern with regard to pro se intervenors where there is a protester represented by counsel admitted to a protective order.

GAO response: Paragraph 2 of GAO's standard protective order requires parties to file proposed redacted versions of every document marked protected. GAO recognizes, however, that the practice among parties in many protests is to agree not to prepare redacted versions of all documents. GAO also recognizes that preparation of redacted versions of documents requires resources on the part of the parties that prepare them and on the part of the other parties who must review them. GAO will revise new paragraph (b) of 4 CFR 21.4 to provide that when a party files a document in EPDS that is marked protected, that party must, at the request of another party, provide a proposed redacted version of the document to the requesting party within 2 days. This revision is intended to balance the legitimate interest in providing public

versions of documents against the parties' costs of preparing and reviewing such documents.

One commentator requested that new paragraph (b) of 4 CFR 21.4 expressly permit party-specific redactions, for example, redactions that may be released only to either the protester or intervenor.

GAO response: GAO has not opposed the preparation and approval of party-specific redactions. Neither 4 CFR 21.4 nor the protective order prohibit this practice, and GAO does not see a need to address this matter in the rule.

One commentator noted that the proposed rule stated that ''Proposed redacted versions of documents should not be filed through EPDS; rather, the party responsible for preparing the proposed redacted version of the document should provide the document to the other parties by email or facsimile.'' The commentator suggested that there is no reason to limit the non-EPDS exchanges between the parties to email or facsimile.

GAO response: Although this instruction was not included in the text of the revised regulation, GAO agrees with the commentator that there is no reason to limit the non-EPDS exchanges between the parties to email or facsimile.

Issues Not for Consideration

Protests of Orders Issued Under Task or Delivery Order Contracts

GAO proposed to add paragraph (l) of 4 CFR 21.5 to reference the provisions of 10 U.S.C. 2304c(e)(1) and 41 U.S.C. 4106(f)(1), which limit GAO's jurisdiction to hear protests in connection with the issuance or proposed issuance of a task or delivery order issued under indefinite-delivery, indefinite-quantity contracts where the order is valued at dollar thresholds established by the statutory provisions, unless it is alleged that the order increases the scope, period, or maximum value of the contract under which the order was issued.

One commentator proposed that paragraph (l) of 4 CFR 21.5 be revised to clarify that GAO has jurisdiction to hear protests concerning orders issued under the Federal Supply Schedule (FSS).

GAO response: The proposed rule states that GAO's jurisdiction to review protests of orders issued under task or delivery order contracts is limited by the provisions of 10 U.S.C. 2304c(e)(1) and 41 U.S.C. 4106(f)(1), which were enacted as part of the Federal Acquisition Streamlining Act of 1994 (FASA), as amended. As GAO has explained in numerous bid protest decisions, the statutory authority under FASA for agencies to award multiple-award task and delivery order contracts and issue orders under those contracts is separate from the statutory authority to award multiple-award FSS contracts and for agencies to issue orders under those contracts. E.g., *Severn Cos., Inc.,* B–275717.2, Apr. 28, 1997, 97–1 CPD ¶ 181. For this reason, we have concluded that the jurisdictional limitations on GAO's review of orders issued under task or delivery order contracts pursuant to FASA does not affect our Office's jurisdiction to hear protests concerning orders issued under the FSS. Because the proposed revision addresses only the jurisdictional limits under FASA, we see no reason to add additional provisions addressing the FSS.

Protests of Awards, or Solicitations for Awards, of Agreements Other Than Procurement Contracts

GAO proposed to add paragraph (m) to 4 CFR 21.5 to clarify that GAO has the authority to review protests that an agency is improperly using a non-procurement instrument.

One commentator proposed that we clarify that our review of protests alleging that an agency is improperly using a non-procurement instrument is limited to whether an agency is improperly using the non-procurement instrument to procure goods or services.

GAO response: We agree that the proposed clarification reflects the longstanding practice by our Office to review such protests and will revise paragraph (m) of 4 CFR 21.5 in the final rule to reflect that GAO will review protests that an agency is improperly using a non-procurement instrument to procure goods or services.

Withholding of Award and Suspension of Contract Performance

GAO proposed to revise 4 CFR 21.6 to require agencies to file a notification in instances where it overrides a requirement to withhold award or suspend contract performance, and to file a copy of any issued determination and finding.

One commentator questioned why GAO proposed to require this information, in light of the statement in the same paragraph that ''GAO does not administer the requirements to stay award or suspend contract performance under CICA at 31 U.S.C. 3553(c) and (d).''

GAO response: GAO's proposed rule noted that 31 U.S.C. 3554(b)(2) requires our Office to consider the basis for an agency's override in determining the remedy to recommend in the event we sustain a protest. To further clarify, 31 U.S.C. 3554(b)(2) states that if an agency issues an override based on the ''best interests of the United States,'' then GAO shall make a recommendation upon sustaining a protest ''without regard to any cost or disruption from terminating, recompeting, or reawarding the contract.'' Since this statutory provision requires GAO to consider the basis for any agency's override decision, GAO proposed to revise 4 CFR 21.6.

One commentator objected to the requirement to file the override decision, and proposed that agencies be required to advise GAO whether an override decision was based on the ''best interests of the United States,'' or ''urgent and compelling circumstances.''

GAO response: GAO agrees that the statutory requirement for our Office to issue recommendations that take into consideration the basis for an override can also be met if the agency advises GAO of that basis, without providing the decision itself. GAO is therefore issuing this final rule to state that, when an agency issues a determination and finding to override a requirement to withhold award or suspend contract performance, the agency must file either the determination and finding itself or a statement by the official who approved the determination and finding that specifies the statutory basis for the override.

One commentator proposed revising the proposed rule to state that the decision must be filed ''unless classified.''

GAO response: GAO does not believe that a revision is required here, as the proposed revision to paragraph (h) of 4 CFR 21.1 states that documents containing classified material cannot be filed through EPDS. As explained above, this proposed revision is further revised in the final rule to make clear that documents containing classified material ''shall not'' be filed through EPDS.

Remedies

Recommendation for Reimbursement of Costs

GAO proposed revising paragraph (e) of 4 CFR 21.8 to provide that a protester must file comments on an agency's response to a request for a recommendation for reimbursement of costs within 10 days and to further provide that GAO will dismiss the request if the protester fails to file comments within 10 days.

One commentator opposed this proposed revision, arguing that GAO should consider requests even where the protester does not file comments on

the agency's response. The commentator suggested that the agency's response to the request should be sufficient for GAO to rule on the request.

GAO response: A protester's comments on an agency's response to a request for a recommendation for reimbursement of protest costs are necessary to provide an adequate record for GAO to review in issuing its decision. GAO believes that where a protester fails to respond within 10 days—the same period of time permitted for filing comments on an agency report—it is appropriate to deem the protester as having abandoned its request. GAO does not believe that resolution of an abandoned request is an appropriate use of our Office's resources.

One commentator expressed concern that the requirement in paragraph (e) of 4 CFR 21.8 that agencies respond to a request for a recommendation for reimbursement of costs within 15 days will require agencies to address requests for costs that are contained in the initial protest—thus requiring the agency to address requests for costs within 15 days of a protest's initial filing, that is, before the due date for filing the agency report as required by paragraph (c) of 4 CFR 21.3.

GAO response: We do not agree with the commentator's interpretation of the requirements of paragraph (e) of 4 CFR 21.8. The plain language of paragraph (e) refers to requests filed by protesters for recommendation of reimbursement of costs after GAO dismisses a protest based on an agency's decision to take corrective action. For this reason, we see no basis to conclude that paragraph (e) requires an agency to file a response to a request that is made outside the procedures set forth in that paragraph.

One commentator proposed that we revise paragraph (e) to state that GAO will not recommend reimbursement of costs where an agency takes corrective action in response to a protest prior to providing the agency report. Another commentator proposed that we revise paragraph (e) to state that GAO will not recommend reimbursement of costs unless the agency has unreasonably delayed taking corrective action.

GAO response: Paragraph (e) of 4 CFR 21.8 provides that GAO ''may recommend'' reimbursement of protest costs where an agency has taken corrective action in response to a protest. The two commentators' suggestions relate to the legal standard applied by our Office in determining when a recommendation for reimbursement is appropriate. The proposed rule is meant to establish the procedure for filing requests for recommendation of reimbursement of costs and does not attempt to set forth the full legal standard that has been applied by our Office. Because it would be impractical to incorporate all circumstances encompassed within our decisions in this rule, we conclude that a revision is not necessary.

Recommendation on the Amount of Costs

One commentator requested that we incorporate a reference to the legislative history concerning the statutory provision at 31 U.S.C. 3554(c), which provides that although reimbursement for a protester's legal fees shall be capped at $150 per hour, small businesses are not subject to this limitation. The commentator noted that the conference committee's report on FASA, which imposed the $150 per hour cap, stated as follows: ''The conferees expect the Comptroller General to be vigilant in reviewing attorneys' fees to ensure that they are reasonable. The cap placed on attorneys' fees for businesses other than small business constitutes a benchmark as to what constitutes a 'reasonable' level for attorneys' fees for small businesses.'' H. Rept. 103–712, section 1403 (Aug. 21, 1994), as reprinted in 1994 U.S.C.C.A.N. 2607, 2621–22.

GAO response: Our Office previously addressed this provision in a decision recommending the amount of attorneys' fees to be reimbursed for a small business whose protest had been sustained. *See Public Communications Services, Inc.—Costs,* B–400058.4, June 25, 2009, 2009 CPD ¶ 131. In that decision, GAO stated that ''we recognize that the FASA conference committee reiterated our Office's responsibility, imposed in 1984 by CICA, to ensure that attorneys' fees sought for reimbursement are reasonable.'' Id. at 8. Nonetheless, we concluded ''we do not view the benchmark language as imposing an additional limitation (*i.e.,* a cap) on attorneys' fees that are otherwise reasonable,'' because ''[s]uch an interpretation would be inconsistent with the plain statutory language of FASA which exempts small businesses from the specific cap imposed on large businesses—and we see no evidence that the Congress intended such a result.'' Id. Because this matter was fully addressed in *Public Communications Services, Inc.—Costs,* we see no reason to add the benchmark language to the final regulation.

Express Options, Flexible Alternative Procedures, Accelerated Schedules, Summary Decisions, and Status And Other Conferences

GAO proposed to revise 4 CFR 21.10 to reflect the requirement to file documents through EPDS.

One commentator proposed that we revise the flexible schedule procedures in 4 CFR 21.10 to provide that GAO will seek the ''concurrence'' of the parties before using an alternate schedule. The commentator notes that the flexible schedule procedures, in particular the express option schedule, may change the parties' filing dates and reduce the amount of time for filings.

GAO response: As a matter of practice, GAO considers the views of the parties when using the flexible schedule procedures in 4 CFR 21.10. However, GAO reserves the right to use these procedures even where the parties do not concur. GAO believes that the use of flexible schedule procedures aids our Office's ability to meet our statutory obligations to provide an inexpensive and expeditious forum for the resolution of protests.

Nonstatutory Protests

Although not addressed in our proposed rule, GAO will revise 4 CFR 21.13(b) to clarify that certain provisions of 4 CFR do not apply to nonstatutory protests. The rule currently states that GAO will not issue recommendations for the payment of costs associated with nonstatutory protests, as otherwise provided for in 4 CFR 21.8(d). The revised rule clarifies that GAO will also not issue recommendations for the payment of costs when an agency takes corrective action in response to a nonstatutory protest, as otherwise provided for in 4 CFR 21.8(e). The revised rule also clarifies that 4 CFR 21.6, which pertains to the withholding of award and the suspension of contract performance pursuant to 31 U.S.C. 3553(c) and (d), does not apply to nonstatutory protests.

List of Subjects in 4 CFR Part 21

Administrative practice and procedure, Appeals, Bid protest regulations, Government contracts.

For the reasons set out in the preamble, title 4, chapter I, subchapter B, part 21 of the Code of Federal Regulations is amended as follows:

PART 21—BID PROTEST REGULATIONS

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

Authority: 31 U.S.C. 3551–3557.

■ 2. In § 21.0:
■ a. Amend paragraph (a)(2) introductory text by adding the abbreviation ''(OMB)'' between the words Budget and Circular;
■ b. Redesignate paragraphs (a)(2)(A) and (B) as paragraphs (a)(2)(i) and (ii), respectively;
■ c. Amend paragraph (b)(2) by removing ''(a)(2)(B)'' and adding in its place (a)(2)(ii)'';
■ d. Amend paragraph (c) by removing the word ''his'' and adding in its place the words ''the Architect's'';
■ e. Redesignate paragraphs (f) and (g) as paragraphs (g) and (h), respectively, and add a new paragraph (f);
■ f. Revise newly redesignated paragraph (g).

The addition and revision read as follows:

§ 21.0 Definitions.

* * * * *

(f) *Electronic Protest Docketing System (EPDS)* is GAO's web-based electronic docketing system. GAO's website [*https://epds.gao.gov/login*] includes instructions and guidance on the use of EPDS.

(g) A document is *filed* on a particular day when it is received in EPDS by 5:30 p.m., Eastern Time. Delivery of a protest or other document by means other than those set forth in the online EPDS instructions does not constitute a filing. Filing a document in EPDS constitutes notice to all parties of that filing.

* * * * *

■ 3. Amend § 21.1 by revising paragraphs (b) and (c)(1), the third sentence of paragraph (g), and by adding a new first sentence to paragraph (h) to read as follows:

§ 21.1 Filing a protest.

* * * * *

(b) Protests must be filed through the EPDS.

(c) * * *

(1) Include the name, street address, email address, and telephone and facsimile numbers of the protester,

* * * * *

(g) * * * This information must be identified wherever it appears, and within 1 day after the filing of its protest, the protester must file a final redacted copy of the protest which omits the information.

(h) Protests and other documents containing classified information shall not be filed through the EPDS. * * *

* * * * *

■ 4. Amend § 21.2 by adding a third sentence to paragraph (a)(1); by revising the second sentence of paragraph (a)(2) and the first sentence of paragraph (a)(3) to read as follows:

§ 21.2 Time for filing.

(a)(1) * * * If no closing time has been established, or if no further submissions are anticipated, any alleged solicitation improprieties must be protested within 10 days of when the alleged impropriety was known or should have been known.

(2) * * * In such cases, with respect to any protest basis which is known or should have been known either before or as a result of the debriefing, and which does not involve an alleged solicitation impropriety covered by paragraph (a)(1) of this section, the initial protest shall not be filed before the debriefing date offered to the protester, but shall be filed not later than 10 days after the date on which the debriefing is held.

(3) If a timely agency-level protest was previously filed, any subsequent protest to GAO must be filed within 10 days of actual or constructive knowledge of initial adverse agency action, provided the agency-level protest was filed in accordance with paragraphs (a)(1) and (2) of this section, unless the agency imposes a more stringent time for filing, in which case the agency's time for filing will control. * * *

■ 5. Amend § 21.3 by revising the section heading, paragraphs (a), (c), (d), (e), the first sentence of paragraph (f), paragraph (g), the first sentence of paragraph (h), and paragraph (i) to read as follows:

§ 21.3 Notice of protest, communications among parties, submission of agency report, and time for filing of comments on report.

(a) GAO shall notify the agency within 1 day after the filing of a protest, and, unless the protest is dismissed under this part, shall promptly provide a written confirmation to the agency and an acknowledgment to the protester. The agency shall immediately give notice of the protest to the awardee if award has been made or, if no award has been made, to all bidders or offerors who appear to have a substantial prospect of receiving an award. The agency shall provide copies of the protest submissions to those parties, except where disclosure of the information is prohibited by law, with instructions to communicate further directly with GAO. All parties shall provide copies of all communications with GAO to the agency and to other participating parties either through EPDS or by email. GAO's website [*https://epds.gao.gov/login*] includes guidance regarding when to file through EPDS versus communicating by email or other means.

* * * * *

(c) The agency shall file a report on the protest within 30 days after receiving notice of the protest from GAO. The report need not contain documents which the agency has previously provided or otherwise made available to the parties in response to the protest. At least 5 days prior to the filing of the report, in cases in which the protester has filed a request for specific documents, the agency shall file a response to the request for documents. If the fifth day prior to the filing of the report falls on a weekend or Federal holiday, the response shall be filed by the last business day that precedes the weekend or holiday. The agency's response shall, at a minimum, identify whether the requested documents exist, which of the requested documents or portions thereof the agency intends to produce, which of the requested documents or portions thereof the agency intends to withhold, and the basis for not producing any of the requested documents or portions thereof. Any objection to the scope of the agency's proposed disclosure or nondisclosure of documents must be filed within 2 days of receipt of this response.

(d) The report shall include the contracting officer's statement of the relevant facts (including a best estimate of the contract value), a memorandum of law, and a list and a copy of all relevant documents, or portions of documents, not previously produced, including, as appropriate: the bid or proposal submitted by the protester; the bid or proposal of the firm which is being considered for award, or whose bid or proposal is being protested; all evaluation documents; the solicitation, including the specifications; the abstract of bids or offers; and any other relevant documents. In appropriate cases, a party may file a request that another party produce relevant documents, or portions of documents, that are not in the agency's possession.

(e) Where a protester or intervenor does not have counsel admitted to a protective order and documents are withheld from the protester or intervenor on that basis, the agency shall file redacted documents that adequately inform the protester and/or intervenor of the basis of the agency's arguments in response to the protest. GAO's website [*https://epds.gao.gov/login*] provides guidance regarding filing documents where no protective order is issued or where a protester or intervenor does not have counsel admitted to a protective order.

(f) The agency may file a request for an extension of time for the submission of the response to be filed by the agency

pursuant to § 21.3(c) or for the submission of the agency report. * * *

(g) The protester may file a request for additional documents after receipt of the agency report when their existence or relevance first becomes evident. Except when authorized by GAO, any request for additional documents must be filed not later than 2 days after their existence or relevance is known or should have been known, whichever is earlier. The agency shall file the requested documents, or portions of documents, within 2 days or explain why it is not required to produce the documents.

(h) Upon a request filed by a party, GAO will decide whether the agency must file any withheld documents, or portions of documents, and whether this should be done under a protective order. * * *

(i)(1) Comments on the agency report shall be filed within 10 days after the agency has filed the report, except where GAO has granted an extension of time, or where GAO has established a shorter period for filing of comments. Extensions will be granted on a case-by-case basis.

(2) The protest shall be dismissed unless the protester files comments within the period of time established in § 21.3(i)(1).

(3) GAO will dismiss any protest allegation or argument where the agency's report responds to the allegation or argument, but the protester's comments fail to address that response.

* * * * *

■ 6. In § 21.4:

■ a. Amend paragraph (a) by removing the word ''under'' in the fourth sentence and adding in its place the word ''to''; and adding a fifth sentence;

■ b. Redesignate paragraphs (b), (c), and (d) as paragraphs (c), (d), and (e), respectively, and add a new paragraph (b);

■ c. Revise the first sentence of newly redesignated paragraph (c); and revise the first and third sentences of newly designated paragraph (d).

The addition and revisions read as follows:

§ 21.4 Protective orders.

(a) * * * GAO generally does not issue a protective order where an intervenor retains counsel, but the protester does not.

(b) Any agency or party filing a document that the agency or party believes to contain protected material shall, if requested by another party, provide to the other parties (unless they are not admitted to the protective order) an initial proposed redacted version of the document within 2 days of the request. Where appropriate, the exhibits to the agency report or other documents may be proposed for redaction in their entirety. The party that authored the document shall file the final redacted version of the document that has been agreed to by all of the parties. Only the final agreed-to version of a redacted document must be filed. If the parties are unable to reach an agreement regarding redactions, the objecting party may submit the matter to GAO for resolution. Until GAO resolves the matter, the disputed information must be treated as protected.

(c) If no protective order has been issued, or a protester or intervenor does not have counsel admitted to a protective order, the agency may withhold from the parties those portions of its report that would ordinarily be subject to a protective order, provided that the requirements of § 21.3(e) are met. * * *

(d) After a protective order has been issued, counsel or consultants retained by counsel appearing on behalf of a party may apply for admission under the order by filing an application. * * * Objections to an applicant's admission shall be filed within 2 days after the application is filed, although GAO may consider objections filed after that time.

* * * * *

■ 7. In § 21.5:

■ a. Amend paragraph (a) by removing ''601–613'' and adding in its place ''7101–7109'';

■ b. Revise paragraph (b) subject heading, paragraph (b)(1), the first sentence of paragraph (b)(2), and paragraph (b)(3);

■ c. Amend paragraph (d) by removing ''423'' and adding in its place ''2101–2107'';

■ d. Amend paragraph (e) by removing the words ''in GAO'' and adding in their place the words ''with GAO'';

■ e. Amend paragraph (f) by removing the word ''which'' in two places and adding in its place the word ''that'';

■ f. Amend paragraph (g) by removing ''472'' and adding in its place ''102'';

■ g. Revise paragraph (h); and

■ h. Add paragraphs (l) and (m).

The revisions and additions read as follows:

§ 21.5 Protest issues not for consideration.

* * * * *

(b) *Small Business Administration (SBA) issues.* (1) *Small business size standards and North American Industry Classification System (NAICS) standards.* Challenges of established size standards or the size status of particular firms, and challenges of the selected NAICS code may be reviewed solely by the SBA. 15 U.S.C. 637(b)(6).

(2) *Small Business Certificate of Competency Program.* Referrals made to the SBA pursuant to sec. 8(b)(7) of the Small Business Act, or the issuance of, or refusal to issue, a certificate of competency under that section will generally not be reviewed by GAO. * * *

(3) *Procurements under sec. 8(a) of the Small Business Act.* Under that section, since contracts are entered into with the SBA at the contracting officer's discretion and on such terms as are agreed upon by the procuring agency and the SBA, the decision to place or not to place a procurement under the 8(a) program is not subject to review absent a showing of possible bad faith on the part of government officials or that regulations may have been violated. 15 U.S.C. 637(a).

* * * * *

(h) *Subcontract protests.* GAO will not consider a protest of the award or proposed award of a subcontract except where the agency awarding the prime contract has filed a request that subcontract protests be decided pursuant to § 21.13.

* * * * *

(l) *Protests of orders issued under task or delivery order contracts.* As established in 10 U.S.C. 2304c(e) and 41 U.S.C. 4106(f), GAO does not have jurisdiction to review protests in connection with the issuance or proposed issuance of a task or delivery order except for the circumstances set forth in those statutory provisions.

(m) *Protests of awards, or solicitations for awards, of agreements other than procurement contracts.* GAO generally does not review protests of awards, or solicitations for awards, of agreements other than procurement contracts, with the exception of awards or agreements as described in § 21.13; GAO does, however, review protests alleging that an agency is improperly using a non-procurement instrument to procure goods or services.

■ 8. Revise § 21.6 to read as follows:

§ 21.6 Withholding of award and suspension of contract performance.

When a protest is filed, the agency may be required to withhold award and to suspend contract performance. The requirements for the withholding of award and the suspension of contract performance are set forth in 31 U.S.C. 3553(c) and (d); GAO does not administer the requirements to withhold award or suspend contract performance. An agency shall file a notification in

instances where it overrides a requirement to withhold award or suspend contract performance, and it shall file either a copy of any issued determination and finding, or a statement by the individual who approved the determination and finding that explains the statutory basis for the override.

■ 9. Amend § 21.7 by revising the first sentence of paragraph (a) and revising paragraph (e) to read as follows:

§ 21.7 Hearings.

(a) Upon a request filed by a party or on its own initiative, GAO may conduct a hearing in connection with a protest. * * *

* * * * *

(e) GAO does not provide for hearing transcripts. If the parties wish to have a hearing transcribed, they may do so at their own expense, so long as a copy of the transcript is provided to GAO at the parties' expense.

* * * * *

■ 10. Amend § 21.8 by revising paragraph (e), adding a paragraph (f) subject heading, revising paragraphs (f)(2) and (3), and adding paragraphs (f)(4) through (6) to read as follows:

§ 21.8 Remedies.

* * * * *

(e) *Recommendation for reimbursement of costs.* If the agency decides to take corrective action in response to a protest, GAO may recommend that the agency pay the protester the reasonable costs of filing and pursuing the protest, including attorneys' fees and consultant and expert witness fees. The protester shall file any request that GAO recommend that costs be paid not later than 15 days after the date on which the protester learned (or should have learned, if that is earlier) that GAO had closed the protest based on the agency's decision to take corrective action. The agency shall file a response within 15 days after the request is filed. The protester shall file comments on the agency response within 10 days of receipt of the response. GAO shall dismiss the request unless the protester files comments within the 10-day period, except where GAO has granted an extension or established a shorter period.

(f) *Recommendation on the amount of costs.*

* * * * *

(2) The agency shall issue a decision on the claim for costs as soon as practicable after the claim is filed.

(3) If the protester and the agency cannot reach agreement regarding the amount of costs within a reasonable time, the protester may file a request that GAO recommend the amount of costs to be paid, but such request shall be filed within 10 days of when the agency advises the protester that the agency will not participate in further discussions regarding the amount of costs.

(4) Within 15 days after receipt of the request that GAO recommend the amount of costs to be paid, the agency shall file a response. The protester shall file comments on the agency response within 10 days of receipt of the response. GAO shall dismiss the request unless the protester files comments within the 10-day period, except where GAO has granted an extension or established a shorter period.

(5) In accordance with 31 U.S.C. 3554(c), GAO may recommend the amount of costs the agency should pay. In such cases, GAO may also recommend that the agency pay the protester the costs of pursuing the claim for costs before GAO.

(6) Within 60 days after GAO recommends the amount of costs the agency should pay the protester, the agency shall file a notification of the action the agency took in response to the recommendation.

■ 11. Amend § 21.9 by revising paragraph (a) to read as follows:

§ 21.9 Time for decision by GAO.

(a) GAO shall issue a decision on a protest within 100 days after it is filed. GAO will attempt to resolve a request for recommendation for reimbursement of protest costs under § 21.8(e), a request for recommendation on the amount of protest costs under § 21.8(f), or a request for reconsideration under § 21.14 within 100 days after the request is filed.

* * * * *

■ 12. Amend § 21.10 by revising paragraph (a), the first sentence of paragraph (c), and paragraphs (d)(1) and (2) and (e) to read as follows:

§ 21.10 Express options, flexible alternative procedures, accelerated schedules, summary decisions, and status and other conferences.

(a) Upon a request filed by a party or on its own initiative, GAO may decide a protest using an express option.

* * * * *

(c) Requests for the express option shall be filed not later than 5 days after the protest or supplemental/amended protest is filed. * * *

(d) * * *

(1) The agency shall file a complete report within 20 days after it receives notice from GAO that the express option will be used.

(2) Comments on the agency report shall be filed within 5 days after receipt of the report.

* * * * *

(e) GAO, on its own initiative or upon a request filed by the parties, may use flexible alternative procedures to promptly and fairly resolve a protest, including alternative dispute resolution, establishing an accelerated schedule, and/or issuing a summary decision.

* * * * *

■ 13. Amend § 21.11 by revising paragraph (a) to read as follows:

§ 21.11 Effect of judicial proceedings.

(a) A protester must immediately advise GAO of any court proceeding which involves the subject matter of a pending protest and must file copies of all relevant court documents.

* * * * *

■ 14. Amend § 21.12 by revising paragraph (b) to read as follows:

§ 21.12 Distribution of decisions.

* * * * *

(b) Decisions will be distributed to the parties through the EPDS.

■ 15. Amend § 21.13 by revising paragraph (b) to read as follows:

§ 21.13 Nonstatutory protests.

* * * * *

(b) The provisions of this part shall apply to nonstatutory protests except for:

(1) Section 21.8(d) and (e) pertaining to recommendations for the payment of costs; and

(2) Section 21.6 pertaining to the withholding of award and the suspension of contract performance pursuant to 31 U.S.C. 3553(c) and (d).

■ 16. Amend § 21.14 by revising paragraph (b) and the second sentence of paragraph (c) to read as follows:

§ 21.14 Request for reconsideration.

* * * * *

(b) A request for reconsideration of a bid protest decision shall be filed not later than 10 days after the basis for reconsideration is known or should have been known, whichever is earlier.

(c) * * * To obtain reconsideration, the requesting party must show that GAO's prior decision contains errors of either fact or law, or must present information not previously considered that warrants reversal or modification of the decision; GAO will not consider a request for reconsideration based on

repetition of arguments previously raised.

Thomas H. Armstrong,

General Counsel, United States Government Accountability Office.

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BILLING CODE 1610–02–P

DEPARTMENT OF HOMELAND SECURITY

6 CFR Part 27

8 CFR Parts 270, 274a, and 280

19 CFR Part 4

Coast Guard

33 CFR Part 27

Transportation Security Administration

49 CFR Part 1503

RIN 1601–AA80

Civil Monetary Penalty Adjustments for Inflation

AGENCY: Department of Homeland Security.

ACTION: Final rule.

SUMMARY: In this final rule, the Department of Homeland Security's (DHS) is making the 2018 annual inflation adjustment to its civil monetary penalties. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act) was signed into law on November 2, 2015. Pursuant to the 2015 Act, all agencies must adjust civil monetary penalties annually and publish the adjustment in the **Federal Register**. Accordingly, this final rule adjusts DHS's civil monetary penalties for 2018 pursuant to the 2015 Act and OMB guidance. The new penalties will be effective for penalties assessed after April 2, 2018 whose associated violations occurred after November 2, 2015.

DATES: This rule is effective on April 2, 2018.

FOR FURTHER INFORMATION CONTACT: Megan Westmoreland, Attorney-Advisor, Office of the General Counsel, U.S. Department of Homeland Security. Phone: 202–447–4384.

SUPPLEMENTARY INFORMATION:

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I. Statutory and Regulatory Background

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Pub. L. 114–74 section 701 (Nov. 2, 2105)) (2015 Act).[1] The 2015 Act amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note) to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. The 2015 Act required agencies to: (1) Adjust the level of civil monetary penalties with an initial ''catch-up'' adjustment through issuance of an Interim Final Rule (IFR) and (2) make subsequent annual adjustments for inflation. Through the ''catch-up'' adjustment, agencies were required to adjust the maximum amounts of civil monetary penalties to more accurately reflect inflation rates.

For the subsequent annual adjustments, the 2015 Act requires agencies to increase the penalty amounts by a cost-of-living adjustment. The 2015 Act directs OMB to provide guidance to agencies each year to assist agencies in making the annual adjustments. The 2015 Act requires agencies to make the annual adjustments no later than January 15 of each year and to publish the adjustments in the **Federal Register**.

Pursuant to the 2015 Act, DHS undertook a review of the civil penalties that DHS and its components administer.[2] On July 1, 2016, DHS published an IFR adjusting the maximum civil monetary penalties with an initial ''catch-up'' adjustment, as required by the 2015 Act. *See* 81 FR 42987. DHS calculated the adjusted penalties based upon nondiscretionary provisions in the 2015 Act and upon guidance that OMB issued to agencies on February 24, 2016.[3] The adjusted penalties were effective for civil penalties assessed after August 1, 2016 (the effective date of the IFR) whose associated violations occurred after November 2, 2015 (the date of enactment of the 2015 Act). On January 27, 2017, DHS published a final rule finalizing the IFR and making the annual adjustment for 2017. See *82 FR 8572.*

II. Overview of the Final Rule

This final rule makes the 2018 annual inflation adjustments to civil monetary penalties pursuant to the 2015 Act and pursuant to guidance OMB issued to agencies on December 15, 2017.[4] The penalty amounts in this final rule will be effective for penalties assessed after April 2, 2018 where the associated violation occurred after November 2, 2015. Consistent with OMB guidance, the 2015 Act does not change previously assessed penalties that the agency is actively collecting or has collected.

The adjusted penalty amounts will apply to penalties assessed after the effective date of this final rule. We discuss civil penalties by DHS component in Section III below. For each component identified in Section III, below, we briefly describe the relevant civil penalty (or penalties), and we provide a table showing the increase in the penalties for 2018. In the table for each component, we show (1) the penalty name, (2) the penalty statutory and/or regulatory citation, (3) the penalty amount as adjusted in the 2017 final rule, (4) the cost-of-living adjustment multiplier for 2018 that OMB provided in its December 15, 2017 guidance, and (5) the new 2018 adjusted penalty. The 2015 Act instructs agencies to round penalties to the nearest $1. For a more complete discussion of the method used for calculating the initial ''catch-up'' inflation adjustments and a component-by-component breakdown to the nature of the civil penalties and relevant legal authorities, please see the IFR preamble at 81 FR 42987–43000.

[1] The 2015 Act was enacted as part of the Bipartisan Budget Act of 2015, Public Law 114–74 (Nov. 2, 2015).

[2] The 2015 Act applies to all agency civil penalties except for any penalty (including any addition to tax and additional amount) under the Internal Revenue Code of 1986 (26 U.S.C. 1 *et seq.*) and the Tariff Act of 1930 (19 U.S.C. 1202 *et seq.*). See sec. 4(a)(1) of the 2015 Act. In the case of DHS, several civil penalties that are assessed by U.S. Customs and Border Protection (CBP) and the U.S. Coast Guard fall under the Tariff Act of 1930, and thus DHS did not adjust those civil penalties in this rulemaking.

[3] OMB, Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Table A, 24 February 2016. *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2016/m-16-06.pdf* (last accessed Dec. 5, 2017).

[4] OMB, Implementation of the 2018 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, December 15, 2017. *https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-03.pdf* (last accessed Dec. 15, 2017).

III. Adjustments by Component

In the following sections, we briefly describe the civil penalties that DHS and its components assess. We include tables at the end of each section, which list the individual adjustments for each penalty.

A. National Protection and Programs Directorate

The National Protection and Programs Directorate (NPPD) administers only one civil penalty that the 2015 Act affects. That penalty assesses fines for violations of the Chemical Facility Anti-Terrorism Standards (CFATS). CFATS is a program that regulates the security of chemical facilities that, in the discretion of the Secretary, present high levels of security risk. DHS established the CFATS program in 2007 pursuant to section 550 of the Department of Homeland Security Appropriations Act of 2007 (Pub. L. 109–295).[5] The CFATS regulation is located in part 27 of title 6 of the Code of Federal Regulations (CFR). Below is a table showing the 2018 adjustment for the CFATS penalty that NPPD administers.

TABLE 1—CFATS CIVIL PENALTY ADJUSTMENT

Penalty name	Citation	Penalty amount as adjusted in the 2017 FR	Multiplier *	New penalty as adjusted by this final rule
Penalty for non-compliance with CFATS regulations.	6 U.S.C. 624(b)(1); 6 CFR 27.300(b)(3)	$33,333 per day	1.02041	$34,013

* OMB, Implementation of the 2018 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, December 15, 2017. *https://obamawhitehouse.archives.gov/sites/default/files/omb/memoranda/2017/m-17-11_0.pdf.*

B. U.S. Customs and Border Protection

U.S. Customs and Border Protection (CBP) assesses civil monetary penalties under various titles of the United States Code and the CFR. These include penalties for certain violations of title 8 of the CFR regarding the Immigration and Nationality Act of 1952 (Pub. L. 82–414, as amended) (INA). The INA contains provisions that impose penalties on persons, including carriers and aliens, who violate specified provisions of the INA. The relevant penalty provisions are located in numerous sections of the INA, however CBP has enumerated these penalties in regulation in one location—in 8 CFR 280.53. For a complete list of the INA sections for which penalties are assessed, in addition to a brief description of each violation, see the IFR preamble at 81 FR 42989–42990.

On December 8, 2017, CBP adjusted three non-INA penalties inadvertently left out of the IFR and 2017 final rule. *See* 82 FR 57821. The three penalties concern the following violations: Transporting passengers between coastwise points in the United States by a non-coastwise qualified vessel; towing a vessel between coastwise points in the United States by a non-coastwise qualified vessel; and dealing in or using an empty stamped imported liquor container after it has already been used once. This final rule incorporates those three penalties alongside the other CBP penalties and adjusts them according to the 2018 multiplier.

Below is a table showing the 2018 adjustment for the penalties that CBP administers.

TABLE 2—U.S. CUSTOMS AND BORDER PROTECTION CIVIL PENALTIES ADJUSTMENTS

Penalty name	Citation	Penalty amount as adjusted in the 2017 FR	Multiplier *	New penalty as adjusted by this final rule
Penalties for non-compliance with arrival and departure manifest requirements for passengers, crewmembers, or occupants transported on commercial vessels or aircraft arriving to or departing from the United States.	8 U.S.C. 1221(g) 8 CFR 280.53(b)(1) (INA section 231(g)).	$1,333	1.02041	$1,360.
Penalties for non-compliance with landing requirements at designated ports of entry for aircraft transporting aliens.	8 U.S.C. 1224 8 CFR 280.53(b)(2) (INA section 234).	$3,621	1.02041	$3,695.
Penalties for failure to depart voluntarily	8 U.S.C. 1229c(d) 8 CFR 280.53(b)(3) (INA section 240B(d)).	$1,527–$7,635	1.02041	$1,558–$7,791.
Penalties for violations of removal orders relating to aliens transported on vessels or aircraft under section 241(d) of the INA, or for costs associated with removal under section 241(e) of the INA.	8 U.S.C. 1253(c)(1)(A) 8 CFR 280.53(b)(4) (INA section 243(c)(1)(A)).	$3,054	1.02041	$3,116.
Penalties for failure to remove alien stowaways under section 241(d)(2) of the INA.	8 U.S.C. 1253(c)(1)(B) 8 CFR 280.53(b)(5) (INA section 243(c)(1)(B)).	$7,635	1.02041	$7,791.

[5] Section 550 has since been superseded by the Protecting and Securing Chemical Facilities from Terrorist Attacks Act of 2014 (Pub. L. 113–254). The new legislation codified the statutory authority for the CFATS program within Title XXI of the Homeland Security Act of 2002, as amended. *See* 6 U.S.C. 621 *et seq.*

TABLE 2—U.S. CUSTOMS AND BORDER PROTECTION CIVIL PENALTIES ADJUSTMENTS—Continued

Penalty name	Citation	Penalty amount as adjusted in the 2017 FR	Multiplier *	New penalty as adjusted by this final rule
Penalties for failure to report an illegal landing or desertion of alien crewmen, and for each alien not reported on arrival or departure manifest or lists required in accordance with section 251 of the INA.	8 U.S.C. 1281(d) 8 CFR 280.53(b)(6) (INA section 251(d)).	$362 for each alien	1.02041	$369 for each alien.
Penalties for use of alien crewmen for longshore work in violation of section 251(d) of the INA.	8 U.S.C. 1281(d) 8 CFR 280.53(b)(6) (INA section 251(d)).	$9,054	1.02041	$9,239.
Penalties for failure to control, detain, or remove alien crewmen.	8 U.S.C. 1284(a) 8 CFR 280.53(b)(7) (INA section 254(a)).	$906–$5,432	1.02041	$924–$5,543.
Penalties for employment on passenger vessels of aliens afflicted with certain disabilities.	8 U.S.C. 1285 8 CFR 280.53(b)(8) (INA section 255).	$1,811	1.02041	$1,848.
Penalties for discharge of alien crewmen.	8 U.S.C. 1286 8 CFR 280.53(b)(9) (INA section 256).	$2,716–$5,432	1.02041	$2,771–$5,543.
Penalties for bringing into the United States alien crewmen with intent to evade immigration laws.	8 U.S.C. 1287 8 CFR 280.53(b)(10) (INA section 257).	$18,107	1.02041	$18,477.
Penalties for failure to prevent the unauthorized landing of aliens.	8 U.S.C. 1321(a) 8 CFR 280.53(b)(11) (INA section 271(a)).	$5,432	1.02041	$5,543.
Penalties for bringing to the United States aliens subject to denial of admission on a health-related ground.	8 U.S.C. 1322(a) 8 CFR 280.53(b)(12) (INA section 272(a)).	$5,432	1.02041	$5,543.
Penalties for bringing to the United States aliens without required documentation.	8 U.S.C. 1323(b) 8 CFR 280.53(b)(13) (INA section 273(b)).	$5,432	1.02041	$5,543.
Penalties for failure to depart	8 U.S.C. 1324d 8 CFR 280.53(b)(14) (INA section 274D).	$763	1.02041	$779.
Penalties for improper entry	8 U.S.C. 1325(b) 8 CFR 280.53(b)(15) (INA section 275(b)).	$76–$382	1.02041	$78–$390.
Penalty for dealing in or using empty stamped imported liquor containers.	19 U.S.C. 469	$508 **	1.02041	$518.
Penalty for transporting passengers between coastwise points in the United States by a non-coastwise qualified vessel.	46 U.S.C. 55103(b) 19 CFR 4.80(b)(2)	$762 **	1.02041	$778.
Penalty for towing a vessel between coastwise points in the United States by a non-coastwise qualified vessel.	46 U.S.C. 55111(c) 19 CFR 4.92	$889–$2795, plus $152 per ton **.	1.02041	$907–$2852, plus $155 per ton.

* OMB, Implementation of the 2018 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, December 15, 2017. *https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-03.pdf.*

** Adjustments made in Dec 8, 2017 final rule, 82 FR 57821.

C. U.S. Immigration and Customs Enforcement

U.S. Immigration and Customs Enforcement (ICE) assesses civil monetary penalties for certain employment-related violations arising from the INA. ICE's civil penalties are located in title 8 of the CFR.

There are three different sections in the INA that impose civil monetary penalties for violations of the laws that relate to employment actions: Sections 274A, 274B, and 274C. ICE has primary enforcement responsibilities for two of these civil penalty provisions (sections 274A and 274C), and the Department of Justice (DOJ) has enforcement responsibilities for one of these civil penalty provisions (section 274B). The INA, in sections 274A and 274C, provides for imposition of civil penalties for various specified unlawful acts pertaining to the employment eligibility verification process (Form I–9, Employment Eligibility Verification) and the employment of unauthorized aliens.

Because both DHS and DOJ implement the three employment-related penalty sections in the INA, both Departments' implementing regulations reflect the civil penalty amounts. For a complete description of the civil money penalties assessed and a discussion of DHS's and DOJ's efforts to update the penalties in years past, see the IFR preamble at 81 FR 42991. Below is a table showing the 2018 adjustment for the penalties that ICE administers.[6]

[6] Table 3 also includes two civil penalties that were previously listed as penalties administered by CBP, but that are now indicated in this final rule as penalties that ICE administers. These are penalties for failure to depart voluntarily, INA section 240B(d), and failure to depart after a final order of removal, INA section 274D. Both CBP and ICE may administer these penalties, but as ICE is the DHS component primarily responsible for assessing and collecting them, they are now also listed among the penalties ICE administers.

TABLE 3—U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT CIVIL PENALTIES ADJUSTMENTS

Penalty name	Citation	Penalty amount as adjusted in the 2017 FR	Multiplier *	New penalty as adjusted by this final rule
Civil penalties for failure to depart voluntarily, Immigration and Naturalization Act section 240B(d).	8 U.S.C. 1229c(d) 8 CFR 280.53(b)(3)	$1,527–$7,635	1.02041	$1,558–$7,791
Civil penalties for violation of Immigration and Naturalization Act (INA) sections 274C(a)(1)–(a)(4), penalty for first offense.	8 CFR 270.3(b)(1)(ii)(A)	$452-$3,621	1.02041	$461–$3,695
Civil penalties for violation of Immigration and Naturalization Act (INA) sections 274C(a)(5)–(a)(6), penalty for first offense.	8 CFR 270.3(b)(1)(ii)(B)	$382–$3,054	1.02041	$390–$3,116
Civil penalties for violation of Immigration and Naturalization Act (INA) sections 274C(a)(1)–(a)(4), penalty for subsequent offenses.	8 CFR 270.3(b)(1)(ii)(C)	$3,621–$9,054	1.02041	$3,695–$9,239
Civil penalties for violation of Immigration and Naturalization Act (INA) sections 274C(a)(5)–(a)(6), penalty for subsequent offenses.	8 CFR 270.3(b)(1)(ii)(D)	$3,054–$7,635	1.02041	$3,116–$7,791
Violation/prohibition of indemnity bonds	8 CFR 274a.8(b)	$2,191	1.02041	$2,236
Civil penalties for knowingly hiring, recruiting, referral, or retention of unauthorized aliens—Penalty for first offense (per unauthorized alien).	8 CFR 274a.10(b)(1)(ii)(A)	$548–$4,384	1.02041	$559–$4,473
Penalty for second offense (per unauthorized alien).	8 CFR 274a.10(b)(1)(ii)(B)	$4,384–$10,957	1.02041	$4,473–$11,181
Penalty for third or subsequent offense (per unauthorized alien).	8 CFR 274a.10(b)(1)(ii)(C)	$6,575–$21,916	1.02041	$6,709–$22,363
Civil penalties for I–9 paperwork violations	8 CFR 274a.10(b)(2)	$220–$2,191	1.02041	$224–$2,236
Civil penalties for failure to depart, Immigration and Naturalization Act (INA) section 274D.	8 U.S.C. 1324d 8 CFR 280.53(b)(14)	$763	1.02041	$779

* OMB, Implementation of the 2018 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, December 15, 2017. *https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-03.pdf.*

D. U.S. Coast Guard

The Coast Guard is authorized to assess close to 150 penalties involving maritime safety and security and environmental stewardship that are critical to the continued success of Coast Guard missions. Various statutes in titles 14, 16, 19, 33, 42, 46, and 49 of the United States Code authorize these penalties. Titles 33 and 46 authorize the vast majority of these penalties as these statutes deal with navigation, navigable waters, and shipping. Beyond titles 33 and 46, the Coast Guard is also authorized to collect civil monetary penalties related to the organization and management of the Coast Guard, aquatic species conservation, obstruction of revenue, and hazardous substances and materials. For a complete discussion of the civil monetary penalties assessed by the Coast Guard, see the IFR preamble at 81 FR 42992.

The Coast Guard has identified the penalties it administers, adjusted those penalties for inflation, and is listing those new penalties in a table located in the CFR—specifically, Table 1 in 33 CFR 27.3. Table 1 in 33 CFR 27.3 identifies the statutes that provide the Coast Guard with civil monetary penalty authority and sets out the inflation-adjusted maximum penalty that the Coast Guard may impose pursuant to each statutory provision. Table 1 in 33 CFR 27.3 provides the current maximum penalty for violations that occurred after November 2, 2015. The applicable civil penalty amounts for violations occurring on or before November 2, 2015 are set forth in previously published regulations amending 33 CFR part 27. To find the applicable penalty amount for a violation that occurred on or before November 2, 2015, look to the prior versions of the CFR that pertain to the date on which the violation occurred. Table 4 below shows the 2018 adjustment for the penalties that the Coast Guard administers.

TABLE 4—U.S. COAST GUARD CIVIL PENALTIES ADJUSTMENTS

Penalty name	Citation	Penalty amount as adjusted in the 2017 FR	Multiplier *	New penalty as adjusted by this final rule
Saving Life and Property	14 U.S.C. 88(c)	$10,181	1.02041	$10,389
Saving Life and Property; Intentional Interference with Broadcast.	14 U.S.C. 88(e)	1,045	1.02041	1,066
Confidentiality of Medical Quality Assurance Records (first offense).	14 U.S.C. 645(i); 33 CFR 27.3	5,114	1.02041	5,218

TABLE 4—U.S. COAST GUARD CIVIL PENALTIES ADJUSTMENTS—Continued

Penalty name	Citation	Penalty amount as adjusted in the 2017 FR	Multiplier *	New penalty as adjusted by this final rule
Confidentiality of Medical Quality Assurance Records (subsequent offenses).	14 U.S.C. 645(i); 33 CFR 27.3	34,095	1.02041	34,791
Aquatic Nuisance Species in Waters of the United States.	16 U.S.C. 4711(g)(1); 33 CFR 27.3	38,175	1.02041	38,954
Obstruction of Revenue Officers by Masters of Vessels.	19 U.S.C. 70; 33 CFR 27.3	7,623	1.02041	7,779
Obstruction of Revenue Officers by Masters of Vessels—Minimum Penalty.	19 U.S.C. 70; 33 CFR 27.3	1,779	1.02041	1,815
Failure to Stop Vessel When Directed; Master, Owner, Operator or Person in Charge.	19 U.S.C. 1581(d)	** 5,000	N/A	** 5,000
Failure to Stop Vessel When Directed; Master, Owner, Operator or Person in Charge—Minimum Penalty.	19 U.S.C. 1581(d)	** 1,000	N/A	** 1,000
Anchorage Ground/Harbor Regulations General.	33 U.S.C. 471; 33 CFR 27.3	11,053	1.02041	11,279
Anchorage Ground/Harbor Regulations St. Mary's river.	33 U.S.C. 474; 33 CFR 27.3	762	1.02041	778
Bridges/Failure to Comply with Regulations	33 U.S.C. 495(b); 33 CFR 27.3	27,904	1.02041	28,474
Bridges/Drawbridges	33 U.S.C. 499(c); 33 CFR 27.3	27,904	1.02041	28,474
Bridges/Failure to Alter Bridge Obstructing Navigation.	33 U.S.C. 502(c); 33 CFR 27.3	27,904	1.02041	28,474
Bridges/Maintenance and Operation	33 U.S.C. 533(b); 33 CFR 27.3	27,904	1.02041	28,474
Bridge to Bridge Communication; Master, Person in Charge or Pilot.	33 U.S.C. 1208(a); 33 CFR 27.3	2,033	1.02041	2,074
Bridge to Bridge Communication; Vessel	33 U.S.C. 1208(b); 33 CFR 27.3	2,033	1.02041	2,074
PWSA Regulations	33 U.S.C. 1232(a); 33 CFR 27.3	90,063	1.02041	91,901
Vessel Navigation: Regattas or Marine Parades; Unlicensed Person in Charge.	33 U.S.C. 1236(b); 33 CFR 27.3	9,054	1.02041	9,239
Vessel Navigation: Regattas or Marine Parades; Owner Onboard Vessel.	33 U.S.C. 1236(c); 33 CFR 27.3	9,054	1.02041	9,239
Vessel Navigation: Regattas or Marine Parades; Other Persons.	33 U.S.C. 1236(d); 33 CFR 27.3	4,527	1.02041	4,619
Oil/Hazardous Substances: Discharges (Class I per violation).	33 U.S.C. 1321(b)(6)(B)(i); 33 CFR 27.3	18,107	1.02041	18,477
Oil/Hazardous Substances: Discharges (Class I total under paragraph).	33 U.S.C. 1321(b)(6)(B)(i); 33 CFR 27.3	45,268	1.02041	46,192
Oil/Hazardous Substances: Discharges (Class II per day of violation).	33 U.S.C. 1321(b)(6)(B)(ii); 33 CFR 27.3	18,107	1.02041	18,477
Oil/Hazardous Substances: Discharges (Class II total under paragraph).	33 U.S.C. 1321(b)(6)(B)(ii); 33 CFR 27.3	226,338	1.02041	230,958
Oil/Hazardous Substances: Discharges (per day of violation) Judicial Assessment.	33 U.S.C. 1321(b)(7)(A); 33 CFR 27.3	45,268	1.02041	46,192
Oil/Hazardous Substances: Discharges (per barrel of oil or unit discharged) Judicial Assessment.	33 U.S.C. 1321(b)(7)(A); 33 CFR 27.3	1,811	1.02041	1,848
Oil/Hazardous Substances: Failure to Carry Out Removal/Comply With Order (Judicial Assessment).	33 U.S.C. 1321(b)(7)(B); 33 CFR 27.3	45,268	1.02041	46,192
Oil/Hazardous Substances: Failure to Comply with Regulation Issued Under 1321(j) (Judicial Assessment).	33 U.S.C. 1321(b)(7)(C); 33 CFR 27.3	45,268	1.02041	46,192
Oil/Hazardous Substances: Discharges, Gross Negligence (per barrel of oil or unit discharged) Judicial Assessment.	33 U.S.C. 1321(b)(7)(D); 33 CFR 27.3	5,432	1.02041	5,543
Oil/Hazardous Substances: Discharges, Gross Negligence—Minimum Penalty (Judicial Assessment).	33 U.S.C. 1321(b)(7)(D); 33 CFR 27.3	181,071	1.02041	184,767
Marine Sanitation Devices; Operating	33 U.S.C. 1322(j); 33 CFR 27.3	7,623	1.02041	7,779
Marine Sanitation Devices; Sale or Manufacture.	33 U.S.C. 1322(j); 33 CFR 27.3	20,327	1.02041	20,742
International Navigation Rules; Operator	33 U.S.C. 1608(a); 33 CFR 27.3	14,252	1.02041	14,543
International Navigation Rules; Vessel	33 U.S.C. 1608(b); 33 CFR 27.3	14,252	1.02041	14,543
Pollution from Ships; General	33 U.S.C. 1908(b)(1); 33 CFR 27.3	71,264	1.02041	72,718
Pollution from Ships; False Statement	33 U.S.C. 1908(b)(1); 33 CFR 27.3	14,252	1.02041	14,543
Inland Navigation Rules; Operator	33 U.S.C. 2072(a); 33 CFR 27.3	14,252	1.02041	14,543
Inland Navigation Rules; Vessel	33 U.S.C. 2072(b); 33 CFR 27.3	14,252	1.02041	14,543
Shore Protection; General	33 U.S.C. 2609(a); 33 CFR 27.3	50,276	1.02041	51,302
Shore Protection; Operating Without Permit	33 U.S.C. 2609(b); 33 CFR 27.3	20,111	1.02041	20,521
Oil Pollution Liability and Compensation	33 U.S.C. 2716a(a); 33 CFR 27.3	45,268	1.02041	46,192

TABLE 4—U.S. COAST GUARD CIVIL PENALTIES ADJUSTMENTS—Continued

Penalty name	Citation	Penalty amount as adjusted in the 2017 FR	Multiplier *	New penalty as adjusted by this final rule
Clean Hulls	33 U.S.C. 3852(a)(1)(A); 33 CFR 27.3	41,446	1.02041	42,292
Clean Hulls-related to false statements	33 U.S.C. 3852(a)(1)(A); 33 CFR 27.3	55,263	1.02041	56,391
Clean Hulls-Recreational Vessel	33 U.S.C. 3852(c); 33 CFR 27.3	5,526	1.02041	5,639
Hazardous Substances, Releases, Liability, Compensation (Class I).	42 U.S.C. 9609(a); 33 CFR 27.3	54,789	1.02041	55,907
Hazardous Substances, Releases, Liability, Compensation (Class II).	42 U.S.C. 9609(b); 33 CFR 27.3	54,789	1.02041	55,907
Hazardous Substances, Releases, Liability, Compensation (Class II subsequent offense).	42 U.S.C. 9609(b); 33 CFR 27.3	164,367	1.02041	167,722
Hazardous Substances, Releases, Liability, Compensation (Judicial Assessment).	42 U.S.C. 9609(c); 33 CFR 27.3	54,789	1.02041	55,907
Hazardous Substances, Releases, Liability, Compensation (Judicial Assessment subsequent offense).	42 U.S.C. 9609(c); 33 CFR 27.3	164,367	1.02041	167,722
Safe Containers for International Cargo	46 U.S.C. App 1505(a)(2) (codified as 46 U.S.C. 80509); 33 CFR 27.3.	5,989	1.02041	6,111
Suspension of Passenger Service	46 U.S.C. App 1805(c)(2) (codified 46 U.S.C. 70305); 33 CFR 27.3.	59,893	1.02041	61,115
Vessel Inspection or Examination Fees	46 U.S.C. 2110(e); 33 CFR 27.3	9,054	1.02041	9,239
Alcohol and Dangerous Drug Testing	46 U.S.C. 2115; 33 CFR 27.3	7,370	1.02041	7,520
Negligent Operations: Recreational Vessels	46 U.S.C. 2302(a); 33 CFR 27.3	6,666	1.02041	6,802
Negligent Operations: Other Vessels	46 U.S.C. 2302(a); 33 CFR 27.3	33,333	1.02041	34,013
Operating a Vessel While Under the Influence of Alcohol or a Dangerous Drug.	46 U.S.C. 2302(c)(1); 33 CFR 27.3	7,370	1.02041	7,520
Vessel Reporting Requirements: Owner, Charterer, Managing Operator, or Agent.	46 U.S.C. 2306(a)(4); 33 CFR 27.3	11,478	1.02041	11,712
Vessel Reporting Requirements: Master	46 U.S.C. 2306(b)(2); 33 CFR 27.3	2,296	1.02041	2,343
Immersion Suits	46 U.S.C. 3102(c)(1); 33 CFR 27.3	11,478	1.02041	11,712
Inspection Permit	46 U.S.C. 3302(i)(5); 33 CFR 27.3	2,394	1.02041	2,443
Vessel Inspection; General	46 U.S.C. 3318(a); 33 CFR 27.3	11,478	1.02041	11,712
Vessel Inspection; Nautical School Vessel	46 U.S.C. 3318(g); 33 CFR 27.3	11,478	1.02041	11,712
Vessel Inspection; Failure to Give Notice IAW 3304(b).	46 U.S.C. 3318(h); 33 CFR 27.3	2,296	1.02041	2,343
Vessel Inspection; Failure to Give Notice IAW 3309(c).	46 U.S.C. 3318(i); 33 CFR 27.3	2,296	1.02041	2,343
Vessel Inspection; Vessel ≥1600 Gross Tons	46 U.S.C. 3318(j)(1); 33 CFR 27.3	22,957	1.02041	23,426
Vessel Inspection; Vessel <1600 Gross Tons	46 U.S.C. 3318(j)(1); 33 CFR 27.3	4,591	1.02041	4,685
Vessel Inspection; Failure to Comply with 3311(b).	46 U.S.C. 3318(k); 33 CFR 27.3	22,957	1.02041	23,426
Vessel Inspection; Violation of 3318(b)–3318(f).	46 U.S.C. 3318(l); 33 CFR 27.3	11,478	1.02041	11,712
List/count of Passengers	46 U.S.C. 3502(e); 33 CFR 27.3	239	1.02041	244
Notification to Passengers	46 U.S.C. 3504(c); 33 CFR 27.3	23,933	1.02041	24,421
Notification to Passengers; Sale of Tickets	46 U.S.C. 3504(c); 33 CFR 27.3	1,196	1.02041	1,220
Copies of Laws on Passenger Vessels; Master.	46 U.S.C. 3506; 33 CFR 27.3	479	1.02041	489
Liquid Bulk/Dangerous Cargo	46 U.S.C. 3718(a)(1); 33 CFR 27.3	59,834	1.02041	61,055
Uninspected Vessels	46 U.S.C. 4106; 33 CFR 27.3	10,055	1.02041	10,260
Recreational Vessels (maximum for related series of violations).	46 U.S.C. 4311(b)(1); 33 CFR 27.3	316,566	1.02041	323,027
Recreational Vessels; Violation of 4307(a)	46 U.S.C. 4311(b)(1); 33 CFR 27.3	6,331	1.02041	6,460
Recreational vessels	46 U.S.C. 4311(c); 33 CFR 27.3	2,394	1.02041	2,443
Uninspected Commercial Fishing Industry Vessels.	46 U.S.C. 4507; 33 CFR 27.3	10,055	1.02041	10,260
Abandonment of Barges	46 U.S.C. 4703; 33 CFR 27.3	1,704	1.02041	1,739
Load Lines	46 U.S.C. 5116(a); 33 CFR 27.3	10,957	1.02041	11,181
Load Lines; Violation of 5112(a)	46 U.S.C. 5116(b); 33 CFR 27.3	21,916	1.02041	22,363
Load Lines; Violation of 5112(b)	46 U.S.C. 5116(c); 33 CFR 27.3	10,957	1.02041	11,181
Reporting Marine Casualties	46 U.S.C. 6103(a); 33 CFR 27.3	38,175	1.02041	38,954
Reporting Marine Casualties; Violation of 6104.	46 U.S.C. 6103(b); 33 CFR 27.3	10,055	1.02041	10,260
Manning of Inspected Vessels; Failure to Report Deficiency in Vessel Complement.	46 U.S.C. 8101(e); 33 CFR 27.3	1,811	1.02041	1,848
Manning of Inspected Vessels	46 U.S.C. 8101(f); 33 CFR 27.3	18,107	1.02041	18,477
Manning of Inspected Vessels; Employing or Serving in Capacity not Licensed by USCG.	46 U.S.C. 8101(g); 33 CFR 27.3	18,107	1.02041	18,477

TABLE 4—U.S. COAST GUARD CIVIL PENALTIES ADJUSTMENTS—Continued

Penalty name	Citation	Penalty amount as adjusted in the 2017 FR	Multiplier *	New penalty as adjusted by this final rule
Manning of Inspected Vessels; Freight Vessel <100 GT, Small Passenger Vessel, or Sailing School Vessel.	46 U.S.C. 8101(h); 33 CFR 27.3	2,394	1.02041	2,443
Watchmen on Passenger Vessels	46 U.S.C. 8102(a)	2,394	1.02041	2,443
Citizenship Requirements	46 U.S.C. 8103(f)	1,196	1.02041	1,220
Watches on Vessels; Violation of 8104(a) or (b).	46 U.S.C. 8104(i)	18,107	1.02041	18,477
Watches on Vessels; Violation of 8104(c), (d), (e), or (h).	46 U.S.C. 8104(j)	18,107	1.02041	18,477
Staff Department on Vessels	46 U.S.C. 8302(e)	239	1.02041	244
Officer's Competency Certificates	46 U.S.C. 8304(d)	239	1.02041	244
Coastwise Pilotage; Owner, Charterer, Managing Operator, Agent, Master or Individual in Charge.	46 U.S.C. 8502(e)	18,107	1.02041	18,477
Coastwise Pilotage; Individual	46 U.S.C. 8502(f)	18,107	1.02041	18,477
Federal Pilots	46 U.S.C. 8503	57,391	1.02041	58,562
Merchant Mariners Documents	46 U.S.C. 8701(d)	1,196	1.02041	1,220
Crew Requirements	46 U.S.C. 8702(e)	18,107	1.02041	18,477
Small Vessel Manning	46 U.S.C. 8906	38,175	1.02041	38,954
Pilotage: Great Lakes; Owner, Charterer, Managing Operator, Agent, Master or Individual in Charge.	46 U.S.C. 9308(a)	18,107	1.02041	18,477
Pilotage: Great Lakes; Individual	46 U.S.C. 9308(b)	18,107	1.02041	18,477
Pilotage: Great Lakes; Violation of 9303	46 U.S.C. 9308(c)	18,107	1.02041	18,477
Failure to Report Sexual Offense	46 U.S.C. 10104(b)	9,623	1.02041	9,819
Pay Advances to Seamen	46 U.S.C. 10314(a)(2)	1,196	1.02041	1,220
Pay Advances to Seamen; Remuneration for Employment.	46 U.S.C. 10314(b)	1,196	1.02041	1,220
Allotment to Seamen	46 U.S.C. 10315(c)	1,196	1.02041	1,220
Seamen Protection; General	46 U.S.C. 10321	8,296	1.02041	8,465
Coastwise Voyages: Advances	46 U.S.C. 10505(a)(2)	8,296	1.02041	8,465
Coastwise Voyages: Advances; Remuneration for Employment.	46 U.S.C. 10505(b)	8,296	1.02041	8,465
Coastwise Voyages: Seamen Protection; General.	46 U.S.C. 10508(b)	8,296	1.02041	8,465
Effects of Deceased Seamen	46 U.S.C. 10711	479	1.02041	489
Complaints of Unfitness	46 U.S.C. 10902(a)(2)	1,196	1.02041	1,220
Proceedings on Examination of Vessel	46 U.S.C. 10903(d)	239	1.02041	244
Permission to Make Complaint	46 U.S.C. 10907(b)	1,196	1.02041	1,220
Accommodations for Seamen	46 U.S.C. 11101(f)	1,196	1.02041	1,220
Medicine Chests on Vessels	46 U.S.C. 11102(b)	1,196	1.02041	1,220
Destitute Seamen	46 U.S.C. 11104(b)	239	1.02041	244
Wages on Discharge	46 U.S.C. 11105(c)	1,196	1.02041	1,220
Log Books; Master Failing to Maintain	46 U.S.C. 11303(a)	479	1.02041	489
Log Books; Master Failing to Make Entry	46 U.S.C. 11303(b)	479	1.02041	489
Log Books; Late Entry	46 U.S.C. 11303(c)	359	1.02041	366
Carrying of Sheath Knives	46 U.S.C. 11506	120	1.02041	122
Vessel Documentation	46 U.S.C. 12151(a)(1)	15,675	1.02041	15,995
Documentation of Vessels—Related to Activities involving mobile offshore drilling units.	46 U.S.C. 12151(a)(2)	26,126	1.02041	26,659
Vessel Documentation; Fishery Endorsement	46 U.S.C. 12151(c)	119,786	1.02041	122,231
Numbering of Undocumented Vessels—Willful violation.	46 U.S.C. 12309(a)	11,967	1.02041	12,211
Numbering of Undocumented Vessels	46 U.S.C. 12309(b)	2,394	1.02041	2,443
Vessel Identification System	46 U.S.C. 12507(b)	20,111	1.02041	20,521
Measurement of Vessels	46 U.S.C. 14701	43,832	1.02041	44,727
Measurement; False Statements	46 U.S.C. 14702	43,832	1.02041	44,727
Commercial Instruments and Maritime Liens	46 U.S.C. 31309	20,111	1.02041	20,521
Commercial Instruments and Maritime Liens; Mortgagor.	46 U.S.C. 31330(a)(2)	20,111	1.02041	20,521
Commercial Instruments and Maritime Liens; Violation of 31329.	46 U.S.C. 31330(b)(2)	50,276	1.02041	51,302
Port Security	46 U.S.C. 70119(a)	33,333	1.02041	34,013
Port Security—Continuing Violations	46 U.S.C. 70119(b)	59,893	1.02041	61,115
Maritime Drug Law Enforcement	46 U.S.C. 70506(c)	5,526	1.02041	5,639
Hazardous Materials: Related to Vessels	49 U.S.C. 5123(a)(1)	78,376	1.02041	79,976
Hazardous Materials: Related to Vessels—Penalty from Fatalities, Serious Injuries/Illness or substantial Damage to Property.	49 U.S.C. 5123(a)(2)	182,877	1.02041	186,610

TABLE 4—U.S. COAST GUARD CIVIL PENALTIES ADJUSTMENTS—Continued

Penalty name	Citation	Penalty amount as adjusted in the 2017 FR	Multiplier *	New penalty as adjusted by this final rule
Hazardous Materials: Related to Vessels; Training.	49 U.S.C. 5123(a)(3)	471	1.02041	481

* OMB, Implementation of the 2017 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, December 15, 2017. *https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-03.pdf.*
** Enacted under the Tariff Act; exempt from inflation adjustments.

E. Transportation Security Administration

The Transportation Security Administration (TSA) is updating its civil penalties regulation in accordance with the 2015 Act. Pursuant to its statutory authority in 49 U.S.C. 46301(a)(1) and (4) and 49 U.S.C. 114(v),[7] TSA may impose penalties for violations of any statute that TSA administers, whether an implementing regulation or order imposes the penalty. TSA assesses these penalties for a wide variety of aviation and surface security requirements, including violations of TSA's requirements applicable to Transportation Worker Identification Credentials (TWIC),[8] as well as violations of requirements described in chapter 449 of title 49 of the United States Code. These penalties can apply to a wide variety of situations, as described in the statutory and regulatory provisions, as well as in guidance that TSA publishes. Below is a table showing the 2018 adjustment for the penalties that TSA administers.

TABLE 5—TRANSPORTATION SECURITY ADMINISTRATION CIVIL PENALTIES ADJUSTMENTS

Penalty name	Citation	Penalty amount as adjusted in the 2017 FR	Multiplier *	New penalty as adjusted by this final rule
Violation of 49 U.S.C. ch. 449 (except secs. 44902, 44903(d), 44907(a)–(d)(1)(A), 44907(d)(1)(C)–(f), 44908, and 44909), or 49 U.S.C. 46302 or 46303, a regulation prescribed, or order issued thereunder by a person operating an aircraft for the transportation of passengers or property for compensation.	49 U.S.C. 46301(a)(1), (4); 49 CFR 1503.401(c)(2).	$32,666 (up to a total of $522,657 per civil penalty action).	1.02041	$33,333 (up to a total of $533,324 per civil penalty action).
Violation of 49 U.S.C. ch. 449 (except secs. 44902, 44903(d), 44907(a)–(d)(1)(A), 44907(d)(1)(C)–(f), 44908, and 44909), or 49 U.S.C. 46302 or 46303, a regulation prescribed, or order issued thereunder by an individual (except an airman serving as an airman), any person not operating an aircraft for the transportation of passengers or property for compensation, or a small business concern.	49 U.S.C. 46301(a)(1), (4); 49 CFR 1503.401(c)(1).	$13,066 (up to a total of $65,333 total for small businesses, $522,657 for others).	1.02041	$13,333(up to a total of $66,666 total for small business, $533,324 for others).
Violation of any other provision of title 49 U.S.C. or of 46 U.S.C. ch. 701, a regulation prescribed, or order issued thereunder.	49 U.S.C. 114(v); 49 CFR 1503.401(b).	$11,182 (up to a total of $55,910 total for small businesses, $447,280 for others).	1.02041	$11,410 (up to a total of $57,051 total for small businesses, $456,409 for others).

* OMB, Implementation of the 2018 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, December 15, 2017. *https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-03.pdf.*

V. Administrative Procedure Act

DHS is promulgating this final rule to ensure that the amount of civil penalties that DHS assesses or enforces reflects the statutorily mandated ranges as adjusted for inflation. The 2015 Act provides a clear formula for adjustment of the civil penalties, leaving DHS and its components with little room for discretion. DHS and its components have been charged only with performing ministerial computations to determine the amounts of adjustments for inflation to civil monetary penalties. In these annual adjustments DHS is merely updating the penalty amounts by applying the cost-of-living adjustment multiplier that OMB has provided to agencies. Furthermore, the 2015 Act specifically instructed that agencies make the required annual adjustments notwithstanding section 553 of title 5 of the United States Code. Thus, as specified in the 2015 Act, the prior public notice-and-comment procedures and delayed effective date requirements of the Administrative Procedure Act (APA) do not apply to this rule.

VI. Regulatory Analyses

A. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and

[7] As amended by sec. 1302 of the Implementing Recommendations of the 9/11 Commission Act of 2007 (Pub. L. 110–53, 121 Stat. 266 (Aug. 3, 2007)).

[8] *See, e.g.,* 46 U.S.C. 70105, 49 U.S.C. 46302 and 46303, and U.S.C. chapter 449.

benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. OMB has not designated this final rule a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed this rule.

This final rule makes nondiscretionary adjustments to existing civil monetary penalties in accordance with the 2015 Act and OMB guidance.[9] DHS therefore did not consider alternatives and does not have the flexibility to alter the adjustments of the civil monetary penalty amounts as provided in this rule. To the extent this final rule increases civil monetary penalties, it would result in an increase in transfers from persons or entities assessed a civil monetary penalty to the government.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act applies only to rules for which an agency publishes a notice of proposed rulemaking pursuant to 5 U.S.C. 553(b). See 5 U.S.C. 601–612. The Regulatory Flexibility Act does not apply to this final rule, because a notice of proposed rulemaking was not required for the reasons stated above.

C. Unfunded Mandates Reform Act

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

D. Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule, because this final rule does not trigger any new or revised recordkeeping or reporting.

List of Subjects

6 CFR Part 27

Reporting and recordkeeping requirements, Security measures.

8 CFR Part 270

Administrative practice and procedure, Aliens, Employment, Fraud, Penalties.

8 CFR Part 274a

Administrative practice and procedure, Aliens, Employment, Penalties, Reporting and recordkeeping requirements.

8 CFR Part 280

Administrative practice and procedure, Immigration, Penalties.

19 CFR Part 4

Customs duties and inspection, Exports, Freight, Harbors, Maritime carriers, Oil pollution, Reporting and recordkeeping requirements, Vessels.

33 CFR Part 27

Administrative practice and procedure, Penalties.

49 CFR Part 1503

Administrative practice and procedure, Investigations, Law enforcement, Penalties.

Amendments to the Regulations

Accordingly, for the reasons stated in the preamble, DHS is amending 6 CFR part 27, 8 CFR parts 270, 274a, and 280, 19 CFR part 4, 33 CFR part 27, and 49 CFR part 1503 as follows:

Title 6—Domestic Security

PART 27—CHEMICAL FACILITY ANTI–TERRORISM STANDARDS

■ 1. The authority citation for part 27 continues to read as follows:

Authority: 6 U.S.C. 624; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 114–74, 129 Stat. 599.

■ 2. In § 27.300, revise paragraph (b)(3) to read as follows:

§ 27.300 Orders.

* * * * *

(b) * * *

(3) Where the Assistant Secretary determines that a facility is in violation of an Order issued pursuant to paragraph (a) of this section and issues an Order Assessing Civil Penalty pursuant to paragraph (b)(1) of this section, a chemical facility is liable to the United States for a civil penalty of not more than $25,000 for each day during which the violation continues, if the violation of the Order occurred on or before November 2, 2015, or $34,013 for each day during which the violation of the Order continues, if the violation occurred after November 2, 2015.

* * * * *

Title 8—Aliens and Nationality

PART 270—PENALTIES FOR DOCUMENT FRAUD

■ 3. The authority citation for part 270 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, and 1324c; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 104–134, 110 Stat. 1321 and Pub. L. 114–74, 129 Stat. 599.

■ 4. In § 270.3, revise paragraphs (b)(1)(ii)(A) through (D) to read as follows:

§ 270.3 Penalties.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(A) *First offense under section 274C(a)(1) through (a)(4).* Not less than $275 and not exceeding $2,200 for each fraudulent document or each proscribed activity described in section 274C(a)(1) through (a)(4) of the Act before March 27, 2008; not less than $375 and not exceeding $3,200 for each fraudulent document or each proscribed activity described in section 274C(a)(1) through (a)(4) of the Act on or after March 27, 2008 and on or before November 2, 2015; and not less than $461 and not exceeding $3,695 for each fraudulent document or each proscribed activity described in section 274C(a)(1) through (a)(4) of the Act after November 2, 2015.

(B) *First offense under section 274C(a)(5) or (a)(6).* Not less than $250 and not exceeding $2,000 for each fraudulent document or each proscribed activity described in section 274C(a)(5) or (a)(6) of the Act before March 27, 2008; not less than $275 and not exceeding $2,200 for each fraudulent document or each proscribed activity described in section 274C(a)(5) or (a)(6) of the Act on or after March 27, 2008 and on or before November 2, 2015; and not less than $390 and not exceeding $3,116 for each fraudulent document or each proscribed activity described in section 274C(a)(5) or (a)(6) of the Act after November 2, 2015.

(C) *Subsequent offenses under section 274C(a)(1) through (a)(4).* Not less than $2,200 and not more than $5,500 for each fraudulent document or each proscribed activity described in section 274C(a)(1) through (a)(4) of the Act before March 27, 2008; not less than

[9] OMB, Implementation of the 2018 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, December 15, 2017. *https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-03.pdf.*

$3,200 and not exceeding $6,500 for each fraudulent document or each proscribed activity described in section 274C(a)(1) through (a)(4) of the Act occurring on or after March 27, 2008 and on or before November 2, 2015; and not less than $3,695 and not more than $9,239 for each fraudulent document or each proscribed activity described in section 274C(a)(1) through (a)(4) of the Act after November 2, 2015.

(D) *Subsequent offenses under section 274C(a)(5) or (a)(6).* Not less than $2,000 and not more than $5,000 for each fraudulent document or each proscribed activity described in section 274C(a)(5) or (a)(6) of the Act before March 27, 2008; not less than $2,200 and not exceeding $5,500 for each fraudulent document or each proscribed activity described in section 274C(a)(5) or (a)(6) of the Act occurring on or after March 27, 2008 and on or before November 2, 2015; and not less than $3,116 and not more than $7,791 for each fraudulent document or each proscribed activity described in section 274C(a)(5) or (a)(6) of the Act after November 2, 2015.

* * * * *

PART 274a—CONTROL OF EMPLOYMENT OF ALIENS

■ 5. The authority citation for part 274a continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1324a; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 114–74, 129 Stat. 599.

■ 6. In § 274a.8, revise paragraph (b) to read as follows:

§ 274a.8 Prohibition of indemnity bonds.

* * * * *

(b) *Penalty.* Any person or other entity who requires any individual to post a bond or security as stated in this section shall, after notice and opportunity for an administrative hearing in accordance with section 274A(e)(3)(B) of the Act, be subject to a civil monetary penalty of $1,000 for each violation before September 29, 1999, of $1,100 for each violation occurring on or after September 29, 1999 but on or before November 2, 2015, and of $2,236 for each violation occurring after November 2, 2015, and to an administrative order requiring the return to the individual of any amounts received in violation of this section or, if the individual cannot be located, to the general fund of the Treasury.

■ 7. In § 274a.10, revise paragraphs (b)(1)(ii)(A) through (C) and (b)(2) introductory text to read as follows:

§ 274a.10 Penalties.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(A) First offense—not less than $275 and not more than $2,200 for each unauthorized alien with respect to whom the offense occurred before March 27, 2008; not less than $375 and not exceeding $3,200, for each unauthorized alien with respect to whom the offense occurred occurring on or after March 27, 2008 and on or before November 2, 2015; and not less than $559 and not more than $4,473 for each unauthorized alien with respect to whom the offense occurred occurring after November 2, 2015.

(B) Second offense—not less than $2,200 and not more than $5,500 for each unauthorized alien with respect to whom the second offense occurred before March 27, 2008; not less than $3,200 and not more than $6,500, for each unauthorized alien with respect to whom the second offense occurred on or after March 27, 2008 and on or before November 2, 2015; and not less than $4,473 and not more than $11,181 for each unauthorized alien with respect to whom the second offense occurred after November 2, 2015; or

(C) More than two offenses—not less than $3,300 and not more than $11,000 for each unauthorized alien with respect to whom the third or subsequent offense occurred before March 27, 2008; not less than $4,300 and not exceeding $16,000, for each unauthorized alien with respect to whom the third or subsequent offense occurred on or after March 27, 2008 and on or before November 2, 2015; and not less than $6,709 and not more than $22,363 for each unauthorized alien with respect to whom the third or subsequent offense occurred after November 2, 2015; and

* * * * *

(2) A respondent determined by the Service (if a respondent fails to request a hearing) or by an administrative law judge, to have failed to comply with the employment verification requirements as set forth in § 274a.2(b), shall be subject to a civil penalty in an amount of not less than $100 and not more than $1,000 for each individual with respect to whom such violation occurred before September 29, 1999; not less than $110 and not more than $1,100 for each individual with respect to whom such violation occurred on or after September 29, 1999 and on or before November 2, 2015; and not less than $224 and not more than $2,236 for each individual with respect to whom such violation occurred after November 2, 2015. In determining the amount of the penalty, consideration shall be given to:

* * * * *

PART 280—IMPOSITION AND COLLECTION OF FINES

■ 8. The authority citation for part 280 continues to read as follows:

Authority: 8 U.S.C. 1103, 1221, 1223, 1227, 1229, 1253, 1281, 1283, 1284, 1285, 1286, 1322, 1323, 1330; 66 Stat. 173, 195, 197, 201, 203, 212, 219, 221–223, 226, 227, 230; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 114–74, 129 Stat. 599.

■ 9. In § 280.53, revise paragraphs (b)(1) through (15) to read as follows:

§ 280.53 Civil monetary penalties inflation adjustment.

* * * * *

(b) * * *

(1) Section 231(g) of the Act, Penalties for non-compliance with arrival and departure manifest requirements for passengers, crewmembers, or occupants transported on commercial vessels or aircraft arriving to or departing from the United States: From $1,333 to $1,360.

(2) Section 234 of the Act, Penalties for non-compliance with landing requirements at designated ports of entry for aircraft transporting aliens: From $3,621 to $3,695.

(3) Section 240B(d) of the Act, Penalties for failure to depart voluntarily: From $1,527 minimum/$7,635 maximum to $1,558 minimum/$7,791 maximum.

(4) Section 243(c)(1)(A) of the Act, Penalties for violations of removal orders relating to aliens transported on vessels or aircraft, under section 241(d) of the Act, or for costs associated with removal under section 241(e) of the Act: From $3,054 to $3,116;

(5) Penalties for failure to remove alien stowaways under section 241(d)(2): From $7,635 to $7,791.

(6) Section 251(d) of the Act, Penalties for failure to report an illegal landing or desertion of alien crewmen, and for each alien not reported on arrival or departure manifest or lists required in accordance with section 251 of the Act: From $362 to $369; and penalties for use of alien crewmen for longshore work in violation of section 251(d) of the Act: From $9,054 to $9,239.

(7) Section 254(a) of the Act, Penalties for failure to control, detain, or remove alien crewmen: From $906 minimum/$5,432 maximum to $924 minimum/$5,543 maximum.

(8) Section 255 of the Act, Penalties for employment on passenger vessels of aliens afflicted with certain disabilities: From $1,811 to $1,848.

(9) Section 256 of the Act, Penalties for discharge of alien crewmen: From

$2,716 minimum/$5,432 maximum to $2,771 minimum/$5,543 maximum.

(10) Section 257 of the Act, Penalties for bringing into the United States alien crewmen with intent to evade immigration laws: From $18,107 maximum to $18,477 maximum.

(11) Section 271(a) of the Act, Penalties for failure to prevent the unauthorized landing of aliens: From $5,432 to $5,543.

(12) Section 272(a) of the Act, Penalties for bringing to the United States aliens subject to denial of admission on a health-related ground: From $5,432 to $5,543.

(13) Section 273(b) of the Act, Penalties for bringing to the United States aliens without required documentation: From $5,432 to $5,543.

(14) Section 274D of the Act, Penalties for failure to depart: From $763 to $779, for each day the alien is in violation.

(15) Section 275(b) of the Act, Penalties for improper entry: From $76 minimum/$382 maximum to $78 minimum/$390 maximum, for each entry or attempted entry.

Title 19—Customs Duties

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

■ 10. The authority citation for part 4 continues to read in part as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1431, 1433, 1434, 1624, 2071 note; 46 U.S.C. 501, 60105.

* * * * *

Sections 4.80, 4.80a, and 4.80b also issued under 19 U.S.C. 1706a; 28 U.S.C. 2461 note; 46 U.S.C. 12112, 12117, 12118, 50501–55106, 55107, 55108, 55110, 55114, 55115, 55116, 55117, 55119, 56101, 55121, 56101, 57109; Pub. L. 108–7, Division B, Title II, § 211;

* * * * *

Section 4.92 also issued under 28 U.S.C. 2461 note; 46 U.S.C. 55111;

* * * * *

■ 11. In § 4.80, revise paragraph (b)(2) to read as follows:

§ 4.80 Vessels entitled to engage in coastwise trade.

* * * * *

(b) * * *

(2) The penalty imposed for the unlawful transportation of passengers between coastwise points is $300 for each passenger so transported and landed on or before November 2, 2015, and $778 for each passenger so transported and landed after November 2, 2015 (46 U.S.C. 55103, as adjusted by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015).

* * * * *

■ 12. In § 4.92, revise the second and third sentences to read as follows:

§ 4.92 Towing.

* * * The penalties for violation of this provision occurring on or before November 2, 2015, are a fine of from $350 to $1,100 against the owner or master of the towing vessel and a further penalty against the towing vessel of $60 per ton of the towed vessel. The penalties for violation of this provision occurring after November 2, 2015, are a fine of from $907 to $2,852 against the owner or master of the towing vessel and a further penalty against the towing vessel of $155 per ton of the towed vessel (46 U.S.C. 55111, as adjusted by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015).

Title 33—Navigation and Navigable Waters

PART 27—ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION

■ 13. The authority citation for part 27 continues to read as follows:

Authority: Secs. 1–6, Pub. L. 101–410, 104 Stat. 890, as amended by Sec. 31001(s)(1), Pub. L. 104–134, 110 Stat. 1321 (28 U.S.C. 2461 note); Department of Homeland Security Delegation No. 0170.1, sec. 2 (106).

■ 14. In § 27.3, revise the third sentence of the introductory text and table 1 to read as follows:

§ 27.3 Penalty adjustment table.

* * * The adjusted civil penalty amounts listed in Table 1 are applicable for penalty assessments issued after April 2, 2018, with respect to violations occurring after November 2, 2015. * * *

TABLE 1—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS

U.S. Code citation	Civil monetary penalty description	2018 adjusted maximum penalty amount
14 U.S.C. 88(c)	Saving Life and Property	$10,389
14 U.S.C. 88(e)	Saving Life and Property; Intentional Interference with Broadcast	1,066
14 U.S.C. 645(i)	Confidentiality of Medical Quality Assurance Records (first offense)	5,218
14 U.S.C. 645(i)	Confidentiality of Medical Quality Assurance Records (subsequent offenses)	34,791
16 U.S.C. 4711(g)(1)	Aquatic Nuisance Species in Waters of the United States	38,954
19 U.S.C. 70	Obstruction of Revenue Officers by Masters of Vessels	7,779
19 U.S.C. 70	Obstruction of Revenue Officers by Masters of Vessels—Minimum Penalty	1,815
19 U.S.C. 1581(d)	Failure to Stop Vessel When Directed; Master, Owner, Operator or Person in Charge [1]	5,000
19 U.S.C. 1581(d)	Failure to Stop Vessel When Directed; Master, Owner, Operator or Person in Charge—Minimum Penalty [1].	1,000
33 U.S.C. 471	Anchorage Ground/Harbor Regulations General	11,279
33 U.S.C. 474	Anchorage Ground/Harbor Regulations St. Mary's River	778
33 U.S.C. 495(b)	Bridges/Failure to Comply with Regulations	28,474
33 U.S.C. 499(c)	Bridges/Drawbridges	28,474
33 U.S.C. 502(c)	Bridges/Failure to Alter Bridge Obstructing Navigation	28,474
33 U.S.C. 533(b)	Bridges/Maintenance and Operation	28,474
33 U.S.C. 1208(a)	Bridge to Bridge Communication; Master, Person in Charge or Pilot	2,074
33 U.S.C. 1208(b)	Bridge to Bridge Communication; Vessel	2,074
33 U.S.C. 1232(a)	PWSA Regulations	91,901
33 U.S.C. 1236(b)	Vessel Navigation: Regattas or Marine Parades; Unlicensed Person in Charge	9,239
33 U.S.C. 1236(c)	Vessel Navigation: Regattas or Marine Parades; Owner Onboard Vessel	9,239
33 U.S.C. 1236(d)	Vessel Navigation: Regattas or Marine Parades; Other Persons	4,619
33 U.S.C. 1321(b)(6)(B)(i)	Oil/Hazardous Substances: Discharges (Class I per violation)	18,477
33 U.S.C. 1321(b)(6)(B)(i)	Oil/Hazardous Substances: Discharges (Class I total under paragraph)	46,192
33 U.S.C. 1321(b)(6)(B)(ii)	Oil/Hazardous Substances: Discharges (Class II per day of violation)	18,477

TABLE 1—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS—Continued

U.S. Code citation	Civil monetary penalty description	2018 adjusted maximum penalty amount
33 U.S.C. 1321(b)(6)(B)(ii)	Oil/Hazardous Substances: Discharges (Class II total under paragraph)	230,958
33 U.S.C. 1321(b)(7)(A)	Oil/Hazardous Substances: Discharges (per day of violation) Judicial Assessment	46,192
33 U.S.C. 1321(b)(7)(A)	Oil/Hazardous Substances: Discharges (per barrel of oil or unit discharged) Judicial Assessment.	1,848
33 U.S.C. 1321(b)(7)(B)	Oil/Hazardous Substances: Failure to Carry Out Removal/Comply With Order (Judicial Assessment).	46,192
33 U.S.C. 1321(b)(7)(C)	Oil/Hazardous Substances: Failure to Comply with Regulation Issued Under 1321(j) (Judicial Assessment).	46,192
33 U.S.C. 1321(b)(7)(D)	Oil/Hazardous Substances: Discharges, Gross Negligence (per barrel of oil or unit discharged) Judicial Assessment.	5,543
33 U.S.C. 1321(b)(7)(D)	Oil/Hazardous Substances: Discharges, Gross Negligence—Minimum Penalty (Judicial Assessment).	184,767
33 U.S.C. 1322(j)	Marine Sanitation Devices; Operating	7,779
33 U.S.C. 1322(j)	Marine Sanitation Devices; Sale or Manufacture	20,742
33 U.S.C. 1608(a)	International Navigation Rules; Operator	14,543
33 U.S.C. 1608(b)	International Navigation Rules; Vessel	14,543
33 U.S.C. 1908(b)(1)	Pollution from Ships; General	72,718
33 U.S.C. 1908(b)(2)	Pollution from Ships; False Statement	14,543
33 U.S.C. 2072(a)	Inland Navigation Rules; Operator	14,543
33 U.S.C. 2072(b)	Inland Navigation Rules; Vessel	14,543
33 U.S.C. 2609(a)	Shore Protection; General	51,302
33 U.S.C. 2609(b)	Shore Protection; Operating Without Permit	20,521
33 U.S.C. 2716a(a)	Oil Pollution Liability and Compensation	46,192
33 U.S.C. 3852(a)(1)(A)	Clean Hulls; Civil Enforcement	42,292
33 U.S.C. 3852(a)(1)(A)	Clean Hulls; related to false statements	56,391
33 U.S.C. 3852(c)	Clean Hulls; Recreational Vessels	5,639
42 U.S.C. 9609(a)	Hazardous Substances, Releases, Liability, Compensation (Class I)	55,907
42 U.S.C. 9609(b)	Hazardous Substances, Releases, Liability, Compensation (Class II)	55,907
42 U.S.C. 9609(b)	Hazardous Substances, Releases, Liability, Compensation (Class II subsequent offense)	167,722
42 U.S.C. 9609(c)	Hazardous Substances, Releases, Liability, Compensation (Judicial Assessment)	55,907
42 U.S.C. 9609(c)	Hazardous Substances, Releases, Liability, Compensation (Judicial Assessment subsequent offense).	167,722
46 U.S.C. 80509(a)	Safe Containers for International Cargo	6,111
46 U.S.C. 70305(c)	Suspension of Passenger Service	61,115
46 U.S.C. 2110(e)	Vessel Inspection or Examination Fees	9,239
46 U.S.C. 2115	Alcohol and Dangerous Drug Testing	7,520
46 U.S.C. 2302(a)	Negligent Operations: Recreational Vessels	6,802
46 U.S.C. 2302(a)	Negligent Operations: Other Vessels	34,013
46 U.S.C. 2302(c)(1)	Operating a Vessel While Under the Influence of Alcohol or a Dangerous Drug	7,520
46 U.S.C. 2306(a)(4)	Vessel Reporting Requirements: Owner, Charterer, Managing Operator, or Agent	11,712
46 U.S.C. 2306(b)(2)	Vessel Reporting Requirements: Master	2,343
46 U.S.C. 3102(c)(1)	Immersion Suits	11,712
46 U.S.C. 3302(i)(5)	Inspection Permit	2,443
46 U.S.C. 3318(a)	Vessel Inspection; General	11,712
46 U.S.C. 3318(g)	Vessel Inspection; Nautical School Vessel	11,712
46 U.S.C. 3318(h)	Vessel Inspection; Failure to Give Notice IAW 3304(b)	2,343
46 U.S.C. 3318(i)	Vessel Inspection; Failure to Give Notice IAW 3309(c)	2,343
46 U.S.C. 3318(j)(1)	Vessel Inspection; Vessel ≥1600 Gross Tons	23,426
46 U.S.C. 3318(j)(1)	Vessel Inspection; Vessel <1600 Gross Tons	4,685
46 U.S.C. 3318(k)	Vessel Inspection; Failure to Comply with 3311(b)	23,426
46 U.S.C. 3318(l)	Vessel Inspection; Violation of 3318(b)–3318(f)	11,712
46 U.S.C. 3502(e)	List/count of Passengers	244
46 U.S.C. 3504(c)	Notification to Passengers	24,421
46 U.S.C. 3504(c)	Notification to Passengers; Sale of Tickets	1,220
46 U.S.C. 3506	Copies of Laws on Passenger Vessels; Master	489
46 U.S.C. 3718(a)(1)	Liquid Bulk/Dangerous Cargo	61,055
46 U.S.C. 4106	Uninspected Vessels	10,260
46 U.S.C. 4311(b)(1)	Recreational Vessels (maximum for related series of violations)	323,027
46 U.S.C. 4311(b)(1)	Recreational Vessels; Violation of 4307(a)	6,460
46 U.S.C. 4311(c)	Recreational Vessels	2,443
46 U.S.C. 4507	Uninspected Commercial Fishing Industry Vessels	10,260
46 U.S.C. 4703	Abandonment of Barges	1,739
46 U.S.C. 5116(a)	Load Lines	11,181
46 U.S.C. 5116(b)	Load Lines; Violation of 5112(a)	22,363
46 U.S.C. 5116(c)	Load Lines; Violation of 5112(b)	11,181
46 U.S.C. 6103(a)	Reporting Marine Casualties	38,954
46 U.S.C. 6103(b)	Reporting Marine Casualties; Violation of 6104	10,260
46 U.S.C. 8101(e)	Manning of Inspected Vessels; Failure to Report Deficiency in Vessel Complement	1,848
46 U.S.C. 8101(f)	Manning of Inspected Vessels	18,477

TABLE 1—CIVIL MONETARY PENALTY INFLATION ADJUSTMENTS—Continued

U.S. Code citation	Civil monetary penalty description	2018 adjusted maximum penalty amount
46 U.S.C. 8101(g)	Manning of Inspected Vessels; Employing or Serving in Capacity not Licensed by USCG	18,477
46 U.S.C. 8101(h)	Manning of Inspected Vessels; Freight Vessel <100 GT, Small Passenger Vessel, or Sailing School Vessel.	2,443
46 U.S.C. 8102(a)	Watchmen on Passenger Vessels	2,443
46 U.S.C. 8103(f)	Citizenship Requirements	1,220
46 U.S.C. 8104(i)	Watches on Vessels; Violation of 8104(a) or (b)	18,477
46 U.S.C. 8104(j)	Watches on Vessels; Violation of 8104(c), (d), (e), or (h)	18,477
46 U.S.C. 8302(e)	Staff Department on Vessels	244
46 U.S.C. 8304(d)	Officer's Competency Certificates	244
46 U.S.C. 8502(e)	Coastwise Pilotage; Owner, Charterer, Managing Operator, Agent, Master or Individual in Charge.	18,477
46 U.S.C. 8502(f)	Coastwise Pilotage; Individual	18,477
46 U.S.C. 8503	Federal Pilots	58,562
46 U.S.C. 8701(d)	Merchant Mariners Documents	1,220
46 U.S.C. 8702(e)	Crew Requirements	18,477
46 U.S.C. 8906	Small Vessel Manning	38,954
46 U.S.C. 9308(a)	Pilotage: Great Lakes; Owner, Charterer, Managing Operator, Agent, Master or Individual in Charge.	18,477
46 U.S.C. 9308(b)	Pilotage: Great Lakes; Individual	18,477
46 U.S.C. 9308(c)	Pilotage: Great Lakes; Violation of 9303	18,477
46 U.S.C. 10104(b)	Failure to Report Sexual Offense	9,819
46 U.S.C. 10314(a)(2)	Pay Advances to Seamen	1,220
46 U.S.C. 10314(b)	Pay Advances to Seamen; Remuneration for Employment	1,220
46 U.S.C. 10315(c)	Allotment to Seamen	1,220
46 U.S.C. 10321	Seamen Protection; General	8,465
46 U.S.C. 10505(a)(2)	Coastwise Voyages: Advances	8,465
46 U.S.C. 10505(b)	Coastwise Voyages: Advances; Remuneration for Employment	8,465
46 U.S.C. 10508(b)	Coastwise Voyages: Seamen Protection; General	8,465
46 U.S.C. 10711	Effects of Deceased Seamen	489
46 U.S.C. 10902(a)(2)	Complaints of Unfitness	1,220
46 U.S.C. 10903(d)	Proceedings on Examination of Vessel	244
46 U.S.C. 10907(b)	Permission to Make Complaint	1,220
46 U.S.C. 11101(f)	Accommodations for Seamen	1,220
46 U.S.C. 11102(b)	Medicine Chests on Vessels	1,220
46 U.S.C. 11104(b)	Destitute Seamen	244
46 U.S.C. 11105(c)	Wages on Discharge	1,220
46 U.S.C. 11303(a)	Log Books; Master Failing to Maintain	489
46 U.S.C. 11303(b)	Log Books; Master Failing to Make Entry	489
46 U.S.C. 11303(c)	Log Books; Late Entry	366
46 U.S.C. 11506	Carrying of Sheath Knives	122
46 U.S.C. 12151(a)(1)	Vessel Documentation	15,995
46 U.S.C. 12151(a)(2)	Documentation of Vessels- Related to activities involving mobile offshore drilling units	26,659
46 U.S.C. 12151(c)	Vessel Documentation; Fishery Endorsement	122,231
46 U.S.C. 12309(a)	Numbering of Undocumented Vessels—Willful violation	12,211
46 U.S.C. 12309(b)	Numbering of Undocumented Vessels	2,443
46 U.S.C. 12507(b)	Vessel Identification System	20,521
46 U.S.C. 14701	Measurement of Vessels	44,727
46 U.S.C. 14702	Measurement; False Statements	44,727
46 U.S.C. 31309	Commercial Instruments and Maritime Liens	20,521
46 U.S.C. 31330(a)(2)	Commercial Instruments and Maritime Liens; Mortgagor	20,521
46 U.S.C. 31330(b)(2)	Commercial Instruments and Maritime Liens; Violation of 31329	51,302
46 U.S.C. 70119(a)	Port Security	34,013
46 U.S.C. 70119(b)	Port Security—Continuing Violations	61,115
46 U.S.C. 70506	Maritime Drug Law Enforcement; Penalties	5,639
49 U.S.C. 5123(a)(1)	Hazardous Materials: Related to Vessels—Maximum Penalty	79,976
49 U.S.C. 5123(a)(2)	Hazardous Materials: Related to Vessels—Penalty from Fatalities, Serious Injuries/Illness or Substantial Damage to Property.	186,610
49 U.S.C. 5123(a)(3)	Hazardous Materials: Related to Vessels—Training	481

[1] Enacted under the Tariff Act of 1930, exempt from inflation adjustments

Title 49—Transportation

PART 1503—INVESTIGATIVE AND ENFORCEMENT PROCEDURES

■ 15. The authority citation for part 1503 continues to read as follows:

Authority: 6 U.S.C. 1142; 18 U.S.C. 6002; 28 U.S.C. 2461 (note); 49 U.S.C. 114, 20109, 31105, 40113–40114, 40119, 44901–44907, 46101–46107, 46109–46110, 46301, 46305, 46311, 46313–46314; Pub. L. 104–134, as amended by Pub. L. 114–74.

■ 16. In § 1503.401, revise paragraphs (b)(1) and (2) and (c)(1) through (3) to read as follows:

§ 1503.401 Maximum penalty amounts.

* * * * *

(b) * * *

(1) For violations that occurred on or before November 2, 2015, $10,000 per violation, up to a total of $50,000 per civil penalty action, in the case of an individual or small business concern, as defined in section 3 of the Small Business Act (15 U.S.C. 632). For violations that occurred after November 2, 2015 $11,410 per violation, up to a total of $57,051 per civil penalty action, in the case of an individual or small business concern; and

(2) For violations that occurred on or before November 2, 2015, $10,000 per violation, up to a total of $400,000 per civil penalty action, in the case of any other person. For violations that occurred after November 2, 2015, $11,410 per violation, up to a total of $456,409 per civil penalty action, in the case of any other person.

(c) * * *

(1) For violations that occurred on or before November 2, 2015, $10,000 per violation, up to a total of $50,000 per civil penalty action, in the case of an individual or small business concern, as defined in section 3 of the Small Business Act (15 U.S.C. 632). For violations that occurred after November 2, 2015, $13,333 per violation, up to a total of $66,666 per civil penalty action, in the case of an individual (except an airman serving as an airman), or a small business concern.

(2) For violations that occurred on or before November 2, 2015, $10,000 per violation, up to a total of $400,000 per civil penalty action, in the case of any other person (except an airman serving as an airman) not operating an aircraft for the transportation of passengers or property for compensation. For violations that occurred after November 2, 2015, $13,333 per violation, up to a total of $533,324 per civil penalty action, in the case of any other person (except an airman serving as an airman) not operating an aircraft for the transportation of passengers or property for compensation.

(3) For violations that occurred on or before November 2, 2015, $25,000 per violation, up to a total of $400,000 per civil penalty action, in the case of a person operating an aircraft for the transportation of passengers or property for compensation (except an individual serving as an airman). For violations that occurred after November 2, 2015, $33,333 per violation, up to a total of $533,324 per civil penalty action, in the case of a person (except an individual serving as an airman) operating an aircraft for the transportation of passengers or property for compensation.

Dated: March 26, 2018.

Kirstjen M. Nielsen,

Secretary.

[FR Doc. 2018–06486 Filed 3–30–18; 8:45 am]

BILLING CODE 9110–9P–P, 9111–14–P; 9111–28–P, 9110–04–P, 9110–05–P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 326 and 391

RIN 3064–AE47

Removal of Transferred OTS Regulations Regarding Minimum Security Procedures Amendments to FDIC Regulations

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Final rule.

SUMMARY: The Federal Deposit Insurance Corporation (''FDIC'') is adopting a final rule to rescind and remove a part from the Code of Federal Regulations entitled ''Security Procedures'' and to amend FDIC regulations to make the removed Office of Thrift Supervision (''OTS'') regulations applicable to State savings associations.

DATES: The final rule is effective on May 2, 2018.

FOR FURTHER INFORMATION CONTACT: Lauren Whitaker, Senior Attorney, Consumer Compliance Section, Legal Division (202) 898–3872; Karen Jones Currie, Senior Examination Specialist, Division of Risk Management and Supervision (202) 898–3981.

SUPPLEMENTARY INFORMATION: Part 391, subpart A, was included in the regulations that were transferred to the FDIC from the Office of Thrift Supervision (''OTS'') on July 21, 2011, in connection with the implementation of applicable provisions of title III of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act'').[1] With the exception of one provision (§ 391.5) the requirements for State savings associations in part 391, subpart A, are substantively identical to the requirements in the FDIC's 12 CFR part 326 (''part 326''), which is entitled ''Minimum Security Procedures.'' The one exception directs savings associations to comply with appendix B to subpart B of *Interagency Guidelines Establishing Information Security Standards* (*Interagency Guidelines*) contained in FDIC rules at part 364, appendix B. The FDIC previously revised part 364 to make the *Interagency Guidelines* applicable to both State nonmember banks and State savings associations.[2]

The FDIC is adopting a final rule (''Final Rule'') to rescind in its entirety part 391, subpart A and to modify the scope of part 326 to include State savings associations to conform to and reflect the scope of the FDIC's current supervisory responsibilities as the appropriate Federal banking agency. The FDIC is also adding definitions of ''FDIC-supervised insured depository institution or institution'' and ''State savings association.'' Upon removal of part 391, subpart A, the Security Procedures, regulations applicable for all insured depository institutions for which the FDIC has been designated the appropriate Federal banking agency will be found at 12 CFR part 326.

I. Background

The Dodd-Frank Act

The Dodd-Frank Act provided for a substantial reorganization of the regulation of State and Federal savings associations and their holding companies. Beginning July 21, 2011, the transfer date established by section 311 of the Dodd-Frank Act, codified at 12 U.S.C. 5411, the powers, duties, and functions formerly performed by the OTS were divided among the FDIC, as to State savings associations, the Office of the Comptroller of the Currency (''OCC''), as to Federal savings associations, and the Board of Governors of the Federal Reserve System (''FRB''), as to savings and loan holding companies. Section 316(b) of the Dodd-Frank Act, codified at 12 U.S.C. 5414(b), provides the manner of treatment for all orders, resolutions, determinations, regulations, and advisory materials that had been issued, made, prescribed, or allowed to become effective by the OTS. This section provides that if such materials were in effect on the day before the transfer date, they continue to be in effect and are enforceable by or against the appropriate successor agency until they are modified, terminated, set aside, or superseded in accordance with applicable law by such successor agency, by any court of competent jurisdiction, or by operation of law.

Section 316(c) of the Dodd-Frank Act, codified at 12 U.S.C. 5414(c), further directed the FDIC and the OCC to consult with one another and to publish a list of the continued OTS regulations that would be enforced by the FDIC and

[1] Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010) (codified at 12 U.S.C. 5301 *et seq.*).

[2] 80 FR 65907 (Oct. 28, 2015).

the OCC, respectively. On June 14, 2011, the FDIC's Board of Directors approved a ''List of OTS Regulations to be Enforced by the OCC and the FDIC Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act.'' This list was published by the FDIC and the OCC as a Joint Notice in the **Federal Register** on July 6, 2011.[3]

Although section 312(b)(2)(B)(i)(II) of the Dodd-Frank Act, codified at 12 U.S.C. 5412(b)(2)(B)(i)(II), granted the OCC rulemaking authority relating to both State and Federal savings associations, nothing in the Dodd-Frank Act affected the FDIC's existing authority to issue regulations under the FDI Act and other laws as the ''appropriate Federal banking agency'' or under similar statutory terminology. Section 312(c) of the Dodd-Frank Act amended the definition of ''appropriate Federal banking agency'' contained in section 3(q) of the FDI Act, 12 U.S.C. 1813(q), to add State savings associations to the list of entities for which the FDIC is designated as the ''appropriate Federal banking agency.'' As a result, when the FDIC acts as the designated ''appropriate Federal banking agency'' (or under similar terminology) for State savings associations, as it does here, the FDIC is authorized to issue, modify, and rescind regulations involving such associations, as well as for State nonmember banks and insured branches of foreign banks.

As noted, on June 14, 2011, pursuant to this authority, the FDIC's Board of Directors reissued and redesignated certain transferring regulations of the former OTS. These transferred OTS regulations were published as new FDIC regulations in the **Federal Register** on August 5, 2011.[4] When it republished the transferred OTS regulations as new FDIC regulations, the FDIC specifically noted that its staff would evaluate the transferred OTS rules, and might later recommend incorporating the transferred OTS regulations into other FDIC rules, amending them, or rescinding them as appropriate.

One of the OTS rules transferred to the FDIC governed OTS oversight of minimum security devices and procedures for State savings associations. The OTS rule, formerly found at 12 CFR part 568, was transferred to the FDIC with only nominal changes, and is now found in the FDIC's rules at part 391, subpart A, entitled ''Security Procedures.'' Before the transfer of the OTS rules and continuing today, the FDIC's rules contained part 326, subpart A, entitled ''Minimum Security Procedures,'' a rule governing FDIC oversight of security devices and procedures to discourage burglaries, robberies, and larcenies, and assist law enforcement in the identification and apprehension of those who commit such crimes with respect to insured depository institutions for which the FDIC has been designated the appropriate Federal banking agency. One provision in part 391, subpart A, namely § 391.5, is not contained in part 326, subpart A. It directs savings associations and certain subsidiaries to comply with the *Interagency Guidelines Establishing Information Security Standards,* which were adopted jointly by the OTS and the FDIC and other banking agencies, and are contained in appendix B to part 364 in FDIC regulations.

After careful review and comparison of part 391, subpart A, and part 326, the FDIC is adopting a Final Rule to rescind part 391, subpart A, because, as discussed below, it is substantively redundant to existing part 326, and simultaneously finalizes the technical conforming edits to the FDIC's existing rule.

FDIC's Existing 12 CFR Part 326 and Former OTS's Part 568 (Transferred to FDIC's Part 391, Subpart A)

Section 3 of the Bank Protection Act of 1968 directed the appropriate Federal banking agencies and the OTS' predecessor, the Federal Home Loan Bank Board (''FHLBB''), to establish minimum security standards for banks and savings associations, at reasonable cost, to serve as a deterrent to robberies, burglaries, and larcenies, and to assist law enforcement in identifying and prosecuting persons who commit such acts.[5] In the initial rulemakings, the agencies consulted and cooperated with each other to promote a goal of uniformity where practicable. The initial minimum security rules were simultaneously issued in January 1969 and were substantively the same.[6]

In 1991, the minimum security rules were substantially revised to reduce unnecessary specificity, remove obsolete requirements, and place greater responsibility on the boards of directors of insured financial institutions for establishing and ensuring the implementation and maintenance of security programs and procedures. The former FHLBB rules at 12 CFR part 563a were redesignated as 12 CFR part 568 by the OTS. The OTS rules remained substantively the same as the FDIC's rules in part 326, subpart A.[7]

In 2001, the FDIC, other Federal banking agencies, and the OTS issued *Interagency Guidelines for Safeguarding Customer Information* pursuant to section 501 of the Gramm Leach Bliley Act (''Protection of Nonpublic Personal Information'').[8] At the same time, the OTS added a provision at the end of its security procedures rules at section 568.5 directing saving associations and certain subsidiaries to comply with appendix B to the *Interagency Guidelines.* In a preamble footnote, the OTS indicated that the reason for the additional provision to its minimum security rules was ''[b]ecause information security guidelines are similar to physical security procedures.''[9] In 2004, following enactment of the Fair and Accurate Credit Transactions Act (FACT Act), the OTS, FDIC, and other banking agencies revised the *Interagency Guidelines for Safeguarding Customer Information* and renamed them the *Interagency Guidelines for Establishing Information Security Standards.* The *Interagency Guidelines* were located in the FDIC rules at part 364. In 2015, the FDIC amended part 364 to, among other reasons, make it applicable to State savings associations.[10] After careful comparison of the FDIC's part 326, subpart A, with the transferred OTS rule in part 391, subpart A, the FDIC has concluded that the transferred OTS rules governing minimum security procedures are substantively redundant. Based on the foregoing, the FDIC is adopting a Final Rule to rescind and remove from the Code of Federal Regulations the transferred OTS rules located at part 391, subpart A, and to make technical amendments to part 326, subpart A, to incorporate State savings associations.

II. The Proposed Rule

Regarding the functions of the former OTS that were transferred to the FDIC, section 316(b)(3) of the Dodd-Frank Act, 12 U.S.C. 5414(b)(3), in pertinent part, provides that the former OTS's regulations will be enforceable by the FDIC until they are modified, terminated, set aside, or superseded in accordance with applicable law. After reviewing the rules currently found in part 391, subpart A, the FDIC issued a Notice of Proposed Rulemaking (''NPR'' or ''Proposed Rule''), which proposed to

[3] 76 FR 39247 (July 6, 2011).

[4] 76 FR 47652 (Aug. 5, 2011).

[5] 12 U.S.C. 1882.

[6] 34 FR 618 (January 16, 1969); 34 FR 621 (January 16, 1969).

[7] 56 FR 29565 (June 28, 1991); 56 FR 13579 (April 3, 1991).

[8] 66 FR 8616 (Feb. 1, 2001).

[9] *Id.* at footnote 2.

[10] 80 FR 65903 (Oct. 28, 2015).

(1) rescind part 391, subpart A, in its entirety; (2) modify the scope of part 326, subpart A, to include State savings associations and their subsidiaries to conform to and reflect the scope of FDIC's current supervisory responsibilities as the appropriate Federal banking agency for State savings associations; (3) delete the definition of ''insured nonmember bank'' and replace it with a definition of ''FDIC-supervised insured depository institution or institution,'' which means ''any State nonmember insured bank or State savings association for which the Federal Deposit Insurance Corporation is the appropriate Federal banking agency pursuant to section 3(q) of the Federal Deposit Insurance Act (12 U.S.C. 1813(q))''; (4) add a new subsection (i), which would define ''State savings association'' as having ''the same meaning as in section 3(b)(3) of the Federal Deposit Insurance Act (12 U.S.C. 1813(b)(3))''; and (5) make conforming technical edits throughout, including replacing the term ''bank'' with ''FDIC-supervised insured depository institution'' or ''institution''. Under the Proposed Rule, oversight of minimum security procedures in part 326, subpart A, would apply to all FDIC-supervised institutions, including State savings associations, and part 391, subpart A, would be removed because it is largely redundant of the rules found in part 326. Rescinding part 391, subpart A, will serve to streamline the FDIC's rules and eliminate unnecessary regulations.

III. Comments

The FDIC issued the NPR with a 60-day comment period, which closed on January 3, 2017. The FDIC received no comments on its Proposed Rule, and consequently the Final Rule is adopted as proposed without any changes.

IV. Explanation of the Final Rule

As discussed in the NPR, with the exception of one provision (§ 391.5), the requirements for State savings associations in part 391, subpart A, are substantively identical to the requirements in the FDIC's 12 CFR part 326 (''part 326''). The one exception directs savings associations to comply with appendix B to subpart B of *Interagency Guidelines Establishing Information Security Standards* (*Interagency Guidelines*) contained in FDIC rules at part 364, appendix B. The FDIC previously revised part 364 to make the *Interagency Guidelines* applicable to both State nonmember banks and State savings associations. The designation of part 326 as a single authority regarding security standards and procedures will serve to streamline the FDIC's rules and eliminate unnecessary regulations. To that effect, the Final Rule removes and rescinds 12 CFR part 391, subpart A, in its entirety.

Consistent with the Proposed Rule, the Final Rule modifies the scope of part 326, subpart A, to include State savings associations and their subsidiaries to conform to and reflect the scope of FDIC's current supervisory responsibilities as the appropriate Federal banking agency for State savings associations. The Final Rule also deletes the definition of ''insured nonmember bank'' and replaces it with a definition of ''FDIC-supervised insured depository institution or institution,'' which means ''any State nonmember insured bank or State savings association for which the Federal Deposit Insurance Corporation is the appropriate Federal banking agency pursuant to section 3(q) of the Federal Deposit Insurance Act (12 U.S.C. 1813(q)).'' Additionally, the Final Rule adds a new subsection (i), which would define ''State savings association'' as having ''the same meaning as in section 3(b)(3) of the Federal Deposit Insurance Act (12 U.S.C. 1813(b)(3)) and makes conforming technical edits throughout, including replacing the term ''bank'' with ''FDIC-supervised insured depository institution'' or ''institution''.

V. Regulatory Analysis and Procedure

A. The Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act (''PRA'') of 1995, 44 U.S.C. 3501–3521, the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (''OMB'') control number.

The Final Rule would rescind and remove part 391, subpart A, from the FDIC regulations. This rule was transferred with only nominal changes to the FDIC from the OTS when the OTS was abolished by title III of the Dodd-Frank Act. Part 391, subpart A, is substantively similar to the FDIC's existing part 326, subpart A, regarding oversight of minimum security procedures for depository institutions with the exception of one provision at the end of part 391, subpart A, which directs savings associations to comply with *Interagency Guidelines,* which are located in Appendix B to part 364. In 2015, the FDIC proposed and finalized revisions to part 364 that made part 364, including the *Interagency Guidelines* in Appendix B, applicable to State savings associations as well as State nonmember banks.

The Final Rule also (1) amends part 326, subpart A to include State savings associations and their subsidiaries within its scope; (2) defines ''FDIC-supervised insured depository institution or institution'' and ''State savings association''; and (3) makes conforming technical edits throughout. These measures clarify that State savings associations, as well as State nonmember banks, are subject to part 326, subpart A. With respect to part 326, subpart A, the Final Rule does not revise any existing, or create any new information collection pursuant to the PRA. Consequently, no submission has been made to the Office of Management and Budget for review.

B. The Regulatory Flexibility Act

The Regulatory Flexibility Act requires an agency to consider the impact that a final rule will have on small entities (defined in regulations promulgated by the Small Business Administration to include banking organizations with total assets of less than or equal to $550 million).[11] However, a regulatory flexibility analysis is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities, and publishes its certification and a short explanatory Statement in the **Federal Register** together with the rule. For the reasons provided below, the FDIC certifies that the Final Rule would not have a significant economic impact on a substantial number of small entities.

As discussed in the NPR, part 391, subpart A, was transferred from OTS part 568, which governed minimum security procedures for depository institutions. The initial minimum security rules, though issued separately by the agencies, were all published in January 1969. The OTS rule, part 568, had been in effect since 1991 and all State savings associations were required to comply with it. Because it is substantially the same as existing part 326, subpart A of the FDIC's rules and therefore redundant, the FDIC is adopting a final rule to rescind and remove the transferred regulation now located in part 391, subpart A. As a result, all FDIC-supervised institutions—including State savings associations and their subsidiaries—would be required to comply with the minimum security procedures in part 326, subpart A. Because all State savings associations and their subsidiaries have

[11] 5 U.S.C. 601 *et seq.*

been required to comply with nearly identical security procedures rules since 1969, the Final Rule would not place additional requirements or burdens on any State savings association irrespective of its size. Therefore, the Final Rule would not have a significant impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act

The Office of Management and Budget has determined that the Final Rule is not a ''major rule'' within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996 (''SBREFA''), 5 U.S.C. 801 *et seq.* As required by SBREFA, the FDIC will submit the Final Rule and other appropriate reports to Congress and the Government Accountability Office for review.

D. Plain Language

Section 722 of the Gramm-Leach-Bliley Act, codified at 12 U.S.C. 4809, requires each Federal banking agency to use plain language in all of its proposed and final rules published after January 1, 2000. In the NPR, the FDIC invited comments on whether the Proposed Rule was clearly stated and effectively organized, and how the FDIC might make it easier to understand. Although the FDIC did not receive any comments, the FDIC sought to present the Final Rule in a simple and straightforward manner.

D. The Economic Growth and Regulatory Paperwork Reduction Act

Under section 2222 of the Economic Growth and Regulatory Paperwork Reduction Act of 1996 (''EGRPRA''), the FDIC is required to review all of its regulations, at least once every 10 years, in order to identify any outdated or otherwise unnecessary regulations imposed on insured institutions.[12] The FDIC, along with the other Federal banking agencies, submitted a Joint Report to Congress on March 21, 2017 (''EGRPRA Report'') discussing how the review was conducted, what has been done to date to address regulatory burden, and further measures we will take to address issues that were identified.[13] As noted in the EGRPRA Report, the FDIC is continuing to streamline and clarify its regulations through the OTS rule integration process. By removing outdated or unnecessary regulations, such as part 391, subpart A, and modifying the Minimum Security Procedures, this rule complements other actions the FDIC has taken, separately and with the other Federal banking agencies, to further the EGRPRA mandate.

E. Riegle Community Development and Regulatory Improvement Act of 1994

The Riegle Community Development and Regulatory Improvement Act of 1994 (RCDRIA) requires the FDIC, in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, consider, consistent with principles 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, new regulations and amendments to regulations that impose additional reporting, disclosures, or other new requirements on insured depository institutions generally must 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.[14] The final rule includes no new reporting, disclosure, or other new requirements on insured depository institutions. Therefore, the final rule is not subject to the requirements of the statute.

List of Subjects

12 CFR Part 326

Banks, Banking, Minimum security procedures, Savings associations.

12 CFR Part 391

Security procedures.

Authority and Issuance

For the reasons stated in the preamble, the Board of Directors of the Federal Deposit Insurance Corporation amends 12 CFR parts 326 and 391 as follows:

PART 326—MINIMUM SECURITY DEVICES AND PROCEDURES AND BANK SECRECY ACT [1] COMPLIANCE

■ 1. The authority citation for part 326 continues to read as follows:

Authority: 12 U.S.C. 1813, 1815, 1817, 1818, 1819 (Tenth), 1881–1883; 31 U.S.C. 5311–5314 and 5316–5332.2.

■ 2. Revise subpart A to read as follows:

Subpart A—Minimum Security Procedures

Sec.
326.0 Authority, purpose, and scope.
326.1 Definitions.
326.2 Designation of security officer.
326.3 Security program.
326.4 Reports.

§ 326.0 Authority, purpose, and scope.

(a) This part is issued by the Federal Deposit Insurance Corporation (''FDIC'') pursuant to section 3 of the Bank Protection Act of 1968 (12 U.S.C. 1882). It applies to FDIC-supervised insured depository institutions. It requires each institution to adopt appropriate security procedures to discourage robberies, burglaries, and larcenies and to assist in identifying and apprehending persons who commit such acts.

(b) It is the responsibility of the institution's board of directors to comply with this part and ensure that a written security program for the institution's main office and branches is developed and implemented.

§ 326.1 Definitions.

For the purposes of this part—

(a) The term *FDIC-supervised insured depository institution* or *institution* means any insured depository institution for which the Federal Deposit Insurance Corporation is the appropriate Federal banking agency pursuant to section 3(q)(2) of the Federal Deposit Insurance Act, 12 U.S.C. 1813(q)(2).

(b) The term *banking office* includes any branch of an institution and, in the case of an FDIC-supervised insured depository institution; it includes the main office of that institution.

(c) The term *branch* for an institution chartered under the laws of any state of the United States includes any branch institution, branch office, branch agency, additional office, or any branch place of business located in any state or territory of the United States, District of Columbia, Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, the Northern Mariana Islands or the Virgin Islands at which deposits are received or checks paid or money lent. In the case of a foreign bank defined in § 347.202 of this chapter, the term branch has the meaning given in § 347.202 of this chapter.

(d) The term *State savings association* has the same meaning as in section (3)(b)(3) of the Federal Deposit Insurance Act, 12 U.S.C. 1813(b)(3).

§ 326.2 Designation of security officer.

Upon the issuance of Federal deposit insurance, the board of directors of each

[12] Public Law 104–208, 110 Stat. 3009 (1996).

[13] 82 FR 15900 (March 31, 2017).

[14] 12 U.S.C. 4802.

[1] In its original form, subchapter II of chapter 53 of title 31, U.S.C. was part of Public Law 91–508 which requires recordkeeping for and reporting of currency transactions by banks and others and is commonly known as the *Bank Secrecy Act.*

institution shall designate a security officer who shall have the authority, subject to the approval of the board of directors, to develop, within a reasonable time, but no later than 180 days, and to administer a written security program for each banking office.

§ 326.3 Security program.

(a) *Contents of security program.* The security program shall:

(1) Establish procedures for opening and closing for business and for the safekeeping of all currency, negotiable securities, and similar valuables at all times;

(2) Establish procedures that will assist in identifying persons committing crimes against the institution and that will preserve evidence that may aid in their identification and prosecution; such procedures may include, but are not limited to:

(i) Retaining a record of any robbery, burglary, or larceny committed against the institution;

(ii) Maintaining a camera that records activity in the banking office; and

(iii) Using identification devices, such as prerecorded serial-numbered bills, or chemical and electronic devices;

(3) Provide for initial and periodic training of officers and employees in their responsibilities under the security program and in proper employee conduct during and after a robbery, burglar or larceny; and

(4) Provide for selecting, testing, operating and maintaining appropriate security devices, as specified in paragraph (b) of this section.

(b) *Security devices.* Each institution shall have, at a minimum, the following security devices:

(1) A means of protecting cash or other liquid assets, such as a vault, safe, or other secure space;

(2) A lighting system for illuminating, during the hours of darkness, the area around the vault, if the vault is visible from outside the banking office;

(3) An alarm system or other appropriate device for promptly notifying the nearest responsible law enforcement officers of an attempted or perpetrated robbery or burglary;

(4) Tamper-resistant locks on exterior doors and exterior windows that may be opened; and

(5) Such other devices as the security officer determines to be appropriate, taking into consideration:

(i) The incidence of crimes against financial institutions in the area;

(ii) The amount of currency or other valuables exposed to robbery, burglary, and larceny;

(iii) The distance of the banking office from the nearest responsible law enforcement officers;

(iv) The cost of the security devices;

(v) Other security measures in effect at the banking office; and

(vi) The physical characteristics of the structure of the banking office and its surroundings.

§ 326.4 Reports.

The security officer for each institution shall report at least annually to the institution's board of directors on the implementation, administration, and effectiveness of the security program.

PART 391—[REMOVED AND RESERVED]

■ 3. Under the authority of 12 U.S.C. 1819(a) Tenth, part 391, consisting of subpart A, is removed and reserved.

Dated at Washington, DC, on March 20, 2018.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 2018–06161 Filed 3–30–18; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 343 and 390

RIN 3064–AE49

Removal of Transferred OTS Regulations Regarding Consumer Protection in Sales of Insurance

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Final rule.

SUMMARY: The Federal Deposit Insurance Corporation (''FDIC'') is adopting a final rule to rescind and remove from the Code of Federal Regulations the part entitled ''Consumer Protection in Sales of Insurance'' and to amend current FDIC regulations to make them applicable to state savings associations.

DATES: This final rule is effective on May 2, 2018.

FOR FURTHER INFORMATION CONTACT: Martha L. Ellett, Counsel, Legal Division, (202) 898–6765; John Jackwood, Senior Policy Analyst, Division of Depositor and Consumer Protection, (202) 898–3991.

SUPPLEMENTARY INFORMATION: Part 390, subpart I was included in the regulations that were transferred to the FDIC from the Office of Thrift Supervision (''OTS'') on July 21, 2011, in connection with the implementation of applicable provisions of title III of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''). The requirements for State savings associations in part 390, subpart I are substantively similar to the requirements in the FDIC's 12 CFR part 343 (''part 343'') which is also entitled ''Consumer Protection in Sales of Insurance.''

The FDIC is adopting a final rule to rescind in its entirety part 390, subpart I and to modify the scope of part 343 to include State savings associations and their subsidiaries to conform to and reflect the scope of the FDIC's current supervisory responsibilities as the appropriate Federal banking agency. The final rule also defines ''FDIC-supervised insured depository institution or institution'' and ''State savings association.'' In the final rule, the FDIC also transfers an anticoercion and antitying provision from part 390, subpart I that is applicable to State savings associations.

Upon removal of part 390, subpart I, the Consumer Protection in Sales of Insurance regulations applicable for all insured depository institutions for which the FDIC has been designated the appropriate Federal banking agency will be found at 12 CFR part 343.

I. Background

The Dodd-Frank Act

The Dodd-Frank Act [1] provided for a substantial reorganization of the regulation of State and Federal savings associations and their holding companies. Beginning July 21, 2011, the transfer date established by section 311 of the Dodd-Frank Act, codified at 12 U.S.C. 5411, the powers, duties, and functions formerly performed by the OTS were divided among the FDIC, as to State savings associations, the Office of the Comptroller of the Currency (''OCC''), as to Federal savings associations, and the Board of Governors of the Federal Reserve System (''FRB''), as to savings and loan holding companies. Section 316(b) of the Dodd-Frank Act, codified at 12 U.S.C. 5414(b), provides the manner of treatment for all orders, resolutions, determinations, regulations, and advisory materials that had been issued, made, prescribed, or allowed to become effective by the OTS. This section provides that if such materials were in effect on the day before the transfer date, they continue to be in effect and

[1] Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010) (codified at 12 U.S.C. 5301 *et seq.*).

are enforceable by or against the appropriate successor agency until they are modified, terminated, set aside, or superseded in accordance with applicable law by such successor agency, by any court of competent jurisdiction, or by operation of law.

Section 316(c) of the Dodd-Frank Act, codified at 12 U.S.C. 5414(c), further directed the FDIC and the OCC to consult with one another and to publish a list of the continued OTS regulations that would be enforced by the FDIC and the OCC, respectively. On June 14, 2011, the FDIC's Board of Directors approved a ''List of OTS Regulations to be enforced by the OCC and the FDIC Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act.'' This list was published by the FDIC and the OCC as a Joint Notice in the **Federal Register** on July 6, 2011.[2]

Although section 312(b)(2)(B)(i)(II) of the Dodd-Frank Act, codified at 12 U.S.C. 5412(b)(2)(B)(i)(II), granted the OCC rulemaking authority relating to both State and Federal savings associations, nothing in the Dodd-Frank Act affected the FDIC's existing authority to issue regulations under the Federal Deposit Insurance Act (''FDI Act'') and other laws as the ''Appropriate Federal Banking Agency'' or under similar statutory terminology. Section 312(c) of the Dodd-Frank Act amended the definition of ''Appropriate Federal Banking Agency'' contained in section 3(q) of the FDI Act, 12 U.S.C. 1813(q), to add State savings associations to the list of entities for which the FDIC is designated as the ''appropriate Federal banking agency.'' As a result, when the FDIC acts as the designated ''Appropriate Federal Banking Agency'' (or under similar terminology) for State savings associations, as it does here, the FDIC is authorized to issue, modify and rescind regulations involving such associations, as well as for State nonmember banks and insured branches of foreign banks.

As noted, on June 14, 2011, pursuant to this authority, the FDIC's Board of Directors reissued and redesignated certain transferring regulations of the former OTS. These transferred OTS regulations were published as new FDIC regulations in the **Federal Register** on August 5, 2011.[3] When it republished the transferred OTS regulations as new FDIC regulations, the FDIC specifically noted that its staff would evaluate the transferred OTS rules and might later recommend incorporating the transferred OTS regulations into other FDIC rules, amending them, or rescinding them, as appropriate.

One of the OTS rules transferred to the FDIC governed OTS oversight of consumer protections for depository institution sales of insurance. The OTS rule, formerly found at 12 CFR part 536, was transferred to the FDIC with only nominal changes and is now found in the FDIC's rules at part 390, subpart I, entitled ''Consumer Protection in Sales of Insurance.'' Before the transfer of the OTS rules and continuing today, the FDIC's rules contained part 343, entitled ''Consumer Protection in Sales of Insurance,'' a rule governing FDIC oversight of consumer protection regulations that apply to retail sales practices, solicitations, advertising, or offers of any insurance product with respect to insured depository institutions for which the FDIC has been designated the appropriate Federal banking agency.

After careful review and comparison of part 390, subpart I, and part 343, the FDIC is adopting a final rule to rescind part 390, subpart I, because, as discussed below, it is substantively redundant to existing part 343 and simultaneously finalize technical conforming edits to the existing rule.

FDIC's Existing 12 CFR Part 343 and Former OTS's Part 536 (Transferred, in Part, to FDIC's Part 390, Subpart I)

Section 305 of the Gramm-Leach-Bliley Act (''GLB Act'')[4] added section 47 to the FDI Act,[5] entitled ''Insurance Consumer Protections.'' Section 47 applies to retail sales practices, solicitations, advertising, or offers of insurance products by depository institutions[6] or persons engaged in these activities at an office of the institution or on behalf of the institution.[7] Section 47 directs the FDIC, the OTS, the OCC, and the FRB (collectively the ''Federal banking agencies'') to include provisions specifically relating to sales practices, disclosures and advertising, the physical separation of banking and nonbanking activities, and domestic violence discrimination.[8] On December 4, 2000, pursuant to section 305 of the GLB Act,[9] the Federal banking agencies published a joint final rule[10] to implement consumer protection in sales of insurance provisions of section 47 of the FDI Act.

Section 47 of the FDI Act instructs the Federal banking agencies to consult and coordinate with one another and prescribe and publish joint consumer protection regulations that apply to retail sales practices, solicitations, advertising, or offers of insurance products by depository institutions or persons engaged in these activities at an office of the institution or on behalf of the institution.[11] Section 47 also requires the Federal banking agencies to consult with the State insurance regulators, as appropriate.[12] Pursuant to Section 47, the Federal banking agencies consulted and coordinated with respect to this rulemaking and on an interagency basis jointly issued rules that are substantively identical with regard to consumer protection in sales of insurance requirements,[13] including the same definition of a ''covered person'' or ''you.''[14]

The scope of part 343 in the FDIC's regulations and of part 390, subpart I in the OTS's regulations is substantively similar. The FDIC regulations apply to any bank[15] or any other person that is engaged in such activities at an office of the bank or on behalf of the bank.[16] Similarly, the OTS regulations apply to any State savings association or any other person that is engaged in such activities at an office of a State savings association or on behalf of a State savings association.[17] In the FDIC's scope provisions, any other person includes subsidiaries[18] because only subsidiaries that are selling insurance products or annuities at an office of the institution or acting on behalf of the depository institution as defined in the

[2] 76 FR 39247 (July 6, 2011).

[3] 76 FR 47652 (Aug. 5, 2011).

[4] Gramm-Leach-Bliley Act, Public Law 106–102, 113 Stat. 1338 (1999).

[5] 12 U.S.C. 1831x.

[6] A ''depository institution'' in this context means a national bank in the case of institutions supervised by the OCC, a State member bank in the case of the FRB, a State nonmember bank in the case of the FDIC, and a savings association in the case of the OTS. 65 FR 75822 fn. 1 (Dec. 4, 2000).

[7] 12 U.S.C. 1831x(a)(1)(A).

[8] 12 U.S.C. 1831x.

[9] 12 U.S.C. 1831x(a)(3).

[10] 65 FR 75822 (Dec. 4, 2000).

[11] 12 U.S.C. 1831x(a)(1).

[12] 12 U.S.C. 1831x(a)(3).

[13] 65 FR 75822 (Dec. 4, 2000).

[14] 65 FR 75822, 75824 (Dec. 4, 2000). A ''covered person'' or ''you'' means ''any depository institution or any other person selling, soliciting, advertising, or offering insurance products or annuities to a consumer at an office of the institution or on behalf of the institution. A 'covered person' includes any person, including a subsidiary or other affiliate, if that person or one of its employees sells, solicits, advertises, or offers insurance products or annuities at an office of an institution or on behalf of an institution. 65 FR 75824 (Dec. 4, 2000). *See also* 12 CFR 343.20(j)(1) and 12 CFR 390.181.

[15] Bank means an FDIC-insured, state-chartered commercial or savings bank that is not a member of the Federal Reserve System and for which the FDIC is the appropriate federal banking agency pursuant to section 3(q) of the Federal Deposit Insurance Act (12 U.S.C. 1813(q)). 12 CFR 343.20(b).

[16] 12 CFR 343.10.

[17] 12 CFR 390.180(a)(1), (2).

[18] *See* 65 FR 75822, 75823 (Dec. 4, 2000).

rules would be subject to the requirements of the rules.[19] The OTS regulation specifically states that its regulation applies to subsidiaries of a State savings association only to the extent that it sells, solicits, advertises, or offers insurance products or annuities at an office of a State savings association or on behalf of a State savings association.[20] This OTS provision will not be carried over to the FDIC's part 343 because it is redundant and unnecessary, since the FDIC scope provision already includes subsidiaries within its definition.[21] The rule specifically states that a covered person (or you) includes any person *including a subsidiary or other affiliate* if that person or one of its employees sells, solicits, advertises, or offers insurance products or annuities at an office of an institution or on behalf of an institution.[22]

Accordingly, the portions of the OTS regulations that applied to State savings associations, their subsidiaries and their affiliates, originally codified at 12 CFR part 536 and subsequently transferred to FDIC's part 390, subpart I, are substantively similar to the current FDIC regulations codified at 12 CFR part 343. By amending part 343 to encompass State savings associations and rescinding part 390, subpart I, the FDIC will streamline its regulations and reduce redundancy.

Although the former OTS rule and part 390, subpart I, covers savings and loan holding companies that are affiliated with savings associations in addition to savings associations, the FDIC does not supervise savings and loan or bank holding companies for purposes of this rule. Section 312 of the Dodd-Frank Act[23] divides and transfers the functions of the former OTS to the FDIC, OCC, and FRB by amending section 1813(q) of the FDI Act. Specifically, section 312 transfers the former OTS's power to regulate State savings associations to the FDIC, while it transfers the power to regulate savings and loan holding companies to the FRB.[24] As a result, whereas the former OTS part 536 applied to savings associations, their subsidiaries and their affiliates, including savings and loan holding companies,[25] upon transfer of part 536 to FDIC's part 390, subpart I, only the authority over State savings associations and their subsidiaries and other affiliates was transferred to the FDIC for purposes of this rule.[26] The FRB currently has jurisdiction over the regulation and supervision of consumer protections in connection with retail insurance sales practices as it applies to affiliates, including savings and loan holding companies of State savings associations.[27] For this reason, the existing references to affiliates in part 390, subpart I, are not transferred to part 343 of the FDIC rules.

After careful comparison of the FDIC's part 343 with the transferred OTS rule in part 390, subpart I, the FDIC has concluded that the transferred OTS rules governing consumer protection in sales of insurance are substantively redundant. Based on the foregoing, the FDIC is adopting a final rule to rescind and remove from the Code of Federal Regulations the transferred OTS rules located at part 390, subpart I, and to make technical and conforming changes to part 343 to incorporate State savings associations.

II. Proposed Rule

The functions of the former OTS that were transferred to the FDIC, section 316(b)(3) of the Dodd-Frank Act, 12 U.S.C. 5414(b)(3), in pertinent part, provide that the former OTS's regulations will be enforceable by the FDIC until they are modified, terminated, set aside, or superseded in accordance with applicable law. After reviewing the rules currently found in part 390, subpart I, on November 15, 2016 the FDIC published a Notice of Proposed Rulemaking (''NPR'' or ''Proposed Rule'') to (1) rescind part 390, subpart I, in its entirety; (2) modify to the scope of part 343 to include State savings associations and their subsidiaries to conform to and reflect the scope of FDIC's current supervisory responsibilities as the appropriate Federal banking agency for State savings associations; (3) delete the definition of ''bank'' and replace it with a definition of ''FDIC-supervised insured depository institution or institution'', which means ''any State nonmember insured bank or State savings association for which the Federal Deposit Insurance Corporation is the appropriate Federal banking agency pursuant to section 3(q) of the Federal Deposit Insurance Act (12 U.S.C. 1813(q));'' (4) add a new subsection (i), which would define ''State savings association'' as having ''the same meaning as in section 3(b)(3) of the Federal Deposit Insurance Act (12 U.S.C. 1813(b)(3));'' (5) transfer an anticoercion and antitying provision from part 390, subpart I that is applicable to State savings associations to part 343; and (6) make conforming technical edits throughout, including replacing the term ''institution'' in place of ''bank'' throughout the rule where necessary.

Under the NPR, oversight of consumer protection in sales of insurance in part 343 would apply to all FDIC-supervised institutions, including State savings associations, and part 390, subpart I, would be removed because it is largely redundant of the rules found in part 343. Rescinding part 390, subpart I, would serve to streamline the FDIC's rules and eliminate unnecessary regulations.

III. Comments

The FDIC issued the NPR with a 60-day comment period which closed on January 20, 2017. The FDIC received no comments on its Proposed Rule. The final rule (''Final Rule'') is adopted as proposed without changes.

IV. Explanation of the Final Rule

As discussed in the NPR, part 390, subpart I is substantively the same as the requirements in part 343 and therefore is redundant. The Final Rule removes and rescinds 12 CFR part 390, subpart I in its entirety. This will serve to streamline the FDIC's rules and eliminate unnecessary regulation.

Consistent with the Proposed Rule, the Final Rule also amends the scope of part 343 to include State savings associations and their subsidiaries. The modified scope conforms to and reflects the scope of FDIC's current supervisory responsibilities as the appropriate Federal banking agency for State savings associations. The Final Rule also deletes the definition of ''bank'' and replaces it with a definition of ''FDIC-supervised insured depository institution or institution'' defined as ''any State nonmember insured bank or State savings association for which the Federal Deposit Insurance Corporation is the appropriate Federal banking agency pursuant to section 3(q) of the Federal Deposit Insurance Act (12 U.S.C. 1813(q)).'' As in the Proposed Rule, the Final Rule adds a new subsection (i), which would define ''State savings association'' as ''having the same meaning as in section 3(b)(3) of the Federal Deposit Insurance Act (12 U.S.C. 1813(b)(3)).'' The Final Rule, as the NPR, transfers an anticoercion and antitying provision that is applicable to State savings associations from part 390, subpart I, to part 343. As in the

[19] 65 FR 75822, 75823 (Dec. 4, 2000) (footnote omitted).

[20] 12 CFR 390.180(b).

[21] 12 CFR 343.10.

[22] 65 FR 75822, 75824 (Dec. 4, 2000) (italics added).

[23] Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010) (codified at 12 U.S.C. 5412).

[24] 12 U.S.C. 5412.

[25] 12 CFR 536.1.

[26] 12 CFR 390.180.

[27] 12 CFR part 208, subpart H.

Proposed Rule, the Final Rule also makes conforming technical edits throughout, including using the term ''institution'' in place of ''bank'' throughout the rule where necessary.

V. Regulatory Process

A. The Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act (''PRA'') of 1995, 44 U.S.C. 3501–3521, the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (''OMB'') control number.

The Final Rule would rescind and remove from the FDIC regulations part 390, subpart I. Part 390, subpart I was transferred with only nominal changes to the FDIC from the OTS when the OTS was abolished by title III of the Dodd-Frank Act and is substantively similar to the FDIC's existing part 343 regarding consumer protection in the sales of insurance by depository institutions. The information collections contained in part 343 are cleared by OMB under the FDIC's Insurance Sales Consumer Protections information collection (OMB Control No. 3064–0140). The FDIC reviewed its burden estimates for the collection at the time it assumed responsibility for supervision of State savings associations transferred from the OTS and determined that no changes to the burden estimates were necessary. The Final Rule would not revise the Insurance Sales Consumer Protections information collection under OMB Control No. 3064–0140 or create any new information collection pursuant to the PRA. Consequently, no submission will be made to the Office of Management and Budget for review. In the Proposed Rule, the FDIC requested comment on its conclusion that the NPR did not revise the Insurance Sales Consumer Protections information collection 3064–0140. No comments were received.

The Final Rule, as the Proposed Rule, (1) amends part 343 to include State savings associations and their subsidiaries within its scope; and (2) defines ''FDIC-supervised insured depository institution or institution'' and ''State savings association;'' (3) transfers an anticoercion and antitying provision from part 390, subpart I, that is applicable to State savings associations to part 343; and (4) makes conforming technical edits throughout. These measures clarify that State savings associations, as well as State nonmember banks, are subject to part 343. With respect to part 343, the Final Rule does not revise any existing, or create any new information collection pursuant to the PRA. Consequently, no submission will be made to the Office of Management and Budget for review. The FDIC requested comment on its conclusion that this aspect of the NPR did not create a new or revise and existing information collection. No comments on this issue were received.

B. The Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA''), requires that, in connection with a final rulemaking, an agency prepare and make available for public comment a final regulatory flexibility analysis that describes the impact of the proposed rule on small entities (defined in regulations promulgated by the Small Business Administration to include banking organizations with total assets of less than or equal to $550 million).[28] However, a regulatory flexibility analysis is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities, and publishes its certification and a short explanatory statement in the **Federal Register** together with the rule. For the reasons provided below, the FDIC certifies that the Final Rule would not have a significant economic impact on a substantial number of small entities.

As discussed in the NPR, Part 390, subpart I, was transferred to the FDIC from OTS part 536, which governed consumer protections for depository institution sales of insurance. OTS part 536 had been in effect since 2001 and all State savings associations were required to comply with it. Because it is substantially the same as existing part 343 of the FDIC's rules and therefore redundant, the FDIC is rescinding and removing the transferred regulation now located in part 390, subpart I, as proposed in the NPR. As a result, all FDIC-supervised institutions—including State savings associations and their subsidiaries—would be required to comply with part 343 if they are selling, soliciting, advertising, or offering any insurance product. Because all State savings associations and their subsidiaries have been required to comply with substantially similar consumer protection rules if they engaged in sales of insurance since 2001,[29] the Final Rule would not place additional requirements or burdens on any State savings association irrespective of its size. Therefore, the Final Rule would not have a significant impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act

The OMB has determined that the Final Rule is not a ''major rule'' within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996 (''SBREFA''), 5 U.S.C. 801 *et seq.* As required by SBREFA, the FDIC will submit the Final Rule and other appropriate reports to Congress and the Government Accountability Office for review.

D. Plain Language

Section 722 of the GLB Act, codified at 12 U.S.C. 4809, requires each Federal banking agency to use plain language in all of its proposed and final rules published after January 1, 2000. In the NPR, the FDIC invited comments on whether the NPR was clearly stated and effectively organized, and how the FDIC might make it easier to understand. No comments on this issue were received. Although the FDIC did not receive any comments, the FDIC sought to present the Final Rule in a simple and straightforward manner.

E. The Economic Growth and Regulatory Paperwork Reduction Act

Under section 2222 of the Economic Growth and Regulatory Paperwork Reduction Act of 1996 (''EGRPRA''), the FDIC is required to review all of its regulations, at least once every 10 years, in order to identify any outdated or otherwise unnecessary regulations imposed on insured institutions.[30] The FDIC, along with the other federal banking agencies, submitted a Joint Report to Congress on March 21, 2017 (''EGRPRA Report'') discussing how the review was conducted, what has been done to date to address regulatory burden, and further measures we will take to address issues that were identified. As noted in the EGRPRA Report, the FDIC is continuing to streamline and clarify its regulations through the OTS rule integration process. By removing outdated or unnecessary regulations, such as part 390, subpart I, and modifying part 343, this rule complements other actions the FDIC has taken, separately and with the other federal banking agencies, to further the EGRPRA mandate.

E. Riegle Community Development and Regulatory Improvement Act of 1994

The Riegle Community Development and Regulatory Improvement Act of

[28] 5 U.S.C. 601 *et seq.*

[29] 65 FR 75822 (Dec. 4, 2000). The final rule became effective April 1, 2001.

[30] Public Law 104–208, 110 Stat. 3009 (1996).

1994 (RCDRIA) requires the FDIC, in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure or other requirements on insured depository institutions to consider, consistent with the principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, as well as the benefits of such regulations.

In addition, new regulations and amendments to regulations that impose additional reporting, disclosures or other new requirements on insured depository institutions generally must take effect on the first day of the calendar quarter that begins on or after the date on which the regulations are published in final form.[31] The Final Rule has no new reporting or other new requirements on insured depository institutions. Therefore, the final rule is not subject to the requirements of the statute.

List of Subjects

12 CFR Part 343

Banks, banking; Consumer protection in sales of insurance; Savings associations.

12 CFR Part 390

Consumer protection in sales of insurance.

Authority and Issuance

For the reasons stated in the preamble, the Board of Directors of the Federal Deposit Insurance Corporation is amending 12 CFR parts 343 and 390 as follows:

■ 1. Revise part 343 to read as follows:

PART 343—CONSUMER PROTECTION IN SALES OF INSURANCE

Sec.
343.10 Purpose and scope.
343.20 Definitions.
343.30 Prohibited practices.
343.40 What you must disclose.
343.50 Where insurance activities may take place.
343.60 Qualification and licensing requirements for insurance sales personnel.
Appendix A to Part 343—Consumer Grievance Process

Authority: 12 U.S.C. 1819 (Seventh and Tenth); 12 U.S.C. 1831x.

§ 343.10 Purpose and scope.

This part establishes consumer protections in connection with retail sales practices, solicitations, advertising, or offers of any insurance product or annuity to a consumer by:

(a) Any institution; or

(b) Any other person that is engaged in such activities at an office of the institution or on behalf of the institution.

§ 343.20 Definitions.

As used in this part:

Affiliate means a company that controls, is controlled by, or is under common control with another company.

Company means any corporation, partnership, business trust, association or similar organization, or any other trust (unless by its terms the trust must terminate within twenty-five years or not later than twenty-one years and ten months after the death of individuals living on the effective date of the trust). It does not include any corporation the majority of the shares of which are owned by the United States or by any State, or a qualified family partnership, as defined in section 2(o)(10) of the Bank Holding Company Act of 1956, as amended (12 U.S.C. 1841(o)(10)).

Consumer means an individual who purchases, applies to purchase, or is solicited to purchase from you insurance products or annuities primarily for personal, family, or household purposes.

Control of a company has the same meaning as in section 3(w)(5) of the Federal Deposit Insurance Act (12 U.S.C. 1813(w)(5)).

Domestic violence means the occurrence of one or more of the following acts by a current or former family member, household member, intimate partner, or caretaker:

(1) Attempting to cause or causing or threatening another person physical harm, severe emotional distress, psychological trauma, rape, or sexual assault;

(2) Engaging in a course of conduct or repeatedly committing acts toward another person, including following the person without proper authority, under circumstances that place the person in reasonable fear of bodily injury or physical harm;

(3) Subjecting another person to false imprisonment; or

(4) Attempting to cause or causing damage to property so as to intimidate or attempt to control the behavior of another person.

Electronic media includes any means for transmitting messages electronically between you and a consumer in a format that allows visual text to be displayed on equipment, for example, a personal computer monitor.

FDIC-supervised insured depository institution or institution means any State nonmember insured bank or State savings association for which the Federal Deposit Insurance Corporation is the appropriate Federal banking agency pursuant to section 3(q) of the Federal Deposit Insurance Act (12 U.S.C. 1813(q)).

Office means the premises of an institution where retail deposits are accepted from the public.

State savings association has the same meaning as in section (3)(b)(3) of the Federal Deposit Insurance Act, 12 U.S.C. 1813(b)(3).

Subsidiary has the same meaning as in section 3(w)(4) of the Federal Deposit Insurance Act (12 U.S.C. 1813(w)(4)).

You—(1) Means:

(i) An institution; or

(ii) Any other person only when the person sells, solicits, advertises, or offers an insurance product or annuity to a consumer at an office of the institution or on behalf of an institution.

(2) For purposes of this definition, activities on behalf of an institution include activities where a person, whether at an office of the institution or at another location sells, solicits, advertises, or offers an insurance product or annuity and at least one of the following applies:

(i) The person represents to a consumer that the sale, solicitation, advertisement, or offer of any insurance product or annuity is by or on behalf of the institution;

(ii) The institution refers a consumer to a seller of insurance products or annuities and the institution has a contractual arrangement to receive commissions or fees derived from a sale of an insurance product or annuity resulting from that referral; or

(iii) Documents evidencing the sale, solicitation, advertising, or offer of an insurance product or annuity identify or refer to the institution.

§ 343.30 Prohibited practices.

(a) *Anticoercion and antitying rules.* You may not engage in any practice that would lead a consumer to believe that an extension of credit, in violation of section 106(b) of the Bank Holding Company Act Amendments of 1970 (12 U.S.C. 1972) in the case of a State nonmember insured bank and a foreign bank having an insured branch, or in violation of section 5(q) of the Home Owners' Loan Act (12 U.S.C. 1464(q)) in the case of a State savings association, is conditional upon either:

(1) The purchase of an insurance product or annuity from the institution or any of its affiliates; or

(2) An agreement by the consumer not to obtain, or a prohibition on the consumer from obtaining, an insurance

[31] 12 U.S.C. 4802.

product or annuity from an unaffiliated entity.

(b) *Prohibition on misrepresentations generally.* You may not engage in any practice or use any advertisement at any office of, or on behalf of, the institution or a subsidiary of the institution that could mislead any person or otherwise cause a reasonable person to reach an erroneous belief with respect to:

(1) The fact that an insurance product or annuity sold or offered for sale by you or any subsidiary of the institution is not backed by the Federal government or the institution, or the fact that the insurance product or annuity is not insured by the Federal Deposit Insurance Corporation;

(2) In the case of an insurance product or annuity that involves investment risk, the fact that there is an investment risk, including the potential that principal may be lost and that the product may decline in value; or

(3) In the case of an institution or subsidiary of the institution at which insurance products or annuities are sold or offered for sale, the fact that:

(i) The approval of an extension of credit to a consumer by the institution or subsidiary may not be conditioned on the purchase of an insurance product or annuity by the consumer from the institution or a subsidiary of the institution; and

(ii) The consumer is free to purchase the insurance product or annuity from another source.

(c) *Prohibition on domestic violence discrimination.* You may not sell or offer for sale, as principal, agent, or broker, any life or health insurance product if the status of the applicant or insured as a victim of domestic violence or as a provider of services to victims of domestic violence is considered as a criterion in any decision with regard to insurance underwriting, pricing, renewal, or scope of coverage of such product, or with regard to the payment of insurance claims on such product, except as required or expressly permitted under State law.

§ 343.40 What you must disclose.

(a) *Insurance disclosures.* In connection with the initial purchase of an insurance product or annuity by a consumer from you, you must disclose to the consumer, except to the extent the disclosure would not be accurate, that:

(1) The insurance product or annuity is not a deposit or other obligation of, or guaranteed by, the institution or an affiliate of the institution;

(2) The insurance product or annuity is not insured by the Federal Deposit Insurance Corporation (FDIC) or any other agency of the United States, the institution, or (if applicable) an affiliate of the institution; and

(3) In the case of an insurance product or annuity that involves an investment risk, there is investment risk associated with the product, including the possible loss of value.

(b) *Credit disclosure.* In the case of an application for credit in connection with which an insurance product or annuity is solicited, offered, or sold, you must disclose that the institution may not condition an extension of credit on either:

(1) The consumer's purchase of an insurance product or annuity from the institution or any of its affiliates; or

(2) The consumer's agreement not to obtain, or a prohibition on the consumer from obtaining, an insurance product or annuity from an unaffiliated entity.

(c) *Timing and method of disclosures*—(1) *In general.* The disclosures required by paragraph (a) of this section must be provided orally and in writing before the completion of the initial sale of an insurance product or annuity to a consumer. The disclosure required by paragraph (b) of this section must be made orally and in writing at the time the consumer applies for an extension of credit in connection with which an insurance product or annuity is solicited, offered, or sold.

(2) *Exception for transactions by mail.* If a sale of an insurance product or annuity is conducted by mail, you are not required to make the oral disclosures required by paragraph (a) of this section. If you take an application for credit by mail, you are not required to make the oral disclosure required by paragraph (b) of this section.

(3) *Exception for transactions by telephone.* If a sale of an insurance product or annuity is conducted by telephone, you may provide the written disclosures required by paragraph (a) of this section by mail within 3 business days beginning on the first business day after the sale, excluding Sundays and the legal public holidays specified in 5 U.S.C. 6103(a). If you take an application for credit by telephone, you may provide the written disclosure required by paragraph (b) of this section by mail, provided you mail it to the consumer within three days beginning the first business day after the application is taken, excluding Sundays and the legal public holidays specified in 5 U.S.C. 6103(a).

(4) *Electronic form of disclosures.* (i) Subject to the requirements of section 101(c) of the Electronic Signatures in Global and National Commerce Act (12 U.S.C. 7001(c)), you may provide the written disclosures required by paragraph (a) and (b) of this section through electronic media instead of on paper, if the consumer affirmatively consents to receiving the disclosures electronically and if the disclosures are provided in a format that the consumer may retain or obtain later, for example, by printing or storing electronically (such as by downloading).

(ii) Any disclosure required by paragraph (a) or (b) of this section that is provided by electronic media is not required to be provided orally.

(5) *Disclosures must be readily understandable.* The disclosures provided shall be conspicuous, simple, direct, readily understandable, and designed to call attention to the nature and significance of the information provided. For instance, you may use the following disclosures in visual media, such as television broadcasting, ATM screens, billboards, signs, posters and written advertisements and promotional materials, as appropriate and consistent with paragraphs (a) and (b) of this section:

(i) ''NOT A DEPOSIT''

(ii) ''NOT FDIC-INSURED''

(iii) ''NOT INSURED BY ANY FEDERAL GOVERNMENT AGENCY''

(iv) ''NOT GUARANTEED BY THE INSTITUTION''

(v) ''MAY GO DOWN IN VALUE''

(6) *Disclosures must be meaningful.* (i) You must provide the disclosures required by paragraphs (a) and (b) of this section in a meaningful form. Examples of the types of methods that could call attention to the nature and significance of the information provided include:

(A) A plain-language heading to call attention to the disclosures;

(B) A typeface and type size that are easy to read;

(C) Wide margins and ample line spacing;

(D) Boldface or italics for key words; and

(E) Distinctive type size, style, and graphic devices, such as shading or sidebars, when the disclosures are combined with other information.

(ii) You have not provided the disclosures in a meaningful form if you merely state to the consumer that the required disclosures are available in printed material, but do not provide the printed material when required and do not orally disclose the information to the consumer when required.

(iii) With respect to those disclosures made through electronic media for which paper or oral disclosures are not required, the disclosures are not meaningfully provided if the consumer may bypass the visual text of the disclosures before purchasing an insurance product or annuity.

(7) *Consumer acknowledgment.* You must obtain from the consumer, at the time a consumer receives the disclosures required under paragraph (a) or (b) of this section, or at the time of the initial purchase by the consumer of an insurance product or annuity, a written acknowledgment by the consumer that the consumer received the disclosures. You may permit a consumer to acknowledge receipt of the disclosures electronically or in paper form. If the disclosures required under paragraph (a) or (b) of this section are provided in connection with a transaction that is conducted by telephone, you must:

(i) Obtain an oral acknowledgment of receipt of the disclosures and maintain sufficient documentation to show that the acknowledgment was given; and

(ii) Make reasonable efforts to obtain a written acknowledgment from the consumer.

(d) *Advertisements and other promotional material for insurance products or annuities.* The disclosures described in paragraph (a) of this section are required in advertisements and promotional material for insurance products or annuities unless the advertisements and promotional materials are of a general nature describing or listing the services or products offered by the institution.

§ 343.50 Where insurance activities may take place.

(a) *General rule.* An institution must, to the extent practicable, keep the area where the institution conducts transactions involving insurance products or annuities physically segregated from areas where retail deposits are routinely accepted from the general public, identify the areas where insurance product or annuity sales activities occur, and clearly delineate and distinguish those areas from the areas where the institution's retail deposit-taking activities occur.

(b) *Referrals.* Any person who accepts deposits from the public in an area where such transactions are routinely conducted in the institution may refer a consumer who seeks to purchase an insurance product or annuity to a qualified person who sells that product only if the person making the referral receives no more than a one-time, nominal fee of a fixed dollar amount for each referral that does not depend on whether the referral results in a transaction.

§ 343.60 Qualification and licensing requirements for insurance sales personnel.

An institution may not permit any person to sell or offer for sale any insurance product or annuity in any part of its office or on its behalf, unless the person is at all times appropriately qualified and licensed under applicable State insurance licensing standards with regard to the specific products being sold or recommended.

Appendix A to Part 343—Consumer Grievance Process

Any consumer who believes that any institution or any other person selling, soliciting, advertising, or offering insurance products or annuities to the consumer at an office of the institution or on behalf of the institution has violated the requirements of this part should contact the Division of Depositor and Consumer Protection, Consumer Response Center, Federal Deposit Insurance Corporation, at the following address: 1100 Walnut Street, Box #11, Kansas City, MO 64106, or telephone 1–877–275–3342, or FDIC Electronic Customer Assistance Form at *http://www5.fdic.gov/starsmail/index.asp.*

PART 390—REGULATIONS TRANSFERRED FROM THE OFFICE OF THRIFT SUPERVISION

■ 2. The authority citation for part 390 is revised to read as follows:

Authority: 12 U.S.C. 1831y.

Subpart I—[Removed and Reserved]

■ 3. Remove and reserve subpart I, consisting of §§ 390.180 through 390.185, and appendix A.

Dated at Washington, DC, on March 20, 2018.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 2018–06163 Filed 3–30–18; 8:45 am]

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 738, 740, 745 and 774

[Docket No. 170306234–7234–01]

RIN 0694–AH37

Implementation of the February 2017 Australia Group (AG) Intersessional Decisions and the June 2017 AG Plenary Understandings; Addition of India to the AG

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) publishes this final rule to amend the Export Administration Regulations (EAR) to implement the recommendations presented at the February 2017 Australia Group (AG) Intersessional Implementation Meeting, and later adopted pursuant to the AG silent approval procedure, and the recommendations made at the June 2017 AG Plenary Implementation Meeting and adopted by the AG Plenary. This rule amends the following Export Control Classification Numbers (ECCNs) on the Commerce Control List (CCL) to reflect the February 2017 Intersessional Implementation Meeting recommendations that were adopted by the AG: ECCN 2B350 (by adding certain prefabricated repair assemblies, and specially designed components therefor, that are designed for attachment to glass-lined reaction vessels, reactors, storage tanks, containers or receivers controlled by this entry); ECCN 2B351 (by clarifying that toxic gas monitoring equipment includes toxic gas monitors and monitoring systems, as well as their dedicated detecting components); and ECCN 2B352 (by adding certain nucleic acid assemblers and synthesizers to this entry and clarifying how the capacity of certain fermenters should be measured for purposes of determining whether they are controlled under this entry).

Consistent with the June 2017 AG Plenary Implementation Meeting recommendations that were adopted by the AG, this rule amends the following ECCNs on the CCL: ECCN 1C353 (to clarify that genetically modified organisms include organisms in which the nucleic acid sequences have been created or altered by deliberate molecular manipulation and that inactivated organisms containing recoverable nucleic acids are considered to be genetic elements) and ECCN 1C350 (by adding N,N-Diisopropylaminoethanethiol hydrochloride). This rule also corrects several typographical errors in a note to ECCN 1C351 and updates the advance notification requirements in the EAR that apply to certain exports of saxitoxin. Finally, this rule amends the EAR to reflect the addition of India as a participating country in the AG.

DATES: This rule is effective April 2, 2018.

FOR FURTHER INFORMATION CONTACT: Richard P. Duncan, Ph.D., Director, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482–3343, Email: *Richard.Duncan@bis.doc.gov.*

SUPPLEMENTARY INFORMATION: The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement the recommendations presented at the Australia Group (AG) Intersessional Implementation Meeting held in Buenos Aires, Argentina, on February 15, 2017, and adopted pursuant to the AG silent approval procedure in April 2017, and the recommendations presented at the Implementation Meeting of the 2017 AG Plenary held in Paris, France, from June 26–30, 2017, and adopted by the AG Plenary. This rule also amends the EAR to reflect the addition of India as a participating country in the AG, as of January 19, 2018. The AG is a multilateral forum consisting of 42 participating countries and the European Union that maintain export controls on a list of chemicals, biological agents, and related equipment and technology that could be used in a chemical or biological weapons program. The AG periodically reviews items on its control list to enhance the effectiveness of participating governments' national controls and to achieve greater harmonization among these controls.

Amendments to the CCL Based on the February 2017 AG Intersessional Recommendations

ECCN 2B350 (Chemical Manufacturing Facilities and Equipment)

This final rule amends ECCN 2B350 on the CCL to reflect changes to the AG ''Control List of Dual-Use Chemical Manufacturing Facilities and Equipment and Related Technology and Software'' based on the February 2017 Intersessional Implementation Meeting recommendations that were adopted by the AG pursuant to its silent approval procedure. Specifically, this rule amends ECCN 2B350 to control prefabricated repair assemblies, and their specially designed components, that: (1) Are designed for mechanical attachment to glass-lined reaction vessels and reactors controlled under 2B350.a or glass-lined storage tanks, containers and receivers controlled under 2B350.c; and (2) have metallic surfaces that are made from tantalum or tantalum alloys and come in direct contact with the chemical(s) being processed. These assemblies and components were added to the AG chemical manufacturing facilities and equipment common control list, because they are capable of being used to prolong the life, or even allow the recommissioning, of glass-lined reactors and storage tanks that are suitable for use in the production of chemical weapons (CW) agents or AG-listed precursor chemicals.

All items controlled under ECCN 2B350 continue to require a license for chemical/biological (CB) reasons to destinations indicated in CB Column 2 on the Commerce Country Chart (see Supplement No. 1 to part 738 of the EAR) and for anti-terrorism (AT) reasons to destinations indicated in AT Column 1 on the Commerce Country Chart.

ECCN 2B351 (Toxic Gas Monitors and Monitoring Systems)

This final rule amends ECCN 2B351 on the CCL to reflect changes to the AG ''Control List of Dual-Use Chemical Manufacturing Facilities and Equipment and Related Technology and Software'' based on the February 2017 Intersessional Implementation Meeting recommendations that were adopted by the AG pursuant to its silent approval procedure. Specifically, this rule amends ECCN 2B351 to clarify that this entry controls toxic gas monitors and monitoring systems, and their dedicated detecting components (*i.e.,* detectors, sensor devices, and replaceable sensor cartridges), having either of the following characteristics: (1) Designed for continuous operation and usable for the detection of chemical warfare agents or precursor chemicals controlled by ECCN 1C350 at concentrations of less than 0.3 mg/m^3; or (2) designed for the detection of cholinesterase-inhibiting activity. The decision to specifically identify toxic gas monitors, in addition to toxic gas monitoring systems, on the AG chemical manufacturing facilities and equipment common control list is based on the fact that certain portable toxic gas monitors (*e.g.,* small handheld detectors) are capable of satisfying the technical control criteria applicable to toxic gas monitoring systems and, as such, may also be suitable for use in a CW production or storage facility. This rule also amends related ''software'' controls in ECCN 2D351 to reflect the updates to ECCN 2B351 described above.

All items controlled under ECCN 2B351 continue to require a license for CB reasons to destinations indicated in CB Column 2 on the Commerce Country Chart and for AT reasons to destinations indicated in AT Column 1 on the Commerce Country Chart.

ECCN 2B352 (Equipment Capable of Use in Handling Biological Materials)

This final rule amends ECCN 2B352 on the CCL to reflect changes to the AG ''Control List of Dual-Use Biological Equipment and Related Technology and Software'' based on the February 2017 Intersessional Implementation Meeting recommendations that were adopted by the AG pursuant to its silent approval procedure. Specifically, this rule amends ECCN 2B352 to indicate that the ''total internal volume'' of a fermenter must be measured to determine whether its capacity meets the control level of ''20 liters or greater'' specified in 2B352.b.1. This clarification was made to ensure that all AG participating countries apply the same criterion to measure capacity for purposes of determining whether a fermenter is subject to control.

This rule also amends ECCN 2B352 by adding a new paragraph .j to control nucleic acid assemblers and synthesizers that are both: (1) Partly or entirely automated; and (2) designed to generate continuous nucleic acids greater than 1.5 kilobases in length with error rates less than 5% in a single run. These items were added to the AG dual-use biological equipment common control list because they are capable of being used to generate pathogens and toxins without the need to acquire controlled genetic elements and organisms.

All items controlled under ECCN 2B352 continue to require a license for CB reasons to destinations indicated in CB Column 2 on the Commerce Country Chart and for AT reasons to destinations indicated in AT Column 1 on the Commerce Country Chart.

Amendments to the CCL Based on the June 2017 AG Plenary Understandings

ECCN 1C350 (Precursor Chemicals)

This final rule amends ECCN 1C350 to reflect updates to the AG ''Chemical Weapons Precursors'' control list adopted at the June 2017 AG Plenary meeting. Specifically, this rule amends ECCN 1C350.b by adding the precursor chemical hydrochloride salt (C.A.S. #41480–75–5) N,N-Diisopropylaminoethanethiol hydrochloride. This rule also alphabetically reorders the precursor chemicals listed in ECCN 1C350.b, .c, and .d to facilitate the identification of these chemicals. The precursor chemicals affected by these amendments to ECCN 1C350 are indicated in the following table.

AG-Controlled precursor chemicals	Previous CCL designation	Current CCL designation
(C.A.S. #683–08–9) Diethyl methylphosphonate	ECCN 1C350.b.22	ECCN 1C350.b.4
(C.A.S. #15715–41–0) Diethyl methylphosphonite	ECCN 1C350.b.4	ECCN 1C350.b.5
(C.A.S. #2404–03–7) Diethyl-N,N-dimethylphosphoroamidate	ECCN 1C350.b.5	ECCN 1C350.b.6
(C.A.S. #41480–75–5) N,N-Diisopropylaminoethanethiol hydrochloride	None—EAR 99	ECCN 1C350.b.7
(C.A.S. #5842–07–9) N,N-Diisopropyl-beta-aminoethane thiol	ECCN 1C350.b.6	ECCN 1C350.b.8
(C.A.S. #96–80–0) N,N-Diisopropyl-beta-aminoethanol	ECCN 1C350.b.8	ECCN 1C350.b.9
(C.A.S. #96–79–7), N,N-Diisopropyl-beta-aminoethyl chloride	ECCN 1C350.b.9	ECCN 1C350.b.10
(C.A.S. #4261–68–1) N,N-Diisopropyl-beta-aminoethyl chloride hydrochloride	ECCN 1C350.b.7	ECCN 1C350.b.11
(C.A.S. #6163–75–3) Dimethyl ethylphosphonate	ECCN 1C350.b.10	ECCN 1C350.b.12
(C.A.S. #756–79–6) Dimethyl methylphosphonate	ECCN 1C350.b.11	ECCN 1C350.b.13
(C.A.S. #677–43–0) N,N-Dimethylamino-phosphoryl dichloride	ECCN 1C350.b.23	ECCN 1C350.b.14
(C.A.S. #1498–40–4) Ethyl phosphonous dichloride [Ethyl phosphinyl dichloride]	ECCN 1C350.b.12	ECCN 1C350.b.15
(C.A.S. #430–78–4) Ethyl phosphonus difluoride [Ethyl phosphinyl difluoride]	ECCN 1C350.b.13	ECCN 1C350.b.16
(C.A.S. #1066–50–8) Ethyl phosphonyl dichloride	ECCN 1C350.b.14	ECCN 1C350.b.17
(C.A.S. #993–13–5) Methylphosphonic acid	ECCN 1C350.b.21	ECCN 1C350.b.18
(C.A.S. #676–98–2) Methylphos-phonothioic dichloride	ECCN 1C350.b.24	ECCN 1C350.b.19
(C.A.S. #464–07–3) Pinacolyl alcohol	ECCN 1C350.b.18	ECCN 1C350.b.20
(C.A.S. #1619–34–7) 3-Quinuclidinol	ECCN 1C350.b.19	ECCN 1C350.b.21
(C.A.S. #111–48–8) Thiodiglycol	ECCN 1C350.b.20	ECCN 1C350.b.22
(C.A.S. #139–87–7) Ethyldiethanolamine	ECCN 1C350.c.12	ECCN 1C350.c.3
(C.A.S. #10025–87–3) Phosphorus oxychloride	ECCN 1C350.c.3	ECCN 1C350.c.4
(C.A.S. #10026–13–8) Phosphorus pentachloride	ECCN 1C350.c.4	ECCN 1C350.c.5
(C.A.S. #7719–12–2) Phosphorus trichloride	ECCN 1C350.c.5	ECCN 1C350.c.6
(C.A.S. #10025–67–9) Sulfur monochloride	ECCN 1C350.c.6	ECCN 1C350.c.8
(C.A.S. #7719–09–7) Thionyl chloride	ECCN 1C350.c.8	ECCN 1C350.c.9
(C.A.S. #102–71–6) Triethanolamine	ECCN 1C350.c.9	ECCN 1C350.c.10
(C.A.S. #122–52–1) Triethyl phosphite	ECCN 1C350.c.10	ECCN 1C350.c.11
(C.A.S. #121–45–9) Trimethyl phosphite	ECCN 1C350.c.11	ECCN 1C350.c.12
(C.A.S. #109–89–7) Diethylamine	ECCN 1C350.d.25	ECCN 1C350.d.3
(C.A.S. #100–37–8) N,N-Diethylaminoethanol	ECCN 1C350.d.3	ECCN 1C350.d.4
(C.A.S. #298–06–6) O,O-Diethyl phosphorodithioate	ECCN 1C350.d.23	ECCN 1C350.d.5
(C.A.S. #2465–65–8) O,O-Diethyl phosphorothioate	ECCN 1C350.d.22	ECCN 1C350.d.6
(C.A.S. #108–18–9) Di-isopropylamine	ECCN 1C350.d.4	ECCN 1C350.d.7
(C.A.S. #124–40–3) Dimethylamine	ECCN 1C350.d.5	ECCN 1C350.d.8
(C.A.S. #506–59–2) Dimethylamine hydrochloride	ECCN 1C350.d.6	ECCN 1C350.d.9
(C.A.S. #7664–39–3) Hydrogen fluoride	ECCN 1C350.d.7	ECCN 1C350.d.10
(C.A.S. #3554–74–3) 3-Hydroxyl-1-methylpiperidine	ECCN 1C350.d.8	ECCN 1C350.d.11
(C.A.S. #76–89–1) Methyl benzilate	ECCN 1C350.d.9	ECCN 1C350.d.12
(C.A.S. #1314–80–3) Phosphorus pentasulfide	ECCN 1C350.d.10	ECCN 1C350.d.13
(C.A.S. #75–97–8) Pinacolone	ECCN 1C350.d.11	ECCN 1C350.d.14
(C.A.S. #7789–29–9) Potassium bifluoride	ECCN 1C350.d.14	ECCN 1C350.d.15
(C.A.S. #151–50–8) Potassium cyanide	ECCN 1C350.d.12	ECCN 1C350.d.16
(C.A.S. #7789–23–3) Potassium fluoride	ECCN 1C350.d.13	ECCN 1C350.d.17
(C.A.S. #3731–38–2) 3-Quinuclidone	ECCN 1C350.d.15	ECCN 1C350.d.18
(C.A.S. #1333–83–1) Sodium bifluoride	ECCN 1C350.d.16	ECCN 1C350.d.19
(C.A.S. #143–33–9) Sodium cyanide	ECCN 1C350.d.17	ECCN 1C350.d.20
(C.A.S. #7681–49–4) Sodium fluoride	ECCN 1C350.d.18	ECCN 1C350.d.21
(C.A.S. #16893–85–9) Sodium hexafluorosilicate	ECCN 1C350.d.24	ECCN 1C350.d.22
(C.A.S. #1313–82–2) Sodium sulfide	ECCN 1C350.d.19	ECCN 1C350.d.23
(C.A.S. #637–39–8) Triethanolamine hydrochloride	ECCN 1C350.d.20	ECCN 1C350.d.24
(C.A.S. #116–17–6) Tri-isopropyl phosphite	ECCN 1C350.d.21	ECCN 1C350.d.25

All items controlled under ECCN 1C350 continue to require a license for CB reasons to destinations indicated in CB Column 2 on the Commerce Country Chart and for AT reasons to countries listed in Country Group E:1 (see Supplement No. 1 to part 740 of the EAR). In addition, items controlled under 1C350.b or .c require a license to certain destinations for chemical weapons (CW) reasons, as described in the License Requirements section of ECCN 1C350 and in Section 742.18 of the EAR.

ECCN 1C353 (Genetic Elements and Genetically Modified Organisms)

This final rule amends ECCN 1C353 on the CCL to reflect updates to the AG controls on certain genetic elements and genetically modified organisms adopted at the June 2017 AG Plenary meeting. Specifically, this rule amends ECCN 1C353 to control any genetically modified organism that contains, or any genetic element that codes for: (1) Any gene or genes specific to any virus controlled by ECCN 1C351.a or .b or 1C354.c; (2) any gene or genes specific to any bacterium controlled by ECCN 1C351.c or 1C354.a, or any fungus controlled by ECCN 1C351.e or 1C354.b, and which in itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health or could endow or enhance pathogenicity; or (3) any toxins, or their subunits, controlled by ECCN 1C351.d.

In addition, this rule amends the Technical Notes to ECCN 1C353 to clarify that ''genetically modified organisms include organisms in which the nucleic acid sequences have been created or altered by deliberate molecular manipulation'' (see Technical Note 1 to ECCN 1C353, as amended by this rule) and that inactivated organisms containing recoverable nucleic acids are

considered to be genetic elements, whether genetically modified or unmodified, or chemically synthesized in whole or in part (see Technical Note 2 to ECCN 1C353, as amended by this rule). Technical Note 3 to ECCN 1C353, as amended by this rule, states that this ECCN does not control nucleic acid sequences of shiga toxin producing Escherichia coli of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups, other than those genetic elements coding for shiga toxin, or for its subunits.

This rule also defines the term ''endow or enhance pathogenicity,'' for purposes of the controls in ECCN 1C353 (see Technical Note 4 to ECCN 1C353, as amended by this rule), as when the insertion or integration of the nucleic acid sequence or sequences is/are likely to enable or increase a recipient organism's ability to be used to deliberately cause disease or death. This might include alterations to, inter alia: virulence, transmissibility, stability, route of infection, host range, reproducibility, ability to evade or suppress host immunity, resistance to medical countermeasures, or detectability.

All items controlled under ECCN 1C353 continue to require a license for CB reasons to destinations indicated in CB Column 1 on the Commerce Country Chart and for AT reasons to destinations indicated in AT Column 1 on the Commerce Country Chart.

Amendments to the EAR To Reflect the Addition of India to the AG

This rule makes conforming amendments to the EAR to reflect the addition of India to the AG, as of January 19, 2018. Specifically, this rule amends the entry for India in the Commerce Country Chart (Supplement No. 1 to part 738 of the EAR) by removing the ''X'' from this entry under the column CB 2. In addition, this rule amends the Country Groups chart (Supplement No. 1 to part 740 of the EAR) by adding an ''X'' to the entry for India under column A:3, Australia Group.

Corrections to ECCN 1C351 (Human and Animal Pathogens and ''Toxins'')

This final rule amends ECCN 1C351 on the CCL by removing several outdated references to former ECCN 1C352 in the Note that follows 1C351.a.4, which describes avian influenza (AI) viruses subject to control under this ECCN, and adding in their place references to the relevant AI controls described in 1C351.a.4. These corrections do not affect the scope of the items subject to control under this ECCN or the license requirements applicable to these items.

Correction To Advance Notification Requirements for Certain Exports of Saxitoxin

This final rule also corrects the Chemical Weapons Convention (CWC) Schedule 1 chemical advance notification requirements in Section 745.1 of the EAR to reflect the April 27, 2006 (71 FR 24918), amendments to the Chemical Weapons Convention Regulations (CWCR) (15 CFR parts 710–722) that, inter alia, amended the definition of *advance notification* in Section 710.1 of the CWCR, as well as the advance notification requirements in Section 712.6(a) of the CWCR, to indicate that the 45-day advance notification requirement for exports or imports of Schedule 1 chemicals does not apply to the export or import of 5 milligrams or less of saxitoxin (see ECCN 1C351.d.12) for medical or diagnostic purposes only—the latter requires only a 3-day advance notification. Specifically, this final rule amends the first sentence in Section 745.1(a) of the EAR to read as follows: ''You must notify BIS at least 45 calendar days prior to exporting any quantity of a Schedule 1 chemical listed in Supplement No. 1 to this part to another State Party, except that notifications for exports of 5 milligrams or less of saxitoxin (for medical or diagnostic purposes only) must be submitted to BIS at least 3 calendar days prior to the date of export (see 15 CFR 712.6(a)).'' The advance notification requirements in Section 745.1 of the EAR refer only to exports, because imports are outside the scope of these EAR requirements. However, as indicated above, the advance notification requirements described in Section 712.6(a) of the CWCR apply to imports, as well as exports. The exemption from the 45-day advance notification requirement, for certain exports and imports of saxitoxin (as described above), was approved and entered into force for all CWC States Parties on October 31, 1999.

Effect of This Rule on the Scope of the CB Controls in the EAR

The changes made by this rule only marginally affect the scope of the EAR controls on chemical weapons precursors, human and animal pathogens/toxins, chemical manufacturing equipment, and equipment capable of use in handling biological materials.

The scope of the CCL-based CB controls on human and animal pathogens and toxins was not affected by the correction to ECCN 1C351 in which outdated references to former ECCN 1C352 were removed from the Note that follows 1C351.a.4 and references to the relevant avian influenza (AI) controls described in 1C351.a.4 were added in their place. In addition, the updates to the controls on genetic elements and genetically modified organisms described in ECCN 1C353 clarified the scope of these controls, but did not actually expand them. In short, neither of these changes is expected to result in an increase in the number of license applications that will have to be submitted to BIS for exports, reexports, or transfers (in-country) of these items.

However, the changes made by this final rule to the CCL entries controlling chemical weapons precursors, chemical manufacturing equipment, and equipment capable of use in handling biological materials are expected to result in a slight increase in the number of license applications that will have to be submitted for these items. Specifically, the addition of the precursor chemical hydrochloride salt N,N-Diisopropylaminoethanethiol hydrochloride (C.A.S. #41480–75–5) to ECCN 1C350.b is expected to result in the submission of one or two additional license applications per year. The addition of controls on certain prefabricated repair assemblies, and their specially designed components, to ECCN 2B350 is expected to result in the submission of four or five additional license applications per year. Specifically listing toxic gas monitors in ECCN 2B351 (to clarify that this entry controls, inter alia, certain portable gas monitors as well as toxic gas monitoring systems) is expected to result in the submission of two or three additional license applications per year. The addition of controls on nucleic acid assemblers and synthesizers to ECCN 2B352 is expected to result in the submission of four or five additional license applications per year.

Therefore, the number of additional license applications that would have to be submitted per year, as a result of the amendments to ECCNs 1C350, 2B350, 2B351 and 2B352 described above, is not expected to exceed fifteen license applications. This total represents a relatively insignificant portion of the overall trade in such items and is well within the scope of the information collection approved by the Office of Management and Budget (OMB) under control number 0694–0088 (see Rulemaking Requirements #2, below).

Saving Clause

Shipments of items removed from eligibility for export or reexport under a license exception or without a license (*i.e.,* under the designator ''NLR'') as a result of this regulatory action that were on dock for loading, on lighter, laden aboard an exporting carrier, or en route aboard a carrier to a port of export, on May 2, 2018, pursuant to actual orders for export or reexport to a foreign destination, may proceed to that destination under the previously applicable license exception or without a license (NLR) so long as they are exported or reexported before May 17, 2018. Any such items not actually exported or reexported before midnight, on May 17, 2018, require a license in accordance with this regulation.

''Deemed'' exports of ''technology'' and ''source code'' removed from eligibility for export under a license exception or without a license (under the designator ''NLR'') as a result of this regulatory action may continue to be made under the previously available license exception orwithout a license (NLR) before May 17, 2018. Beginning at midnight on May 17, 2018, such ''technology'' and ''source code'' may no longer be released, without a license, to a foreign national subject to the ''deemed'' export controls in the EAR when a license would be required to the home country of the foreign national in accordance with this regulation.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 15, 2017 (82 FR 39005 (August 16, 2017)), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*). BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

The cost-benefit analysis required pursuant to Executive Orders 13563 and 12866 indicates that this rule is intended to improve national security as its primary direct benefit. Specifically, implementation, in a timely manner, of the AG agreements described herein would enhance the national security of the United States by reducing the risk that global international trade involving dual-use chemical/biological items would contribute to the proliferation of chemical and biological weapons of mass destruction. The first meeting of what subsequently became known as the Australia Group (AG) took place in Brussels in June 1985. At that meeting, the 15 participating countries and the European Commission agreed to explore how existing export controls might be made more effective to prevent the spread of chemical weapons. The AG has met regularly since then, and annual meetings are now held in Paris. The scope of the export controls addressed by the AG has evolved to address emerging threats and challenges. Evidence of the diversion of dual-use materials to biological weapons programs in the early 1990s led to participants' adoption of export controls on specific biological agents. The common control lists developed by the AG have also expanded to include technology and equipment that can be used in the manufacturing or disposal of chemical and biological weapons. The number of countries participating in the AG has grown from 15 in 1985 to 42, plus the European Union. The principal objective of AG participating countries is to use licensing measures to ensure that exports of certain chemicals, biological agents, and dual-use chemical and biological manufacturing facilities and equipment, do not contribute to the proliferation of chemical and biological weapons (CBW) of mass destruction, which has been identified as a threat to domestic and international peace and security. The AG achieves this objective by harmonizing participating countries' national export licensing measures. The AG's activities are especially important given that the international chemical and biotechnology industries are a target for proliferators as a source of materials for CBW programs. In calculating the costs that would be imposed by this rule, Commerce estimates that no more than 15 additional license applications would have to be submitted to BIS, annually, as a result of the implementation of the AG-related amendments described in this rule (see Rulemaking Requirements #2, below). Application of the cost-benefit analysis required under Executive Orders 13563 and 12866 to this rule, as described above, indicates that this rule is intended to improve the national security of the United States as its primary direct benefit. Furthermore, this rule qualifies for a good cause exception under 5 U.S.C. 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date—this finding, and a brief statement of the reasons therefor, are described under Rulemaking Requirements #4, below. Accordingly, this rule meets the requirements set forth in the April 5, 2017, OMB guidance implementing E.O. 13771 (82 FR 9339, February 3, 2017), regarding what constitutes a regulation issued ''with respect to a national security function of the United States'' and it is, therefore, exempt from the requirements of E.O. 13771.

2. Notwithstanding any other provision of 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 of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule contains a collection of information subject to the requirements of the PRA. This collection has been approved by OMB under control number 0694–0088, Simplified Network Application Processing System. This collection includes license applications, among other things, and carries a burden estimate of 29.6 minutes per manual or electronic submission for a total burden estimate of 31,833 hours. Although this final rule makes important changes to the EAR for items controlled for chemical/biological (CB) reasons, Commerce believes the overall increase in costs and burdens due to this rule will be minimal. Specifically, BIS expects the burden hours associated with this collection to increase, slightly, by 7 hours and 24 minutes (*i.e.,* 15 applications × 29.6 minutes per

response) for an estimated cost increase of $222 (*i.e.,* 7 hours and 24 minutes × $30 per hour). This increase is not expected to exceed the existing estimates currently associated with OMB control number 0694–0088. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Jasmeet Seehra, Office of Management and Budget, by email to *Jasmeet_K._Seehra@omb.eop.gov* or by fax to (202) 395–7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, 14th Street & Pennsylvania Avenue NW, Room 2705, Washington, DC 20230 or by email to *RPD2@bis.doc.gov*.

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

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Immediate implementation of these amendments is non-discretionary and fulfills the United States' international obligation to the Australia Group (AG). The AG contributes to international security and regional stability through the harmonization of export controls and seeks to ensure that exports do not contribute to the development of chemical and biological weapons. The AG consists of 42 member countries that act on a consensus basis and the amendments set forth in this rule implement changes made to the AG common control lists (as a result of the adoption of the recommendations made at the February 2017 AG Intersessional Implementation Meeting and the understandings reached at the June 2017 AG Plenary Implementation Meeting) and other changes that are necessary to ensure consistency with the controls maintained by the AG. Because the United States is a significant exporter of the items in this rule, immediate implementation of this provision is necessary for the AG to achieve its purpose.

Although the APA requirements in section 553 are not applicable to this action under the provisions of paragraph (a)(1), this action also falls within two other exceptions in the section. The subsection (b) requirement that agencies publish a notice of proposed rulemaking, which includes information on the public proceedings, does not apply when an agency for good cause finds that the notice and public procedures are impracticable, unnecessary, or contrary to the public interest, and the agency incorporates the finding (and the reasons therefor) in the rule that is issued (5 U.S.C. 553(b)(B)). In addition, the section 553(d) requirement that publication of a rule shall be made not less than 30 days before its effective date can be waived if an agency findsthere is good cause to do so.

The section 553 requirements for notice and public procedures and for a delay in the date of effectiveness do not apply to this rule, as there is good cause to waive such practices. Any delay in implementation will create a disruption in the movement of affected items globally because of disharmony between export control measures implemented by AG members, resulting in tension between member countries. Export controls work best when all countries implement the same export controls in a timely manner. Delaying this rulemaking would prevent the United States from fulfilling its commitment to the AG in a timely manner, would injure the credibility of the United States in this and other multilateral regimes, and may impair the international community's ability to effectively control the export of certain potentially national- and international security-threatening items. Therefore, this regulation is issued in final form, and is effective April 2, 2018.

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

List of Subjects

15 CFR Part 738

Administrative practice and procedure, Exports, Foreign trade.

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 745

Administrative practice and procedure, Chemicals, Exports, Foreign trade, Reporting and recordkeeping requirements.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, parts 738, 740, 745 and 774 of the Export Administration Regulations (15 CFR parts 730–774) are amended as follows:

PART 738—[AMENDED]

■ 1. The authority citation for part 738 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824a; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2017, 82 FR 39005 (August 16, 2017).

■ 2. Supplement No. 1 to Part 738 is amended by revising the entry for ''India'' to read as follows:

SUPPLEMENT NO. 1 TO PART 738—COMMERCE COUNTRY CHART

[Reason for control]

Countries	Chemical and biological weapons			Nuclear nonproliferation		National security		Missile tech	Regional stability		Firearms convention	Crime control			Anti-terrorism	
	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
	*		*		*		*		*		*		*			
India [7]	X			X		X	X	X	X							
	*		*		*		*		*		*		*			

[7] See § 758.1(b)(9) for an AES filing requirement for exports of CC column 1 or 3, or RS column 2 items to India. Also note that a license is still required for items controlled under ECCNs 6A003.b.4.b and 9A515.e for RS column 2 reasons when destined to India.

* * * * *

PART 740—[AMENDED]

■ 3. The authority citation for part 740 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 7201 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2017, 82 FR 39005 (August 16, 2017).

■ 4. In Supplement No. 1 to Part 740, Country Groups, Country Group A is amended by revising the entry for ''India'' to read as follows:

SUPPLEMENT NO. 1 TO PART 740—COUNTRY GROUPS

[Country Group A]

Country	[A:1] Wassenaar participating states [1]	[A:2] Missile technology control regime	[A:3] Australia group	[A:4] Nuclear suppliers group [2]	[A:5]	[A:6]
*	*	*	*	*	*	*
India		X	X			X
*	*	*	*	*	*	*

[1] Country Group A:1 is a list of the Wassenaar Arrangement Participating States, except for Malta, Russia and Ukraine.
[2] Country Group A:4 is a list of the Nuclear Suppliers Group countries, except for the People's Republic of China (PRC).

* * * * *

PART 745—[AMENDED]

■ 5. The authority citation for part 745 continues to read as follows:

Authority: 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of November 8, 2016, 81 FR 79379 (November 10, 2016).

■ 6. In § 745.1, the first sentence in paragraph (a) is revised to read as follows:

§ 745.1 Advance notification and annual report of all exports of Schedule 1 chemicals to other States Parties.

* * * * *

(a) *Advance notification of exports.* You must notify BIS at least 45 calendar days prior to exporting any quantity of a Schedule 1 chemical listed in Supplement No. 1 to this part to another State Party, except that notifications for exports of 5 milligrams or less of saxitoxin (for medical or diagnostic purposes only) must be submitted to BIS at least 3 calendar days prior to the date of export (see 15 CFR 712.6(a)). * * *

* * * * *

PART 774—[AMENDED]

■ 7. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2017, 82 FR 39005 (August 16, 2017).

■ 8. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1, ECCN 1C350 is revised to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

1C350 Chemicals that may be used as precursors for toxic chemical agents (see List of Items Controlled).

License Requirements

Reason for Control: CB, CW, AT

Control(s)	*Country chart (See Supp. No. 1 to part 738)*
CB applies to entire entry.	CB Column 2

CW applies to 1C350 .b, and .c. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons. A license is required, for CW reasons, to export or reexport Schedule 2 chemicals and mixtures identified in 1C350.b to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR). A license is required, for CW reasons, to export Schedule 3 chemicals and mixtures identified in 1C350.c to States not Party to the CWC, unless an End-Use Certificate issued by the government of the importing country has been obtained by the exporter prior to export. A license is required, for CW reasons, to reexport Schedule 3 chemicals and mixtures identified in 1C350.c from a State not Party to the CWC to any other State not Party to the CWC. (See § 742.18 of the EAR for license requirements and policies for toxic and precursor chemicals controlled for CW reasons. See § 745.2 of the EAR for End-Use Certificate requirements that apply to exports of Schedule 3 chemicals to countries not listed in Supplement No. 2 to part 745 of the EAR.)

AT applies to entire entry. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for AT reasons in 1C350. A license is required, for AT reasons, to export or reexport items controlled by 1C350 to a country in Country Group E:1 of Supplement No. 1 to part 740 of the EAR. (See part 742 of the EAR for additional information on the AT controls that apply to Iran, North Korea, Sudan, and Syria. See part 746 of the EAR for additional information on sanctions that apply to Iran, North Korea, and Syria.)

License Requirement Notes: *1. Sample Shipments: Subject to the following requirements and restrictions, a license is not required for sample shipments when the cumulative total of these shipments does not exceed a 55-gallon container or 200 kg of a single chemical to any one consignee during a calendar year. A consignee that receives a sample shipment under this exclusion may not resell, transfer, or reexport the sample shipment, but may use the sample shipment for any other legal purpose unrelated to chemical weapons.*

a. Chemicals Not Eligible:

A. [Reserved]

B. CWC Schedule 2 chemicals (States not Party to the CWC). No CWC Schedule 2 chemical or mixture identified in 1C350.b is eligible for sample shipment to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR) without a license.

b. Countries Not Eligible: Countries in Country Group E:1 of Supplement No. 1 to part 740 of the EAR are not eligible to receive sample shipments of any chemicals controlled by this ECCN without a license.

c. Sample shipments that require an End-Use Certificate for CW reasons: No CWC Schedule 3 chemical or mixture identified in 1C350.c is eligible for sample shipment to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR) without a license, unless an End-Use Certificate issued by the government of the importing country is obtained by the exporter prior to export (see § 745.2 of the EAR for End-Use Certificate requirements).

d. Sample shipments that require a license for reasons set forth elsewhere in the EAR: Sample shipments, as described in this Note

1, may require a license for reasons set forth elsewhere in the EAR. See, in particular, the end-use/end-user restrictions in part 744 of the EAR, and the restrictions that apply to embargoed countries in part 746 of the EAR.

e. Annual report requirement. The exporter is required to submit an annual written report for shipments of samples made under this Note 1. The report must be on company letterhead stationery (titled ''Report of Sample Shipments of Chemical Precursors'' at the top of the first page) and identify the chemical(s), Chemical Abstract Service Registry (C.A.S.) number(s), quantity(ies), the ultimate consignee's name and address, and the date of export for all sample shipments that were made during the previous calendar year. The report must be submitted no later than February 28 of the year following the calendar year in which the sample shipments were made, to: U.S. Department of Commerce, Bureau of Industry and Security, 14th Street and Pennsylvania Ave. NW, Room 2099B, Washington, DC 20230, Attn: ''Report of Sample Shipments of Chemical Precursors.''

2. Mixtures:

a. Mixtures that contain precursor chemicals identified in ECCN 1C350, in concentrations that are below the levels indicated in 1C350.b through .d, are controlled by ECCN 1C395 or 1C995 and are subject to the licensing requirements specified in those ECCNs.

b. A license is not required under this ECCN for a mixture, when the controlled chemical in the mixture is a normal ingredient in consumer goods packaged for retail sale for personal use. Such consumer goods are designated EAR99. However, a license may be required for reasons set forth elsewhere in the EAR.

Note to mixtures: Calculation of concentrations of AG-controlled chemicals:

a. Exclusion. No chemical may be added to the mixture (solution) for the sole purpose of circumventing the Export Administration Regulations;

b. Percent Weight Calculation. When calculating the percentage, by weight, of ingredients in a chemical mixture, include all ingredients of the mixture, including those that act as solvents.

3. Compounds. Compounds created with any chemicals identified in this ECCN 1C350 may be shipped NLR (No License Required), without obtaining an End-Use Certificate, unless those compounds are also identified in this entry or require a license for reasons set forth elsewhere in the EAR.

4. Testing Kits: Certain medical, analytical, diagnostic, and food testing kits containing small quantities of chemicals identified in this ECCN 1C350, are excluded from the scope of this ECCN and are controlled under ECCN 1C395 or 1C995. (Note that replacement reagents for such kits are controlled by this ECCN 1C350 if the reagents contain one or more of the precursor chemicals identified in 1C350 in concentrations equal to or greater than the control levels for mixtures indicated in 1C350.)

Technical Notes: *1. For purposes of this entry, a ''mixture'' is defined as a solid, liquid or gaseous product made up of two or more ingredients that do not react together under normal storage conditions.*

2. The scope of this control applicable to Hydrogen Fluoride (see 1C350.d.7 in the List of Items Controlled) includes its liquid, gaseous, and aqueous phases, and hydrates.

3. Precursor chemicals in ECCN 1C350 are listed by name, Chemical Abstract Service (CAS) number and CWC Schedule (where applicable). Precursor chemicals of the same structural formula (e.g., hydrates) are controlled by ECCN 1C350, regardless of name or CAS number. CAS numbers are shown to assist in identifying whether a particular precursor chemical or mixture is controlled under ECCN 1C350, irrespective of nomenclature. However, CAS numbers cannot be used as unique identifiers in all situations because some forms of the listed precursor chemical have different CAS numbers, and mixtures containing a precursor chemical listed in ECCN 1C350 may also have different CAS numbers.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A
GBS: N/A
CIV: N/A

List of Items Controlled

Related Controls: See USML Category XIV(c) for related chemicals ''subject to the ITAR'' (see 22 CFR parts 120 through 130).

Related Definitions: See § 770.2(k) of the EAR for synonyms for the chemicals listed in this entry.

Items:

a. [Reserved]

b. Australia Group-controlled precursor chemicals also identified as Schedule 2 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:

b.1. (C.A.S. #7784–34–1) Arsenic trichloride;

b.2. (C.A.S. #76–93–7) Benzilic acid;

b.3. (C.A.S. #78–38–6) Diethyl ethylphosphonate;

b.4. (C.A.S. #683–08–9) Diethyl methylphosphonate;

b.5. (C.A.S. #15715–41–0) Diethyl methylphosphonite;

b.6. (C.A.S. #2404–03–7) Diethyl-N,N-dimethylphosphoroamidate;

b.7. (C.A.S. #41480–75–5) N,N-Diisopropylaminoethanethiol hydrochloride;

b.8. (C.A.S. #5842–07–9) N,N-Diisopropyl-beta-aminoethane thiol;

b.9. (C.A.S. #96–80–0) N,N-Diisopropyl-beta-aminoethanol;

b.10. (C.A.S. #96–79–7), N,N-Diisopropyl-beta-aminoethyl chloride;

b.11. (C.A.S. #4261–68–1) N,N-Diisopropyl-beta-aminoethyl chloride hydrochloride;

b.12. (C.A.S. #6163–75–3) Dimethyl ethylphosphonate;

b.13. (C.A.S. #756–79–6) Dimethyl methylphosphonate;

b.14. (C.A.S. #677–43–0) N,N-Dimethylamino-phosphoryl dichloride;

b.15. (C.A.S. #1498–40–4) Ethyl phosphonous dichloride [Ethyl phosphinyl dichloride];

b.16. (C.A.S. #430–78–4) Ethyl phosphonus difluoride [Ethyl phosphinyl difluoride];

b.17. (C.A.S. #1066–50–8) Ethyl phosphonyl dichloride;

b.18. (C.A.S. #993–13–5) Methylphosphonic acid;

b.19. (C.A.S. #676–98–2) Methylphosphonothioic dichloride;

b.20. (C.A.S. #464–07–3) Pinacolyl alcohol;

b.21. (C.A.S. #1619–34–7) 3-Quinuclidinol;

b.22. (C.A.S. #111–48–8) Thiodiglycol.

c. Australia Group-controlled precursor chemicals also identified as Schedule 3 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:

c.1. (C.A.S. #762–04–9) Diethyl phosphite;

c.2. (C.A.S. #868–85–9) Dimethyl phosphite (dimethyl hydrogen phosphite);

c.3. (C.A.S. #139–87–7) Ethyldiethanolamine;

c.4. (C.A.S. #10025–87–3) Phosphorus oxychloride;

c.5. (C.A.S. #10026–13–8) Phosphorus pentachloride;

c.6. (C.A.S. #7719–12–2) Phosphorus trichloride;

c.7. (C.A.S. #10545–99–0) Sulfur dichloride;

c.8. (C.A.S. #10025–67–9) Sulfur monochloride;

c.9. (C.A.S. #7719–09–7) Thionyl chloride;

c.10. (C.A.S. #102–71–6) Triethanolamine;

c.11. (C.A.S. #122–52–1) Triethyl phosphite;

c.12. (C.A.S. #121–45–9) Trimethyl phosphite.

d. Other Australia Group-controlled precursor chemicals not also identified as Schedule 1, 2, or 3 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:

d.1. (C.A.S. #1341–49–7) Ammonium hydrogen fluoride;

d.2. (C.A.S. #107–07–3) 2-Chloroethanol;

d.3. (C.A.S. #109–89–7) Diethylamine;

d.4. (C.A.S. #100–37–8) N,N-Diethylaminoethanol;

d.5. (C.A.S. #298–06–6) O,O-Diethyl phosphorodithioate;

d.6. (C.A.S. #2465–65–8) O,O-Diethyl phosphorothioate;

d.7. (C.A.S. #108–18–9) Di-isopropylamine;

d.8. (C.A.S. #124–40–3) Dimethylamine;

d.9. (C.A.S. #506–59–2) Dimethylamine hydrochloride;

d.10. (C.A.S. #7664–39–3) Hydrogen fluoride;

d.11. (C.A.S. #3554–74–3) 3-Hydroxyl-1-methylpiperidine;

d.12. (C.A.S. #76–89–1) Methyl benzilate;

d.13. (C.A.S. #1314–80–3) Phosphorus pentasulfide;

d.14. (C.A.S. #75–97–8) Pinacolone;

d.15. (C.A.S. #7789–29–9) Potassium bifluoride;

d.16. (C.A.S. #151–50–8) Potassium cyanide;

d.17. (C.A.S. #7789–23–3) Potassium fluoride;

d.18. (C.A.S. #3731–38–2) 3-Quinuclidone;

d.19. (C.A.S. #1333–83–1) Sodium bifluoride;

d.20. (C.A.S. #143–33–9) Sodium cyanide;
d.21. (C.A.S. #7681–49–4) Sodium fluoride;
d.22. (C.A.S. #16893–85–9) Sodium hexafluorosilicate;
d.23. (C.A.S. #1313–82–2) Sodium sulfide;
d.24. (C.A.S. #637–39–8) Triethanolamine hydrochloride;
d.25. (C.A.S. #116–17–6) Tri-isopropyl phosphite.

■ 9. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1, ECCN 1C351 is revised to read as follows:

1C351 Human and animal pathogens and ''toxins'', as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, CW, AT

Control(s)	*Country chart (See Supp. No. 1 to part 738)*
CB applies to entire entry.	CB Column 1

CW applies to 1C351.d.11 and d.12 and a license is required for CW reasons for all destinations, including Canada, as follows: CW applies to 1C351.d.11 for ricin in the form of (1) Ricinus Communis AgglutininII (RCAII), also known as ricin D or Ricinus Communis LectinIII (RCLIII) and (2) Ricinus Communis LectinIV (RCLIV), also known as ricin E. CW applies to 1C351.d.12 for saxitoxin identified by C.A.S. #35523–89–8. See § 742.18 of the EAR for licensing information pertaining to chemicals subject to restriction pursuant to the Chemical Weapons Convention (CWC). The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons.

Control(s)	*Country chart (See Supp. No. 1 to part 738)*
AT applies to entire entry.	AT Column 1

License Requirement Notes: *1. All vaccines and ''immunotoxins'' are excluded from the scope of this entry. Certain medical products and diagnostic and food testing kits that contain biological toxins controlled under paragraph (d) of this entry, with the exception of toxins controlled for CW reasons under d.11 and d.12, are excluded from the scope of this entry. Vaccines, ''immunotoxins'', certain medical products, and diagnostic and food testing kits excluded from the scope of this entry are controlled under ECCN 1C991.*

2. For the purposes of this entry, only saxitoxin is controlled under paragraph d.12; other members of the paralytic shellfish poison family (e.g., neosaxitoxin) are designated EAR99.

3. Clostridium perfringens strains, other than the epsilon toxin-producing strains of Clostridium perfringens described in c.12, are excluded from the scope of this entry, since they may be used as positive control cultures for food testing and quality control.

4. Unless specified elsewhere in this ECCN 1C351 (e.g., in License Requirement Notes 1–3), this ECCN controls all biological agents and ''toxins,'' regardless of quantity or attenuation, that are identified in the List of Items Controlled for this ECCN, including small quantities or attenuated strains of select biological agents or ''toxins'' that are excluded from the lists of select biological agents or ''toxins'' by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, or the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, in accordance with their regulations in 9 CFR part 121 and 42 CFR part 73, respectively.

5. Biological agents and pathogens are controlled under this ECCN 1C351 when they are an isolated live culture of a pathogen agent, or a preparation of a toxin agent that has been isolated or extracted from any source or material, including living material that has been deliberately inoculated or contaminated with the agent. Isolated live cultures of a pathogen agent include live cultures in dormant form or in dried preparations, whether the agent is natural, enhanced or modified.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A
GBS: N/A
CIV: N/A

Special Conditions for STA

STA: (1) Paragraph (c)(1) of License Exception STA (§ 740.20(c)(1)) may be used for items in 1C351.d.1 through 1C351.d.10 and 1C351.d.13 through 1C351.d.19. See § 740.20(b)(2)(vi) for restrictions on the quantity of any one toxin that may be exported in a single shipment and the number of shipments that may be made to any one end user in a single calendar year. Also see the Automated Export System (AES) requirements in § 758.1(b)(4) of the EAR. (2) Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any items in 1C351.

List of Items Controlled

Related Controls: (1) Certain forms of ricin and saxitoxin in 1C351.d.11. and d.12 are CWC Schedule 1 chemicals (see § 742.18 of the EAR). The U.S. Government must provide advance notification and annual reports to the OPCW of all exports of Schedule 1 chemicals. See § 745.1 of the EAR for notification procedures. See 22 CFR part 121, Category XIV and § 121.7 for CWC Schedule 1 chemicals that are ''subject to the ITAR.'' (2) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, maintain controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN (for APHIS, see 7 CFR 331.3(b), 9 CFR 121.3(b), and 9 CFR 121.4(b); for CDC, see 42 CFR 73.3(b) and 42 CFR 73.4(b)). (3) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are ''subject to the ITAR.''

Related Definitions: (1) For the purposes of this entry ''immunotoxin'' is defined as an antibody-toxin conjugate intended to destroy specific target cells (*e.g.,* tumor cells) that bear antigens homologous to the antibody. (2) For the purposes of this entry ''subunit'' is defined as a portion of the ''toxin''.

Items:

a. Viruses identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows:

a.1. African horse sickness virus;
a.2. African swine fever virus;
a.3. Andes virus;
a.4. Avian influenza (AI) viruses identified as having high pathogenicity (HP), as follows:
a.4.a. AI viruses that have an intravenous pathogenicity index (IVPI) in 6-week-old chickens greater than 1.2; or
a.4.b. AI viruses that cause at least 75% mortality in 4- to 8-week-old chickens infected intravenously.

Note: *Avian influenza (AI) viruses of the H5 or H7 subtype that do not have either of the characteristics described in 1C351.a.4 (specifically, 1C351.a.4.a or a.4.b) should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0). If the amino acid motif is similar to that observed for other HPAI isolates, then the isolate being tested should be considered as HPAI and the virus is controlled under 1C351.a.4.*

a.5. Bluetongue virus;
a.6. Chapare virus;
a.7. Chikungunya virus;
a.8. Choclo virus;
a.9. Classical swine fever virus (Hog cholera virus);
a.10. Crimean-Congo hemorrhagic fever virus;
a.11. Dobrava-Belgrade virus;
a.12. Eastern equine encephalitis virus;
a.13. Ebolavirus (includes all members of the Ebolavirus genus);
a.14. Foot-and-mouth disease virus;
a.15. Goatpox virus;
a.16. Guanarito virus;
a.17. Hantaan virus;
a.18. Hendra virus (Equine morbillivirus);
a.19. Japanese encephalitis virus;
a.20. Junin virus;
a.21. Kyasanur Forest disease virus;
a.22. Laguna Negra virus;
a.23. Lassa virus;
a.24. Louping ill virus;
a.25. Lujo virus;
a.26. Lumpy skin disease virus;
a.27. Lymphocytic choriomeningitis virus;
a.28. Machupo virus;
a.29. Marburgvirus (includes all members of the Marburgvirus genus);
a.30. Monkeypox virus;
a.31. Murray Valley encephalitis virus;
a.32. Newcastle disease virus;
a.33. Nipah virus;
a.34. Omsk hemorrhagic fever virus;
a.35. Oropouche virus;
a.36. Peste-des-petits ruminants virus;
a.37. Porcine Teschovirus;
a.38. Powassan virus;
a.39. Rabies virus and all other members of the Lyssavirus genus;

a.40. Reconstructed 1918 influenza virus;

Technical Note: *1C351.a.40 includes reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.*

a.41. Rift Valley fever virus;
a.42. Rinderpest virus;
a.43. Rocio virus;
a.44. Sabia virus;
a.45. Seoul virus;
a.46. Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus);
a.47. Sheeppox virus;
a.48. Sin Nombre virus;
a.49. St. Louis encephalitis virus;
a.50. Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease);
a.51. Swine vesicular disease virus;
a.52. Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus—see 1C351.b.3 for Siberian subtype);
a.53. Variola virus;
a.54. Venezuelan equine encephalitis virus;
a.55. Vesicular stomatitis virus;
a.56. Western equine encephalitis virus; *or*
a.57. Yellow fever virus.

b. Viruses identified on the APHIS/CDC ''select agents'' lists (see Related Controls paragraph #2 for this ECCN), but not identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows:
b.1. [Reserved];
b.2. [Reserved]; *or*
b.3. Tick-borne encephalitis virus (Siberian subtype, formerly West Siberian virus—see 1C351.a.52 for Far Eastern subtype).

c. Bacteria identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows:
c.1. Bacillus anthracis;
c.2. Brucella abortus;
c.3. Brucella melitensis;
c.4. Brucella suis;
c.5. Burkholderia mallei (Pseudomonas mallei);
c.6. Burkholderia pseudomallei (Pseudomonas pseudomallei);
c.7. Chlamydia psittaci (Chlamydophila psittaci);
c.8. Clostriduim argentinense (formerly known as Clostridium botulinum Type G), botulinum neurotoxin producing strains;
c.9. Clostridium baratii, botulinum neurotoxin producing strains;
c.10. Clostridium botulinum;
c.11. Clostridium butyricum, botulinum neurotoxin producing strains;
c.12. Clostridium perfringens, epsilon toxin producing types;
c.13. Coxiella burnetii;
c.14. Francisella tularensis;
c.15. Mycoplasma capricolum subspecies capripneumoniae (''strain F38'');
c.16. Mycoplasma mycoides subspecies mycoides SC (small colony) (a.k.a. contagious bovine pleuropneumonia);
c.17. Rickettsia prowazekii;
c.18. Salmonella enterica subspecies enterica serovar Typhi (Salmonella typhi);
c.19. Shiga toxin producing Escherichia coli (STEC) of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups;

Note: *Shiga toxin producing Escherichia coli (STEC) includes, inter alia, enterohaemorrhagic E. coli (EHEC), verotoxin producing E. coli (VTEC) or verocytotoxin producing E. coli (VTEC).*

c.20. Shigella dysenteriae;
c.21. Vibrio cholerae; *or*
c.22. Yersinia pestis.

d. ''Toxins'' identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows, and ''subunits'' thereof:
d.1. Abrin;
d.2. Aflatoxins;
d.3. Botulinum toxins;
d.4. Cholera toxin;
d.5. Clostridium perfringens alpha, beta 1, beta 2, epsilon and iota toxins;
d.6. Conotoxins;
d.7. Diacetoxyscirpenol;
d.8. HT–2 toxin;
d.9. Microcystins (Cyanginosins);
d.10. Modeccin;
d.11. Ricin;
d.12. Saxitoxin;
d.13. Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins);
d.14. Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as Staphylococcus enterotoxin F);
d.15. T–2 toxin;
d.16. Tetrodotoxin;
d.17. Viscumin (Viscum album lectin 1); *or*
d.18. Volkensin.

e. ''Fungi'', as follows:
e.1. Coccidioides immitis; *or*
e.2. Coccidioides posadasii.

■ 10. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1, ECCN 1C353 is revised to read as follows:

1C353 Genetic elements and genetically modified organisms, as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, AT

Control(s)	*Country Chart (See Supp. No. 1 to part 738)*
CB applies to entire entry	CB Column 1
AT applies to entire entry	AT Column 1

License Requirements Notes: *1. Vaccines that contain genetic elements or genetically modified organisms identified in this ECCN are controlled by ECCN 1C991.*

2. Unless specified elsewhere in this ECCN 1C353 (e.g., in License Requirement Note 1), this ECCN controls genetic elements or genetically modified organisms for all biological agents and ''toxins,'' regardless of quantity or attenuation, that are identified in the List of Items Controlled for this ECCN, including genetic elements or genetically modified organisms for attenuated strains of select biological agents or ''toxins'' that are excluded from the lists of select biological agents or ''toxins'' by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, or the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, in accordance with the APHIS regulations in 7 CFR part 331 and 9 CFR part 121 and the CDC regulations in 42 CFR part 73.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A
GBS: N/A
CIV: N/A

List of Items Controlled

Related Controls: (1) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, maintain controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN, including (but not limited to) certain genetic elements, recombinant nucleic acids, and recombinant organisms associated with the agents or toxins in ECCN 1C351 or 1C354 (for APHIS, see 7 CFR 331.3(c), 9 CFR 121.3(c), and 9 CFR 121.4(c); for CDC, see 42 CFR 73.3(c) and 42 CFR 73.4(c)). (2) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are subject to the export licensing jurisdiction of the U.S. Department of State, Directorate of Defense Trade Controls.

Related Definition: N/A

Items:

a. Any genetically modified organism that contains, or any genetic element that codes for, any of the following:
a.1. Any gene or genes specific to any virus controlled by 1C351.a or .b or 1C354.c;
a.2. Any gene or genes specific to any bacterium controlled by 1C351.c or 1C354.a, or any fungus controlled by 1C351.e or 1C354.b, and which;
a.2.a. In itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health; *or*
a.2.b. Could endow or enhance pathogenicity; *or*
a.3. Any toxins, or their subunits, controlled by 1C351.d.

b. [Reserved].

Technical Notes: *1. Genetically modified organisms include organisms in which the nucleic acid sequences have been created or altered by deliberate molecular manipulation.*

2. ''Genetic elements'' include, inter alia, chromosomes, genomes, plasmids, transposons, vectors, and inactivated organisms containing recoverable nucleic acid fragments, whether genetically modified or unmodified, or chemically synthesized in whole or in part. For the purposes of this ECCN 1C353, nucleic acids from an inactivated organism, virus, or sample are considered to be 'recoverable' if the inactivation and preparation of the material is intended or known to facilitate isolation, purification, amplification, detection, or identification of nucleic acids.

3. This ECCN does not control nucleic acid sequences of shiga toxin producing

Escherichia coli of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups, other than those genetic elements coding for shiga toxin, or for its subunits.

4. 'Endow or enhance pathogenicity' is defined as when the insertion or integration of the nucleic acid sequence or sequences is/are likely to enable or increase a recipient organism's ability to be used to deliberately cause disease or death. This might include alterations to, inter alia: virulence, transmissibility, stability, route of infection, host range, reproducibility, ability to evade or suppress host immunity, resistance to medical countermeasures, or detectability.

■ 11. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2, ECCN 2B350 is revised to read as follows:

2B350 Chemical manufacturing facilities and equipment, except valves controlled by 2A226, as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, AT

Control(s)	*Country Chart (See Supp. No. 1 to part 738)*
CB applies to entire entry.	CB Column 2
AT applies to entire entry.	AT Column 1

License Requirement Note: *This ECCN does not control equipment that is both: (1) ''Specially Designed'' for use in civil applications e.g., food processing, pulp and paper processing, or water purification) and (2) inappropriate, by the nature of its design, for use in storing, processing, producing or conducting and controlling the flow of the chemical weapons precursors controlled by 1C350.*

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: $2,000 for all Country Group B destinations, except those also listed under Country Group D:3 (see Supplement No. 1 to part 740 of the EAR).
GBS: N/A
CIV: N/A

List of Items Controlled

Related Controls: See also ECCNs 2A226, 2A992, 2A993, 2B231, and 2B999.
Related Definitions: For purposes of this entry the term 'chemical warfare agents' includes those agents ''subject to the ITAR'' (see 22 CFR parts 120 through 130).
Items:

a. Reaction vessels, reactors and prefabricated repair assemblies therefor, as follows:

a.1. Reaction vessels or reactors, with or without agitators, with total internal (geometric) volume greater than 0.1 m^3 (100 liters) and less than 20 m^3 (20,000 liters), where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

a.1.a Alloys with more than 25% nickel and 20% chromium by weight;

a.1.b. Nickel or alloys with more than 40% nickel by weight;

a.1.c. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

a.1.d. Glass (including vitrified or enameled coating or glass lining);

a.1.e. Tantalum or tantalum alloys;

a.1.f. Titanium or titanium alloys;

a.1.g. Zirconium or zirconium alloys; *or*

a.1.h. Niobium (columbium) or niobium alloys;

a.2. Prefabricated repair assemblies, and their specially designed components, that:

a.2.a. Are designed for mechanical attachment to glass-lined reaction vessels or reactors described in 2B350.a.1; *and*

a.2.b. Have metallic surfaces that are made from tantalum or tantalum alloys and come in direct contact with the chemical(s) being processed.

b. Agitators designed for use in reaction vessels or reactors described in 2B350.a.1, and impellers, blades or shafts designed for such agitators, where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

b.1. Alloys with more than 25% nickel and 20% chromium by weight;

b.2. Nickel or alloys with more than 40% nickel by weight;

b.3. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

b.4. Glass (including vitrified or enameled coatings or glass lining);

b.5. Tantalum or tantalum alloys;

b.6. Titanium or titanium alloys;

b.7. Zirconium or zirconium alloys; *or*

b.8. Niobium (columbium) or niobium alloys.

c. Storage tanks, containers, receivers and prefabricated repair assemblies therefor, as follows:

c.1. Storage tanks, containers or receivers with a total internal (geometric) volume greater than 0.1 m^3 (100 liters) where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

c.1.a. Alloys with more than 25% nickel and 20% chromium by weight;

c.1.b. Nickel or alloys with more than 40% nickel by weight;

c.1.c. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

c.1.d. Glass (including vitrified or enameled coatings or glass lining);

c.1.e. Tantalum or tantalum alloys;

c.1.f. Titanium or titanium alloys;

c.1.g. Zirconium or zirconium alloys; *or*

c.1.h. Niobium (columbium) or niobium alloys;

c.2. Prefabricated repair assemblies, and their specially designed components, that:

c.2.a. Are designed for mechanical attachment to glass-lined storage tanks, containers or receivers described in 2B350.c.1; *and*

c.2.b. Have metallic surfaces that are made from tantalum or tantalum alloys and come in direct contact with the chemical(s) being processed.

d. Heat exchangers or condensers with a heat transfer surface area of less than 20 m^2, but greater than 0.15 m^2, and tubes, plates, coils or blocks (cores) designed for such heat exchangers or condensers, where all surfaces that come in direct contact with the chemical(s) being processed are made from any of the following materials:

d.1. Alloys with more than 25% nickel and 20% chromium by weight;

d.2. Nickel or alloys with more than 40% nickel by weight;

d.3. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

d.4. Glass (including vitrified or enameled coatings or glass lining);

d.5. Tantalum or tantalum alloys;

d.6. Titanium or titanium alloys;

d.7. Zirconium or zirconium alloys;

d.8. Niobium (columbium) or niobium alloys;

d.9. Graphite or carbon-graphite;

d.10. Silicon carbide; *or*

d.11. Titanium carbide.

e. Distillation or absorption columns of internal diameter greater than 0.1 m, and liquid distributors, vapor distributors or liquid collectors designed for such distillation or absorption columns, where all surfaces that come in direct contact with the chemical(s) being processed are made from any of the following materials:

e.1. Alloys with more than 25% nickel and 20% chromium by weight;

e.2. Nickel or alloys with more than 40% nickel by weight;

e.3. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

e.4. Glass (including vitrified or enameled coatings or glass lining);

e.5. Tantalum or tantalum alloys;

e.6. Titanium or titanium alloys;

e.7. Zirconium or zirconium alloys;

e.8. Niobium (columbium) or niobium alloys; *or*

e.9. Graphite or carbon-graphite.

f. Remotely operated filling equipment in which all surfaces that come in direct contact with the chemical(s) being processed are made from any of the following materials:

f.1. Alloys with more than 25% nickel and 20% chromium by weight; *or*

f.2. Nickel or alloys with more than 40% nickel by weight.

g. Valves, as follows:

g.1. Valves having both of the following characteristics:

g.1.a. A nominal size greater than 1.0 cm (⅜ in.); *and*

g.1.b. All surfaces that come in direct contact with the chemical(s) being produced, processed, or contained are made from materials identified in Technical Note 1 to 2B350.g.

g.2. Valves, except for valves controlled by 2B350.g.1, having all of the following characteristics:

g.2.a. A nominal size equal to or greater than 2.54 cm (1 inch) and equal to or less than 10.16 cm (4 inches);

g.2.b. Casings (valve bodies) or preformed casing liners controlled by 2B350.g.3, in which all surfaces that come in direct contact with the chemical(s) being produced,

processed, or contained are made from materials identified in Technical Note 1 to 2B350.g; *and*

g.2.c. A closure element designed to be interchangeable.

g.3. Casings (valve bodies) and preformed casing liners having both of the following characteristics:

g.3.a. Designed for valves in 2B350.g.1 or .g.2; *and*

g.3.b. All surfaces that come in direct contact with the chemical(s) being produced, processed, or contained are made from materials identified in Technical Note 1 to 2B350.g.

Technical Note 1 to 2B350.g: *All surfaces of the valves controlled by 2B350.g.1, and the casings (valve bodies) and preformed casing liners controlled by 2B350.g.3, that come in direct contact with the chemical(s) being produced, processed, or contained are made from the following materials:*

a. Alloys with more than 25% nickel and 20% chromium by weight;

b. Nickel or alloys with more than 40% nickel by weight;

c. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

d. Glass (including vitrified or enameled coating or glass lining);

e. Tantalum or tantalum alloys;

f. Titanium or titanium alloys;

g. Zirconium or zirconium alloys;

h. Niobium (columbium) or niobium alloys; or

i. Ceramic materials, as follows:

i.1. Silicon carbide with a purity of 80% or more by weight;

i.2. Aluminum oxide (alumina) with a purity of 99.9% or more by weight; or

i.3. Zirconium oxide (zirconia).

Technical Note 2 to 2B350.g: *The 'nominal size' is defined as the smaller of the inlet and outlet port diameters.*

h. Multi-walled piping incorporating a leak detection port, in which all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

h.1. Alloys with more than 25% nickel and 20% chromium by weight;

h.2. Nickel or alloys with more than 40% nickel by weight;

h.3. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

h.4. Glass (including vitrified or enameled coatings or glass lining);

h.5. Tantalum or tantalum alloys;

h.6. Titanium or titanium alloys;

h.7. Zirconium or zirconium alloys;

h.8. Niobium (columbium) or niobium alloys; *or*

h.9. Graphite or carbon-graphite.

i. Multiple-seal and seal-less pumps with manufacturer's specified maximum flow-rate greater than 0.6 m^3/hour (600 liters/hour), or vacuum pumps with manufacturer's specified maximum flow-rate greater than 5 m^3/hour (5,000 liters/hour) (under standard temperature (273 K (0 °C)) and pressure (101.3 kPa) conditions), and casings (pump bodies), preformed casing liners, impellers, rotors or jet pump nozzles designed for such pumps, in which all surfaces that come into direct contact with the chemical(s) being processed are made from any of the following materials:

i.1. Alloys with more than 25% nickel and 20% chromium by weight;

i.2. Nickel or alloys with more than 40% nickel by weight;

i.3. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

i.4. Glass (including vitrified or enameled coatings or glass lining);

i.5. Tantalum or tantalum alloys;

i.6. Titanium or titanium alloys;

i.7. Zirconium or zirconium alloys;

i.8. Niobium (columbium) or niobium alloys.

i.9. Graphite or carbon-graphite;

i.10. Ceramics; *or*

i.11. Ferrosilicon (high silicon iron alloys).

Technical Note to 2B350.i: *The seals referred to in 2B350.i come into direct contact with the chemical(s) being processed (or are designed to do so), and provide a sealing function where a rotary or reciprocating drive shaft passes through a pump body.*

j. Incinerators designed to destroy chemical warfare agents, chemical weapons precursors controlled by 1C350, or chemical munitions having ''specially designed'' waste supply systems, special handling facilities and an average combustion chamber temperature greater than 1000 °C in which all surfaces in the waste supply system that come into direct contact with the waste products are made from or lined with any of the following materials:

j.1. Alloys with more than 25% nickel and 20% chromium by weight;

j.2. Nickel or alloys with more than 40% nickel by weight; *or*

j.3. Ceramics.

Technical Note 1: *Carbon-graphite is a composition consisting primarily of graphite and amorphous carbon, in which the graphite is 8 percent or more by weight of the composition.*

Technical Note 2: *For the items listed in 2B350, the term 'alloy,' when not accompanied by a specific elemental concentration, is understood as identifying those alloys where the identified metal is present in a higher percentage by weight than any other element.*

Technical Note 3: *The materials used for gaskets, packing, seals, screws or washers, or other materials performing a sealing function, do not determine the control status of the items in this ECCN, provided that such components are designed to be interchangeable.*

Note: *See Categories V and XIV of the United States Munitions List for all chemicals that are ''subject to the ITAR'' (see 22 CFR parts 120 through 130).*

■ 12. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2, ECCN 2B351 is revised to read as follows:

2B351 Toxic gas monitors and monitoring systems, and their dedicated detecting ''parts'' and ''components'' (*i.e.,* detectors, sensor devices, and replaceable sensor cartridges), as follows, except those systems and detectors controlled by ECCN 1A004.c (see List of Items Controlled).

License Requirements

Reason for Control: CB, AT

Control(s)	*Country Chart (See Supp. No. 1 to part 738)*
CB applies to entire entry.	CB Column 2
AT applies to entire entry.	AT Column 1

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

CIV: N/A

List of Items Controlled

Related Controls: See ECCN 2D351 for ''software'' for toxic gas monitors and monitoring systems, and their dedicated detecting ''parts'' and ''components,'' controlled by this ECCN. Also see ECCN 1A004, which controls chemical detection systems and ''specially designed'' ''parts'' and ''components'' therefor that are ''specially designed'' or modified for detection or identification of chemical warfare agents, but not ''specially designed'' for military use, and ECCN 1A995, which controls certain detection equipment, ''parts'' and ''components'' not controlled by ECCN 1A004 or by this ECCN.

Related Definitions: (1) For the purposes of this entry, the term ''dedicated'' means committed entirely to a single purpose or device. (2) For the purposes of this entry, the term ''continuous operation'' describes the capability of the equipment to operate on line without human intervention. The intent of this entry is to control toxic gas monitors and monitoring systems capable of collection and detection of samples in environments such as chemical plants, rather than those used for batch-mode operation in laboratories.

Items:

a. Designed for continuous operation and usable for the detection of chemical warfare agents or precursor chemicals controlled by 1C350 at concentrations of less than 0.3 mg/m^3; *or*

b. Designed for the detection of cholinesterase-inhibiting activity.

■ 13. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2—Materials Processing, ECCN 2B352 is revised to read as follows:

2B352 Equipment capable of use in handling biological materials, as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, AT

Control(s)	Country Chart (See Supp. No. 1 to part 738)
CB applies to entire entry.	CB Column 2
AT applies to entire entry.	AT Column 1

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A
GBS: N/A
CIV: N/A

List of Items Controlled

Related Controls: See ECCNs 1A004 and 1A995 for protective equipment that is not covered by this entry. Also see ECCN 9A120 for controls on certain ''UAV'' systems designed or modified to dispense an aerosol and capable of carrying elements of a payload in the form of a particulate or liquid, other than fuel ''parts'' or ''components'' of such vehicles, of a volume greater than 20 liters.

Related Definitions: (1) ''Lighter than air vehicles''—balloons and airships that rely on hot air or on lighter-than-air gases, such as helium or hydrogen, for their lift. (2) ''UAVs''—Unmanned Aerial Vehicles. (3) ''VMD''—Volume Median Diameter.

Items:

a. Containment facilities and related equipment, as follows:

a.1. Complete containment facilities at P3 or P4 containment level.

Technical Note: *P3 or P4 (BL3, BL4, L3, L4) containment levels are as specified in the WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004).*

a.2. Equipment designed for fixed installation in containment facilities specified in paragraph a.1 of this ECCN, as follows:

a.2.a. Double-door pass-through decontamination autoclaves;

a.2.b. Breathing air suit decontamination showers;

a.2.c. Mechanical-seal or inflatable-seal walkthrough doors.

b. Fermenters and components as follows:

b.1. Fermenters capable of cultivation of micro-organisms or of live cells for the production of viruses or toxins, without the propagation of aerosols, having a total internal volume of 20 liters or greater.

b.2. Components designed for such fermenters, as follows:

b.2.a. Cultivation chambers designed to be sterilized or disinfected in situ;

b.2.b. Cultivation chamber holding devices; *or*

b.2.c. Process control units capable of simultaneously monitoring and controlling two or more fermentation system parameters (*e.g.,* temperature, pH, nutrients, agitation, dissolved oxygen, air flow, foam control).

Technical Note: *Fermenters include bioreactors (including single-use (disposable) bioreactors), chemostats and continuous-flow systems.*

c. Centrifugal separators capable of the continuous separation of pathogenic microorganisms, without the propagation of aerosols, and having all of the following characteristics:

c.1. One or more sealing joints within the steam containment area;

c.2. A flow rate greater than 100 liters per hour;

c.3. ''Parts'' or ''components'' of polished stainless steel or titanium; *and*

c.4. Capable of in-situ steam sterilization in a closed state.

Technical Note: *Centrifugal separators include decanters.*

d. Cross (tangential) flow filtration equipment and ''accessories'', as follows:

d.1. Cross (tangential) flow filtration equipment capable of separation of microorganisms, viruses, toxins or cell cultures having all of the following characteristics:

d.1.a. A total filtration area equal to or greater than 1 square meter (1 m^2); *and*

d.1.b. Having any of the following characteristics:

d.1.b.1. Capable of being sterilized or disinfected in-situ; *or*

d.1.b.2. Using disposable or single-use filtration ''parts'' or ''components''.

N.B.: *2B352.d.1 does not control reverse osmosis and hemodialysis equipment, as specified by the manufacturer.*

d.2. Cross (tangential) flow filtration ''parts'' or ''components'' (*e.g.,* modules, elements, cassettes, cartridges, units or plates) with filtration area equal to or greater than 0.2 square meters (0.2 m^2) for each ''part'' or ''component'' and designed for use in cross (tangential) flow filtration equipment controlled by 2B352.d.1.

Technical Note: *In this ECCN, ''sterilized'' denotes the elimination of all viable microbes from the equipment through the use of either physical (e.g., steam) or chemical agents. ''Disinfected'' denotes the destruction of potential microbial infectivity in the equipment through the use of chemical agents with a germicidal effect. ''Disinfection'' and ''sterilization'' are distinct from ''sanitization'', the latter referring to cleaning procedures designed to lower the microbial content of equipment without necessarily achieving elimination of all microbial infectivity or viability.*

e. Steam, gas or vapor sterilizable freeze-drying equipment with a condenser capacity of 10 kg of ice or greater in 24 hours (10 liters of water or greater in 24 hours) and less than 1000 kg of ice in 24 hours (less than 1,000 liters of water in 24 hours).

f. Spray-drying equipment capable of drying toxins or pathogenic microorganisms having all of the following characteristics:

f.1. A water evaporation capacity of ≥0.4 kg/h and ≤400 kg/h;

f.2. The ability to generate a typical mean product particle size of ≤10 micrometers with existing fittings or by minimal modification of the spray-dryer with atomization nozzles enabling generation of the required particle size; *and*

f.3. Capable of being sterilized or disinfected in situ.

g. Protective and containment equipment, as follows:

g.1. Protective full or half suits, or hoods dependant upon a tethered external air supply and operating under positive pressure.

Technical Note: *This entry does not control suits designed to be worn with self-contained breathing apparatus.*

g.2. Biocontainment chambers, isolators, or biological safety cabinets having all of the following characteristics, for normal operation:

g.2.a. Fully enclosed workspace where the operator is separated from the work by a physical barrier;

g.2.b. Able to operate at negative pressure;

g.2.c. Means to safely manipulate items in the workspace; *and*

g.2.d. Supply and exhaust air to and from the workspace is high-efficiency particulate air (HEPA) filtered.

Note 1 to 2B352.g.2: 2B352.g.2 controls class III biosafety cabinets, as specified in the WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004) or constructed in accordance with national standards, regulations or guidance.

Note 2 to 2B352.g.2: 2B352.g.2 does not control isolators ''specially designed'' for barrier nursing or transportation of infected patients.

h. Aerosol inhalation equipment designed for aerosol challenge testing with microorganisms, viruses or toxins, as follows:

h.1. Whole-body exposure chambers having a capacity of 1 cubic meter or greater;

h.2. Nose-only exposure apparatus utilizing directed aerosol flow and having a capacity for the exposure of 12 or more rodents, or two or more animals other than rodents, and closed animal restraint tubes designed for use with such apparatus.

i. Spraying or fogging systems and ''parts'' and ''components'' therefor, as follows:

i.1. Complete spraying or fogging systems, ''specially designed'' or modified for fitting to aircraft, ''lighter than air vehicles,'' or ''UAVs,'' capable of delivering, from a liquid suspension, an initial droplet ''VMD'' of less than 50 microns at a flow rate of greater than 2 liters per minute;

i.2. Spray booms or arrays of aerosol generating units, ''specially designed'' or modified for fitting to aircraft, ''lighter than air vehicles,'' or ''UAVs,'' capable of delivering, from a liquid suspension, an initial droplet ''VMD'' of less than 50 microns at a flow rate of greater than 2 liters per minute;

i.3. Aerosol generating units ''specially designed'' for fitting to the systems as specified in paragraphs i.1 and i.2 of this ECCN.

Technical Notes: *1. Aerosol generating units are devices ''specially designed'' or modified for fitting to aircraft and include nozzles, rotary drum atomizers and similar devices.*

2. This ECCN does not control spraying or fogging systems, ''parts'' and ''components,'' as specified in 2B352.i, that are demonstrated not to be capable of delivering biological agents in the form of infectious aerosols.

3. Droplet size for spray equipment or nozzles ''specially designed'' for use on aircraft or ''UAVs'' should be measured using

either of the following methods (pending the adoption of internationally accepted standards):

a. Doppler laser method,

b. Forward laser diffraction method.

j. Nucleic acid assemblers and synthesizers that are both:

j.1 Partly or entirely automated; *and*

j.2. Designed to generate continuous nucleic acids greater than 1.5 kilobases in length with error rates less than 5% in a single run.

■ 14. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2, ECCN 2D351 is revised to read as follows:

2D351 Dedicated ''software'' for toxic gas monitors and monitoring systems, and their dedicated detecting ''parts'' and ''components,'' controlled by ECCN 2B351.

License Requirements

Reason for Control: CB, AT

Control(s)	*Country Chart (See Supp. No. 1 to part 738)*
CB applies to entire entry.	CB Column 2
AT applies to entire entry.	AT Column 1

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

CIV: N/A

TSR: N/A

List of Items Controlled

Related Controls: N/A

Related Definitions: (1) For the purposes of this entry, the term ''dedicated'' means committed entirely to a single purpose or device. (2) See Section 772.1 of the EAR for the definitions of ''software,'' ''program,'' and ''microprogram.''

Items: The list of items controlled is contained in the ECCN heading.

Dated: March 27, 2018.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2018–06581 Filed 3–30–18; 8:45 am]

BILLING CODE 3510–33–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA–2018–0007]

RIN 0960–AI18

Extension of Expiration Dates for Two Body System Listings

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: We are extending the expiration dates of the following body systems in the Listing of Impairments (listings) in our regulations: Special Senses and Speech and Congenital Disorders That Affect Multiple Body Systems. We are making no other revisions to these body systems in this final rule. This extension ensures that we will continue to have the criteria we need to evaluate impairments in the affected body systems at step three of the sequential evaluation processes for initial claims and continuing disability reviews.

DATES: This final rule is effective on April 2, 2018.

FOR FURTHER INFORMATION CONTACT: Cheryl A. Williams, Director, Office of Medical Policy, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–1020. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213, or TTY 1–800–325–0778, or visit our internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION:

Background

We use the listings in appendix 1 to subpart P of part 404 of 20 CFR at the third step of the sequential evaluation process to evaluate claims filed by adults and children for benefits based on disability under the title II and title XVI programs.[1] 20 CFR 404.1520(d), 416.920(d), 416.924(d). The listings are in two parts: Part A has listings criteria for adults and Part B has listings criteria for children. If you are age 18 or over, we apply the listings criteria in Part A when we assess your impairment or combination of impairments. If you are under age 18, we first use the criteria in Part B of the listings when we assess your impairment(s). If the criteria in Part B do not apply, we may use the criteria in Part A when those criteria consider the effects of your impairment(s). 20 CFR 404.1525(b), 416.925(b).

Explanation of Changes

In this final rule, we are extending the dates on which the listings for the following two body systems will no longer be effective as set out in the following chart:

Listing	Current expiration date	Extended expiration date
Special Senses and Speech (2.00 and 102.00)	April 29, 2018	April 24, 2020.
Congenital Disorders That Affect Multiple Body Systems (10.00 and 110.00).	April 5, 2018	April 3, 2020.

We continue to revise and update the listings on a regular basis, including those body systems not affected by this final rule.[2] We intend to update the two listings affected by this final rule as quickly as possible, but may not be able to publish final rules revising these listings by the current expiration dates. Therefore, we are extending the expiration dates listed above.

Regulatory Procedures

Justification for Final Rule

We follow the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553 in promulgating regulations. Section 702(a)(5) of the Social Security Act, 42 U.S.C. 902(a)(5). Generally, the APA requires that an agency provide prior notice and opportunity for public comment before issuing a final regulation. The APA provides exceptions to the notice-and-comment requirements when an agency finds there is good cause for dispensing with such procedures because they are impracticable, unnecessary, or contrary to the public interest.

We have determined that good cause exists for dispensing with the notice and public comment procedures. 5 U.S.C. 553(b)(B). This final rule only extends the date on which two body system listings will no longer be effective. It makes no substantive changes to our rules. Our current regulations[3] provide that we may extend, revise, or

[1] We also use the listings in the sequential evaluation processes we use to determine whether a beneficiary's disability continues. See 20 CFR 404.1594, 416.994, and 416.994a.

[2] Since we last extended the expiration dates of the listings affected by this rule in August 2016 (81 FR 51100), we have published final rules revising the medical criteria for evaluating mental disorders (81 FR 66137 (2016)) and human immunodeficiency virus (HIV infection (81 FR 86915 (2016)).

[3] See the first sentence of appendix 1 to subpart P of part 404 of 20 CFR.

promulgate the body system listings again. Therefore, we have determined that opportunity for prior comment is unnecessary, and we are issuing this regulation as a final rule.

In addition, for the reasons cited above, we find good cause for dispensing with the 30-day delay in the effective date of this final rule. 5 U.S.C. 553(d)(3). We are not making any substantive changes to the listings in these body systems. Without an extension of the expiration dates for these listings, we will not have the criteria we need to assess medical impairments in these two body systems at step three of the sequential evaluation processes. We therefore find it is in the public interest to make this final rule effective on the publication date.

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that this final rule does not meet the requirements for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB did not review it. We also determined that this final rule meets the plain language requirement of Executive Order 12866.

Regulatory Flexibility Act

We certify that this final rule does not have a significant economic impact on a substantial number of small entities because it affects only individuals. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

This final rule does not create any new or affect any existing collections and, therefore, it does not require OMB's approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Nancy Berryhill,

Deputy Commissioner for Operations, performing the duties and functions not reserved to the Commissioner of Social Security.

For the reasons set out in the preamble, we are amending appendix 1 to subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—[Amended]

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a)–(b) and (d)–(h), 216(i), 221(a) and (h)-(j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a) and (h)–(j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Amend appendix 1 to subpart P of part 404 by revising items 3 and 11 of the introductory text before Part A to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

3. Special Senses and Speech (2.00 and 102.00): April 24, 2020.

* * * * *

11. Congenital Disorders That Affect Multiple Body Systems (10.00 and 110.00): April 3, 2020.

* * * * *

[FR Doc. 2018–06671 Filed 3–30–18; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 890, 900, 1020, and 1040

[Docket No. FDA–2018–N–0011]

Medical Devices; Technical Amendment

AGENCY: Food and Drug Administration; HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending certain medical device regulations. This action is editorial in nature to correct typographical errors and to ensure accuracy and clarity in the Agency's regulations.

DATES: This rule is effective April 2, 2018.

FOR FURTHER INFORMATION CONTACT: Karen Fikes, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5244, Silver Spring, MD 20993–0002, 301–796–9603.

SUPPLEMENTARY INFORMATION: FDA is amending our regulations in 21 CFR parts 890, 900, 1020, and 1040 to correct typographical errors and to update addresses, office titles, and wording to ensure accuracy and clarity in the Agency's medical device regulations.

FDA is making nonsubstantive changes to the following regulations:

1. FDA is revising § 890.5525(b)(2)(i)(A) by replacing ''Testing using a drug approved for iontophoretic delivery, or a solution, if identified in the labeling, to demonstrate safe use of the device as intended'' with ''Testing using a drug approved for iontophoretic delivery, or a solution if identified in the labeling, to demonstrate safe use of the device as intended''.

2. FDA is revising § 900.3(b)(1) by replacing ''Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiology Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, marked Attn: Mammography Standards Branch'' with ''Division of Mammography Quality Standards, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4445, Silver Spring, MD 20993, Attn: Program Management Branch''.

3. FDA is revising § 900.11(b)(2)(i) by replacing ''42 U.S.C. 263b(c)(2)'' with ''42 U.S.C. 263b(c)(4)''.

4. FDA is revising § 1020.30(c) by replacing ''Director of the Office of Communication, Education, and Radiation Programs of the Center for Devices and Radiological Health'' with ''Director, Center for Devices and Radiological Health''.

5. FDA is revising § 1040.10(a)(3)(i) by replacing ''Food and Drug Administration, Center for Devices and Radiological Health, Director, Office of Compliance, 10903 New Hampshire Ave., Bldg. 66, Rm. 3521, Silver Spring, MD 20993–0002'' with ''Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002''.

6. FDA is revising § 1040.10(f)(6)(ii) by replacing ''Director, Office of

Compliance (HFZ–300), Center for Devices and Radiological Health'' with ''Director, Center for Devices and Radiological Health''.

7. FDA is revising § 1040.10(g)(10) by replacing ''Director, Office of Compliance (HFZ–300), Center for Devices and Radiological Health'' with ''Director, Center for Devices and Radiological Health''.

8. FDA is revising § 1040.20(d)(3)(iii) by replacing ''Director, Office of Communication, Education, and Radiation Programs 10903 New Hampshire Ave., Bldg. 66, Rm. 4312, Silver Spring, MD 20993–0002, Center for Devices and Radiological Health'' with ''Director, Center for Devices and Radiological Health''.

9. FDA is revising § 1040.20(d)(3)(iv) by replacing ''manfacturer'' with ''manufacturer,'' and replacing ''Director, Office of Compliance (HFZ–300), Center for Devices and Radiological Health'' with ''Director, Center for Devices and Radiological Health''.

List of Subjects

21 CFR Part 890

Medical devices, Physical medicine devices.

21 CFR Part 900

Electronic products, Health facilities, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

21 CFR Part 1020

Electronic products, Medical devices, Radiation protection, Reporting and recordkeeping requirements, Television, X-rays.

21 CFR Part 1040

Electronic funds transfers, Incorporation by reference, Labeling, Lasers, Medical devices, Radiation protection, 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 890, 900, 1020, and 1040 are amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for part 890 continues to read as follows:

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

■ 2. Revise § 890.5525(b)(2)(i)(A) to read as follows:

§ 890.5525 Iontophoresis device.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(A) Testing using a drug approved for iontophoretic delivery, or a solution if identified in the labeling, to demonstrate safe use of the device as intended;

* * * * *

PART 900—MAMMOGRAPHY

■ 3. The authority citation for part 900 continues to read as follows:

Authority: 21 U.S.C. 360i, 360nn, 374(e), 42 U.S.C. 263b.

■ 4. Revise § 900.3(b)(1) to read as follows:

§ 900.3 Application for approval as an accreditation body.

* * * * *

(b) * * *

(1) An applicant seeking initial FDA approval as an accreditation body shall inform the Division of Mammography Quality Standards, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4445, Silver Spring, MD 20993, Attn: Program Management Branch, of its desire to be approved as an accreditation body and of its requested scope of authority.

* * * * *

■ 5. Revise § 900.11(b)(2)(i) to read as follows:

§ 900.11 Requirements for certification.

* * * * *

(b) * * *

(2) * * *

(i) A new facility beginning operation after October 1, 1994, is eligible to apply for a provisional certificate. The provisional certificate will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive a provisional certificate, a facility must meet the requirements of 42 U.S.C. 263b(c)(4) and submit the necessary information to an approved accreditation body or other entity designated by FDA.

* * * * *

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

■ 6. The authority citation for part 1020 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360e–360j, 360hh–360ss, 371, 381.

■ 7. Revise § 1020.30(c) to read as follows:

§ 1020.30 Diagnostic x-ray systems and their major components.

* * * * *

(c) *Manufacturers' responsibility.* Manufacturers of products subject to §§ 1020.30 through 1020.33 shall certify that each of their products meets all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in § 1010.2 of this chapter. Manufacturers may certify a combination of two or more components if they obtain prior authorization in writing from the Director, Center for Devices and Radiological Health. Manufacturers shall not be held responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person; however, manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of §§ 1020.30 through 1020.33.

* * * * *

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

■ 8. The authority citation for part 1040 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e-360j, 360hh-360ss, 371, 381.

■ 9. In § 1040.10 revise paragraphs (a)(3)(i), (f)(6)(ii), and (g)(10) to read as follows:

§ 1040.10 Laser products.

(a) * * *

(3) * * *

(i) Registers, and provides a listing by type of such laser products manufactured that includes the product name, model number, and laser medium or emitted wavelength(s), and the name and address of the manufacturer. The manufacturer must submit the registration and listing to the Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002.

* * * * *

(f) * * *

(6) * * *

(ii) If the configuration, design, or function of the laser product would make unnecessary compliance with the requirement in paragraph (f)(6)(i) of this section, the Director, Center for Devices and Radiological Health, may, upon written application by the manufacturer, approve alternate means to accomplish

the radiation protection provided by the beam attenuator.

* * * * *

(g) * * *

(10) *Label specifications.* Labels required by this section and § 1040.11 shall be permanently affixed to, or inscribed on, the laser product, legible, and clearly visible during operation, maintenance, or service, as appropriate. If the size, configuration, design, or function of the laser product would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, the Director, Center for Devices and Radiological Health, on the Director's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s) or alternate wording for such label(s) as applicable.

* * * * *

■ 10. In § 1040.20 revise paragraphs (d)(3)(iii) and (iv) to read as follows:

§ 1040.20 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

* * * * *

(d) * * *

(3) * * *

(iii) If the size, configuration, design, or function of the sunlamp product or ultraviolet lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, or would render the required label unnecessary, the Director, Center for Devices and Radiological Health, on the center's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s), alternate wording for such label(s), or deletion, as applicable.

(iv) In lieu of permanently affixing or inscribing tags or labels on the ultraviolet lamp as required by §§ 1010.2(b) and 1010.3(a), the manufacturer of the ultraviolet lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the lamp, if the name of the manufacturer and month and year of manufacture are permanently affixed or inscribed on the exterior surface of the ultraviolet lamp so as to be legible and readily accessible to view. The name of the manufacturer and month and year of manufacture affixed or inscribed on the exterior surface of the lamp may be expressed in code or symbols, if the manufacturer has previously supplied the Director, Center for Devices and Radiological Health, with the key to such code or symbols and the location of the coded information or symbols on the ultraviolet lamp. The label or tag affixed or inscribed on the lamp packaging may provide either the month and year of manufacture without abbreviation, or information to allow the date to be readily decoded.

* * * * *

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06308 Filed 3–30–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0110]

Drawbridge Operation Regulation; Hackensack River, Jersey City, New Jersey

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the PATH Bridge across the Hackensack River, mile 3.0, at Jersey City, New Jersey. This temporary deviation is necessary to allow the bridge to remain in the closed-to-navigation position to facilitate the replacement of rails and timbers across the length of the span of the bridge.

DATES: This deviation is effective from 12:01 a.m. on March 31, 2018, to 12:01 a.m. on September 26, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0110 is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Judy Leung-Yee, Project Officer, First Coast Guard District, telephone 212–514–4330, email *Judy.K.Leung-yee@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Port Authority Trans-Hudson Corporation, the owner of the bridge, requested a temporary deviation from the normal operating schedule to facilitate the replacement of rails and timbers across the length of the span of the bridge. The PATH Bridge across the Hackensack River, mile 3.0, has a vertical clearance in the closed position of 40 feet at mean high water and 45 feet at mean low water. The existing bridge operating regulations are listed at 33 CFR 117.723(b).

Under this temporary deviation, the PATH Bridge shall remain in the closed position between 12:01 a.m. Saturday and 12:01 a.m. Monday as follows: March 31–April 2, 2018; April 7–9, 14–16, 21–23, and 28–30, 2018; May 5–7, 12–14, and 19–21, 2018; June 2–4, 9–11, 16–18, 23–25, and 30-July 2, 2018; July 7–9, 14–16, 21–23, and 28–30, 2018; August 4–6, 11–13, 18–20, and 25–27, 2018; September 8–10, 15–17, 22–24, 2018.

The waterway is transited by commercial and recreational traffic. The Coast Guard notified known companies of the commercial vessels that transit the area, including the Sandy Hook Pilots and the local Tug/Tow Committee; there were no objections to this temporary deviation. Vessels able to pass under the bridge in the closed position may do so at any time. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass.

The Coast Guard will inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operations can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 27, 2018.

Christopher J. Bisignano,

Supervisory Bridge Management Specialist, First Coast Guard District.

[FR Doc. 2018–06540 Filed 3–30–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0253]

Drawbridge Operation Regulation; Lake Washington Ship Canal, Seattle, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Fremont Bridge, mile 2.6, and the University Bridge, mile 4.3, both crossing the Lake Washington Ship Canal at Seattle, WA. The deviation is necessary to accommodate the Tenacious Ten run event. This deviation allows the bridges to remain in the closed-to-navigation position to allow for the safe movement of event participants.

DATES: This deviation is effective from 8 a.m. to 10:15 a.m. on April 21, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0253 is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Seattle Department of Transportation, bridge owner, requested a temporary deviation from the operating schedule for the Fremont Bridge, mile 2.6, and the University Bridge, mile 4.3, both crossing the Lake Washington Ship Canal at Seattle, WA, to facilitate safe passage of participants in the Tenacious Ten run event. The Fremont Bridge provides a vertical clearance of 14 feet (31 feet of vertical clearance for the center 36 horizontal feet) in the closed-to-navigation position. The University Bridge provides a vertical clearance of 30 feet in the closed-to-navigation position. Both bridge clearances are referenced to the mean water elevation of Lake Washington. The normal operating schedule for both the Fremont Bridge and the University Bridge is in 33 CFR 117.1051. During this deviation period, the Fremont Bridge need not open to marine vessels from 8:15 a.m. to 10:15 a.m. on April 21, 2018, and the University Bridge need not open to marine vessel from 8 a.m. to 8:30 a.m. on April 21, 2018. Waterway usage on the Lake Washington Ship Canal ranges from commercial tug and barge to small pleasure craft.

Vessels able to pass through the bridges in the closed-to-navigation positions may do so at any time. Both bridges will be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), both drawbridges must return to their regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 21, 2018.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2018–06562 Filed 3–30–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0195]

Drawbridge Operation Regulation; Willamette River at Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Hawthorne Bridge across the Willamette River, mile 13.1, at Portland, OR. The deviation is necessary to accommodate the Walk MS Portland event. This deviation authorizes the bridge to remain in the closed-to-navigation position to allow safe roadway movement of event participants.

DATES: This deviation is effective from 9 a.m. to 11:30 a.m. on April 7, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0195 is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: Multnomah County, the bridge owner, has requested a temporary deviation from the operating schedule for the Hawthorne Bridge across the Willamette River, mile 13.1, at Portland, OR. The requested deviation is to accommodate the Walk MS Portland event. To facilitate this event, the draw of the subject bridge will be allowed to remain in the closed-to-navigation position and need not open to marine traffic from 7 a.m. to 11:30 on April 7, 2018. The Hawthorne Bridge provides a vertical clearance of 49 feet in the closed-to-navigation position referenced to the vertical clearance above Columbia River Datum 0.0. The normal operating schedule is in 33 CFR 117.897(c)(3(v). Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft. The Coast Guard requested objections to this deviation from local mariners via the Local Notice Mariners, and email. No objections were submitted to the Coast Guard.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The bridge will be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard will inform the users of the waterway, through our Local and Broadcast Notices to Mariners, of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 8, 2018.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2018–06561 Filed 3–30–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0122]

Drawbridge Operation Regulation; Sacramento River, Sacramento, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating

schedule that governs the Tower Drawbridge across the Sacramento River, mile 59.0 at Sacramento, CA. The deviation is necessary to allow the local community to participate in the Sactown Run 10-mile and 5K races. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period.

DATES: This deviation is effective from 5 a.m. to 11:30 a.m. on April 8, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0122, is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Carl T. Hausner, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–437–3516, email *Carl.T.Hausner@uscg.mil.*

SUPPLEMENTARY INFORMATION: The California Department of Transportation has requested a temporary change to the operation of the Tower Drawbridge, mile 59.0, over the Sacramento River, at Sacramento, CA. The drawbridge navigation span provides a vertical clearance of 30 feet above Mean High Water in the closed-to-navigation position. The draw operates as required by 33 CFR 117.189(a). Navigation on the waterway is commercial and recreational.

The drawspan will be secured in the closed-to-navigation position 5 a.m. to 11:30 a.m. on April 8, 2018, to allow the community to participate in the Sactown Run 10 mile and 5K races. This temporary deviation has been coordinated with the waterway users. No objections to the proposed temporary deviation were raised.

Vessels able to pass through the bridge in the closed position may do so at any time. The bridge will be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 19, 2018.

Carl T. Hausner,

District Bridge Chief, Eleventh Coast Guard District.

[FR Doc. 2018–06536 Filed 3–30–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0200]

Drawbridge Operation Regulation; Willamette River, Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the lower deck of the Steel Bridge across the Willamette River, mile 12.1, in Portland, OR. The deviation is necessary to support the Bridge to Brews run event. This deviation allows the upper lift span of the bridge to remain in the closed-to-navigation position to ensure the safety of event participants.

DATES: This deviation is effective from 8:30 a.m. to 10:45 a.m. on April 15, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0200, is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION: Union Pacific Railroad Company (UPRR) owns and operates the Steel Bridge across the Willamette River, at mile 12.1, in Portland, OR. UPRR has requested a temporary deviation from the operating schedule for the Steel Bridge upper lift span. The deviation is necessary to accommodate the annual Bridge to Brews run event. The Steel Bridge is a double-deck lift bridge, and the lower lift span operates independent of the upper lift span. To facilitate this temporary deviation request, the upper lift span is authorized to remain in the closed-to-navigation position, and need not open to marine vessels from 8:30 a.m. to 10:45 a.m. on April 15, 2018. When the lower span is in the closed-to-navigation position, the bridge provides 26 feet of vertical clearance above Columbia River Datum 0.0. When the upper span is in the closed-to-navigation position, and the lower span is in the open-to-navigation position, the vertical clearance is 71 feet above Columbia River Datum 0.0. The lower lift span of the Steel Bridge operates in accordance with 33 CFR 117.5.

Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft. Vessels able to pass through the subject bridge with the lower deck in the closed-to-navigation position, or in the open-to-navigation position may do so at any time. The lower and upper lift of the Steel Bridge will be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard requested objections to this deviation be submitted to the Local Notice to Mariners. We have not received any objections to this temporary deviation from the operating schedule. The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the subject bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 13, 2018.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2018–06534 Filed 3–30–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2017–0680; FRL–9975–65—Region 9]

Approval of California Air Plan Revisions, Yolo-Solano Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to

approve a revision to the Yolo-Solano Air Quality Management District (YSAQMD) portion of the California State Implementation Plan (SIP). This revision concerns emissions of volatile organic compounds (VOCs) from organic liquid storage and transfer operations. We are approving a local rule that regulates these emission sources under the Clean Air Act (CAA or the Act).

DATES: This rule will be effective on May 2, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2017–0680. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Rebecca Newhouse, EPA Region IX, (415) 972–3004, *newhouse.rebecca@epa.gov.*

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

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I. Proposed Action
II. Public Comments
III. EPA Action
IV. Incorporation by Reference
V. Statutory and Executive Order Reviews

I. Proposed Action

On January 9, 2018 (83 FR 1001), the EPA proposed to approve the following rule into the California SIP.

Local agency	Rule #	Rule Title	Revised	Submitted
YSAQMD	2.21	Organic Liquid Storage and Transfer	09/14/16	01/24/17

We proposed to approve this rule based on a determination that it satisfies the applicable CAA requirements. Our proposed action contains more information on the rule and our evaluation.

II. Public Comments

The EPA's proposed action provided a 30-day public comment period. During this period, we received one public comment that fails to identify any specific issue that is germane to our action on the rule. The comment letter is available in the docket for this rulemaking.

III. EPA Action

No comments were submitted that change our assessment of the rule as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving this rule into the California SIP.

IV. Incorporation by Reference

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

V. Statutory and Executive Order Reviews

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

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

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of

Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 1, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: March 2, 2018.

Alexis Strauss,

Acting Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(342)(i)(A)(*2*) and (c)(497)(i)(D) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(342) * * *

(i) * * *

(A) * * *

(*2*) Previously approved on October 31, 2006 in paragraph (c)(342)(i)(A)(*1*) of this section and now deleted with replacement in paragraph (c)(497)(i)(D)(*1*) of this section, Rule 2.21 amended on September 14, 2005.

* * * * *

(497) * * *

(i) * * *

(D) Yolo-Solano Air Quality Management District.

(*1*) Rule 2.21, ''Organic Liquid Storage and Transfer,'' revised on September 14, 2016.

* * * * *

[FR Doc. 2018–06558 Filed 3–30–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2017–0140; FRL–9975–66—Region 9]

Approval of California Air Plan Revisions, San Diego County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the San Diego County Air Pollution Control District (SDCAPCD) portion of the California State Implementation Plan (SIP). These revisions concern volatile organic compound (VOC) emissions from polyester resin operations. We are approving a local rule to regulate these emission sources, as well as a rule rescission, under the Clean Air Act (CAA or ''the Act'').

DATES: This rule will be effective on May 2, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2017–0140. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Arnold Lazarus, EPA Region IX, (415) 972–3024, *lazarus.arnold@epa.gov.*

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

Table of Contents

I. Proposed Action
II. Public Comments
III. EPA Action
IV. Incorporation by Reference
V. Statutory and Executive Order Reviews

I. Proposed Action

On December 20, 2017, the EPA proposed to approve the following rule and rule rescission into the California SIP (82 FR 60348).

Table 1 lists the rules addressed by this action with the date that they were adopted and repealed by the local air agency, and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULES

Local agency	Rule No.	Rule title	Adopted/ amended	Repealed/ rescinded	Submitted
SDCAPCD	67.12	Polyester Resin Operations	5/15/1996	5/11/2016	8/22/2016
SDCAPCD	67.12.1	Polyester Resin Operations	5/11/2016		8/22/2016

We proposed to approve this rule and rule rescission because we determined that they comply with the relevant CAA requirements. Our proposed action contains more information on the rule and rule rescission, and our evaluation.

II. Public Comments

The EPA's proposed action provided a 30-day public comment period. During this period, we received seven comments. Commenters generally raised issues that are outside the scope of this rulemaking, including bird and bat deaths associated with wind and solar facilities, the regulation of wildfire risks and emissions from wildfires, and the study of hydraulic fracturing and drinking water. One commenter supported the regulation of emissions from polyester resin operations, and one

commenter wrote that ''I do not want to repeal the regulations of air pollution.'' The EPA notes that it proposed to approve the rescission of SDCAPCD Rule 67.12, while simultaneously proposing to approve its replacement: Rule 67.12.1. The EPA's Technical Support Document, included in the docket for this action, contains the EPA's evaluation, including a SIP relaxation analysis, detailing the EPA's proposed conclusion that the rescission of Rule 67.12 and its replacement with Rule 67.12.1 met the requirements of the Act.

The EPA is required to approve a state submittal if the submittal meets all applicable requirements. 42 U.S.C. 7410(k)(3). The submitted comments either fail to identify any specific issue that is germane to our action, or they do not change our assessment of the SDCAPCD Polyester Resin Operations Rule as described in our proposed action and supporting documents.

III. EPA Action

No comments were submitted that change our assessment of the rule and rule rescission as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is fully approving this rule and rule rescission into the California SIP.

IV. Incorporation by Reference

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

V. Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 1, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: March 6, 2018.

Alexis Strauss,

Acting Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(241)(i)(A)(*7*) and (c)(488)(i)(A)(*2*) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(241) * * *

(i) * * *

(A) * * *

(*7*) Previously approved on March 27, 1997 in paragraph (c)(241)(i)(A)(*1*) of this section and now deleted with replacement by Rule 67.12.1 in

paragraph (c)(488)(i)(A)(*2*) of this section, Rule 67.12, ''Polyester Resin Operations,'' adopted on May 15, 1996.

* * * * *

(488) * * *

(i) * * *

(A) * * *

(*2*) Rule 67.12.1, ''Polyester Resin Operations,'' adopted and effective on May 11, 2016.

* * * * *

[FR Doc. 2018–06559 Filed 3–30–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2017–0737; FRL–9976–08—Region 9]

Approval of California Air Plan Revisions, Northern Sierra Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the Northern Sierra Air Quality Management District (NSAQMD) portion of the California State Implementation Plan (SIP). This revision concerns emissions of particulate matter (PM) from wood burning devices. We are approving a local measure to reduce emissions from these emission sources under the Clean Air Act (CAA or the Act).

DATES: This rule will be effective on May 2, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2017–0737. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Rynda Kay, EPA Region IX, (415) 947–4118, *kay.rynda@epa.gov.*

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

Table of Contents

I. Proposed Action
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I. Proposed Action

On December 27, 2017 (82 FR 61203), the EPA proposed to approve the following measure into the California SIP.

Local agency	Resolution No.	Measure title	Adopted	Submitted
NSAQMD	2017–01	Northern Sierra Air Quality Management District Resolution #2017–01 ..	01/23/17	02/28/17

We proposed to approve this rule based on a determination that it satisfies the applicable CAA requirements. Our proposed action contains more information on the measure and our evaluation.

II. Public Comments

The EPA's proposed action provided a 30-day public comment period. During this period, we received three public comments that fail to identify any specific issue that is germane to our action on the rule. Two of these comments identify issues that are outside of the scope of this rulemaking, including forest management, wildfire suppression, and greenhouse-gas and other emissions from wildfires. The third comment fails to identify any specific issue. The comment letters are available in the docket for this rulemaking.

III. EPA Action

No comments were submitted that change our assessment of the rule as described in our proposed action. Therefore, the EPA is fully approving this rule into the California SIP in accordance with section 110(k)(3) of the Act.

IV. Incorporation by Reference

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

V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 1, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: March 9, 2018.

Alexis Strauss,

Acting Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(500) to read as follows:

§ 52.220 Identification of plan-in part.

* * * * *

(c) * * *

(500) The following plan was submitted on February 28, 2017 by the Governor's designee.

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

(*1*) Northern Sierra Air Quality Management District Resolution #2017–01, adopted January 23, 2017.

[FR Doc. 2018–06538 Filed 3–30–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2017–0389; FRL–9976–20—Region 4]

Air Plan Approval; KY: Removal of Reliance on Reformulated Gasoline in the Kentucky Portion of the Cincinnati-Hamilton Area

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted on September 13, 2017, by the Commonwealth of Kentucky, through the Kentucky Division for Air Quality (KDAQ) in support of the Commonwealth's separate petition requesting that EPA remove the federal reformulated gasoline (RFG) requirements for Boone, Campbell, and Kenton counties in the Kentucky portion of the Cincinnati-Hamilton, Ohio-Kentucky-Indiana 2008 8-hr ozone maintenance area (hereinafter referred to as the ''Northern Kentucky Area'' or ''Area''). The SIP revision revises the Commonwealth's maintenance plan emissions inventory and associated motor vehicle emissions budgets (MVEBs), for years 2020 and 2030, to remove reliance on emissions reductions from the federal RFG program requirements, a program that the Commonwealth voluntarily opted into in 1995. The SIP revision also includes a non-interference demonstration evaluating whether removing reliance on the RFG requirements in the Northern Kentucky Area would interfere with the requirements of the Clean Air Act (CAA or Act). EPA is approving this SIP revision and the corresponding non-interference demonstration because EPA determined that the revision is consistent with the applicable provisions of the CAA. Please note that this final rule does not remove the federal RFG requirement. On April 18, 2017, Kentucky's Energy and Environment Cabinet submitted a separate petition to the EPA Administrator requesting to opt-out of the federal RFG program in the Northern Kentucky Area, and the Administrator will act on that petition in the near future.

DATES: This rule will be effective April 2, 2018.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. No. EPA–R04–OAR–2017–0389 at *http://www.regulations.gov.* All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday

through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Dianna Myers, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street, SW, Atlanta, Georgia 30303–8960. Ms. Myers can be reached via telephone at (404) 562–9207 or via electronic mail at *Myers.Dianna@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What is the Background for this final action?

The Northern Kentucky Area was included in the Cincinnati-Hamilton Area, which was originally designated as a moderate nonattainment area for the 1-hour ozone standard on November 6, 1991 (56 FR 56694). In 1995, Kentucky voluntarily opted into the RFG program under Phase I of a two-phase nationwide program to reduce the volatility of commercial gasoline during the summer ozone season. Kentucky elected to stay in the program under Phase II which was more stringent than Phase I.

On July 18, 1997, EPA promulgated a revised 8-hour ozone standard of 0.08 parts per million (ppm). This standard was more stringent than the 1-hour ozone standard. On June 19, 2000 (65 FR 37879), the Cincinnati-Hamilton 1-hour nonattainment Area was redesignated as attainment for the 1-hour ozone NAAQS, and was considered to be a maintenance area subject to a CAA section 175A maintenance plan for the 1-hour ozone NAAQS. On April 30, 2004, EPA designated the Cincinnati-Hamilton OH-KY-IN Area under subpart 1 as a ''basic'' 1997 8-hour ozone NAAQS nonattainment area (69 FR 23857).[1] On August 5, 2010 (75 FR 47218), the Kentucky portion of the Cincinnati-Hamilton 1997 8-hour ozone area was redesignated to attainment.

On March 12, 2008, EPA revised both the primary and secondary NAAQS for ozone to a level of 0.075 ppm to provide increased protection of public health and the environment. *See* 73 FR 16436 (March 27, 2008). The 2008 ozone NAAQS retains the same general form and averaging time as the 0.08 ppm NAAQS set in 1997, but is set at a more protective level. Under EPA's regulations at 40 CFR part 50, the 2008 8-hour ozone NAAQS is attained when the 3-year average of the annual fourth highest daily maximum 8-hour average ambient air quality ozone concentrations is less than or equal to 0.075 ppm. *See* 40 CFR 50.15.

Effective July 20, 2012, EPA designated any area that was violating the 2008 8-hour ozone NAAQS based on the three most recent years (2008–2010) of air monitoring data as a nonattainment area. *See* 77 FR 30088 (May 21, 2012). The Cincinnati-Hamilton, OH-KY-IN Area was designated as a marginal ozone nonattainment area. *See* 40 CFR 81.318. Areas that were designated as marginal nonattainment areas were required to attain the 2008 8-hour ozone NAAQS as expeditiously as possible but no later than July 20, 2015, based on 2012–2014 monitoring data. On May 4, 2016 (81 FR 26697), EPA published its determination that the Cincinnati-Hamilton, OH-KY-IN Area had attained the 2008 8-hour ozone NAAQS by the attainment deadline.

On August 26, 2016, Kentucky submitted a 2008 8-hour ozone redesignation request and maintenance plan for the Cincinnati-Hamilton Area, which EPA approved on July 5, 2017 (82 FR 30976).[2] With its redesignation request, Kentucky included a maintenance demonstration plan that estimated emissions through 2030 that modeled RFG because Kentucky previously opted into the RFG program.

In a September 13, 2017, SIP revision submittal, KDAQ updated the mobile (on-road and non-road) emissions inventory for the August 26, 2016, maintenance plan (including the MVEBs) to reflect Kentucky's petition (see below) to opt-out of the RFG requirements for Boone, Campbell, and Kenton counties in the Northern Kentucky Area. The updates were summarized in KDAQ's submittal. On April 18, 2017, Kentucky's Energy and Environment Cabinet submitted a petition to the EPA Administrator requesting to opt-out of the federal RFG program in the Northern Kentucky Area, and as stated above, the September 13, 2017, SIP revision was submitted in support of that petition (particularly the requirements of 40 CFR 80.72(b)(3) and (4)). Kentucky's opt-out petition will be acted on by the Administrator in a separate action, and if approved in that separate action, will establish the effective date of the opt-out. EPA's RFG regulations require that the opt-out cannot become effective less than 90 days from the effective date of this final action. EPA will also publish a notice in the **Federal Register** to notify the public of the approval and effective date of the opt-out (*See* 40 CFR 80.72(c)(7) and (d).)

In a notice of proposed rulemaking (NPRM) published on February 14, 2018 (83 FR 6496), EPA proposed to approve the September 13, 2017, SIP revision. The Agency did not receive any adverse comments on the NPRM.

II. Revised MVEBs

EPA is approving the changes in the September 13, 2017, SIP revision which includes updating the 2008 maintenance plan 2020 and 2030 MVEBs. The same criteria used to develop the MVEBs in the August 26, 2016, maintenance SIP are used for this SIP revision. The revised MVEBs for nitrogen oxides (NO_X) and volatile organic compounds (VOC) are outlined in Table 1below.

TABLE 1—MVEBS FOR THE KENTUCKY PORTION OF CINCINNATI-HAMILTON, OH-KY-IN AREA

[Tons per summer day]

	2020		2030	
	NO_X	VOC	NO_X	VOC
On-Road Emissions	8.42	4.17	3.56	2.31
Safety Margin [3]	0.61	0.19	1.63	.55

[1] The 1997 8-hour ozone area included in its entirety Boone, Campbell, and Kenton Counties in Kentucky and Butler, Clermont, Clinton, Hamilton and Warren Counties in Ohio; and a portion of Dearborn County in Indiana.

[2] The Cincinnati-Hamilton, OH-KY-IN Area is composed of portions of Boone, Campbell, and Kenton Counties in Kentucky; Butler, Clermont, Clinton, Hamilton and Warren Counties in Ohio; and a portion of Dearborn County in Indiana. This action only pertains to the Kentucky portion of the maintenance area.

[3] The safety margin is the difference between the attainment level of emissions (from all sources) and the projected level of emissions (from all sources) in the maintenance plan. KDAQ chose to allocate a total of 2.24 tpd to the available NO_X safety margin and a total 0.74 tons per day of the available VOC safety margin. The transportation conformity rule provides for establishing safety margins for use in transportation conformity determinations. (*See* 40 CFR 93.124(a).)

TABLE 1—MVEBS FOR THE KENTUCKY PORTION OF CINCINNATI-HAMILTON, OH-KY-IN AREA—Continued

[Tons per summer day]

	2020		2030	
	NO_X	VOC	NO_X	VOC
MVEBs with Safety Margin	9.03	4.36	5.19	2.86

III. Final Action

EPA is approving Kentucky's September 13, 2017, SIP revision seeking to revise the maintenance plan emissions inventory and associated MVEBs for years 2020 and 2030 to remove reliance on emissions reductions from the federal RFG program requirements; a program that the Commonwealth voluntarily opted into in 1995. The SIP revision also includes a non-interference demonstration evaluating whether removing reliance on the RFG requirements in the Northern Kentucky Area would interfere with the requirements of the CAA. Within 24 months from this final rule, the transportation partners will need to demonstrate conformity to the new NO_X and VOC MVEBs pursuant to 40 CFR 93.104(e)(3). For analysis years 2020 through 2029, the new 2020 MVEBs will be used, and for analysis years 2030 and beyond, the new 2030 MVEBs will be used.

In accordance with 5 U.S.C. 553(d), EPA finds that there is good cause for this action to become effective immediately upon publication. This is because a delayed effective date is unnecessary because this action approves a SIP revision and noninterference demonstration that serves as the basis of a subsequent action to relieve the Area from certain CAA requirements that would otherwise apply to it. The immediate effective date for this action is authorized under both 5 U.S.C. 553(d)(1), which provides that rulemaking actions may become effective less than 30 days after publication if the rule grants or recognizes an exemption or relieves a restriction, and section 553(d)(3), which allows an effective date less than 30 days after publication as otherwise provided by the agency for good cause found and published with the rule. The purpose of the 30-day waiting period prescribed in section 553(d) is to give affected parties a reasonable time to adjust their behavior and prepare before the final rule takes effect. This rule however, does not create any new regulatory requirements such that affected parties would need time to prepare before the rule takes effect. Rather, this rule will serve as a basis for a subsequent action to relieve the Area from certain CAA requirements. For these reasons, EPA finds good cause under 5 U.S.C. 553(d)(3) for this action to become effective on the date of publication of this action.

IV. Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 1, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to

enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

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

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

Dated: March 21, 2018.

Onis ''Trey'' Glenn, III,

Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart S—Kentucky

■ 2. Section 52.920(e) is amended by adding an entry for ''Removal of Reliance on Reformulated Gasoline in the Kentucky portion of the Cincinnati-Hamilton, OH–KY–IN Area'' at the end of the table to read as follows:

§ 52.920 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED KENTUCKY NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/ effective date	EPA approval date	Explanations
*	*	*	*	*
Removal of Reliance on Reformulated Gasoline in the Kentucky portion of the Cincinnati-Hamilton, OH–KY–IN Area.	Boone, Campbell and Kenton Counties (Kentucky portion of the Cincinnati-Hamilton Area).	09/13/17	4/2/2018 [Insert citation of publication].	

[FR Doc. 2018–06557 Filed 3–30–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2017–0500; FRL–9976–17—Region 4]

Air Plan Approval; Florida; Stationary Sources Emissions Monitoring

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a portion of a State Implementation Plan (SIP) revision submitted by the State of Florida, through the Florida Department of Environmental Protection (FDEP) on February 1, 2017, for the purpose of revising Florida's requirements and procedures for emissions monitoring at stationary sources. Specifically, Florida's February 1, 2017, SIP submittal includes amendments to three Florida Administrative Code (F.A.C.) rule sections, as well as the removal of one F.A.C. rule section from the Florida SIP, in order to eliminate redundant language and make updates to the requirements for emissions monitoring at stationary sources. Additionally, this action includes a correction to remove an additional F.A.C. rule that was previously approved by EPA for removal from the SIP but was never removed. This action is being taken pursuant to the Clean Air Act (CAA or Act).

DATES: This rule is effective May 2, 2018.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2017–0500. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Andres Febres, Air Regulatory Management Section, Air Planning and Implementation Branch, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8966. Mr. Febres can also be reached via electronic mail at *febres-martinez.andres@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What actions is EPA taking today?

On February 1, 2017, FDEP submitted to EPA for approval a SIP revision for the purpose of updating Florida's requirements and procedures for emissions monitoring at stationary sources. Florida's February 1, 2017, SIP revision includes amendments to three F.A.C. rule sections and the removal of one F.A.C. rule section from the Florida SIP. Specifically, these changes to Florida's rules include the amendments of Rule 62–297.310, F.A.C.—''General Emissions Test Requirement;'' Rule 62–297.440, F.A.C.—''Supplementary Test Procedures;'' and Rule 62–297.450, F.A.C.—''EPA VOC Capture Efficiency Test Procedures.'' In addition, Florida's February 1, 2017, SIP submittal includes the removal of one of Florida's rule sections from the SIP. Specifically, Florida requested to remove Rule 62–297.401, F.A.C.—''Compliance Test Methods'' from the State's implementation plan because it has been repealed at the state level, and, according to the submittal, the section is unnecessary, obsolete or duplicative of other F.A.C. Rules.

Through this rulemaking, EPA is finalizing approval of the portions of Florida's February 1, 2017, SIP revision regarding amendments to Rule 62–297.440, F.A.C., and Rule 62–297.450, F.A.C., as well as the removal of Rules 62–297.401, F.A.C., from the State's implementation plan. The portion of the SIP regarding Rule 62–297.310 was previously approved in a separate rulemaking, which approved several SIP amendments making administrative and recodification changes to Florida's SIP. *See* 82 FR 46682 (October 6, 2017).

In addition to the removal of Rule 62–297.401, F.A.C., EPA is removing Rule 62–297.400, F.A.C.—''EPA Methods Adopted by Reference'' from the Florida SIP. The removal of this rule section was previously approved by EPA, but was never reflected in Florida's SIP-approved rules table in 40 CFR 52.520(c). For more detail on the approval to remove Rule 62–297.400, F.A.C., see the June 16, 1999, rulemaking (64 FR 32346).

II. Background

On October 13, 2017, EPA published a proposed rulemaking (82 FR 47662), which accompanied a direct final rulemaking (82 FR 47636) published on the same date. The proposed rule proposed to approve the portion of Florida's February 1, 2017 SIP revision described above. It also stated that if EPA received adverse comment on the direct final rule, the direct final rule would be withdrawn and all public comments received would be addressed in a subsequent final rule based on the proposed rule. EPA received 11 comments on the direct final rule, 10 of which were not relevant to the action. However, one of those comments was adverse. As a result, the direct final rule was subsequently withdrawn. After considering the adverse comment, EPA is now taking final action, based on the proposed rule, on the portion of Florida's February 1, 2017 SIP revision described above.

III. Analysis of Florida's Submittal

As stated in the proposed rule (82 FR 47662), a detailed rationale for EPA's approval of the above-described portions of Florida's February 1, 2017 SIP revision is set forth in the preamble to the direct final rule (82 FR 47636). In summary, EPA is approving amendments to Rule 62–297.440, F.A.C. that remove several subsections which contain test methods that are either adopted by reference in other rule sections or are now obsolete. EPA is approving amendments to Rule 62–297.450, F.A.C. because the changes clarify and simplify the language in the rule, and are consistent with EPA's VOC capture efficiency test procedure guidelines, as established in the agency's GD–035 guideline. EPA is approving the removal of Rule 62–297.401, F.A.C. from Florida's SIP because the requirements are still in place in other state rules and is unnecessary. Finally, EPA is removing Rule 62–297.400, F.A.C. from Florida's SIP because removal was previously approved by EPA, but was never reflected in Florida's SIP-approved rules table in 40 CFR 52.520(c).

IV. Response to Comments

Comment: As mentioned above, EPA received one adverse public comment on the direct final rule published on October 13, 2017. The comment is available for public viewing as a part of the electronic docket for this rulemaking.[1] In summary, the Commenter requested EPA to take additional public comments on these SIP revisions because the information in the docket was not fully accessible to the public during the initial comment period for this action. A second portion of the comment was not relevant to the action being taken by EPA.

Response: EPA subsequently made the state submittals and related materials fully accessible to the public in the electronic docket, and on December 14, 2017 (82 FR 58790), reopened the comment period for the proposed rule that accompanied the now withdrawn direct final rule. In the rulemaking reopening the comment period, EPA explained that it would accept public comments until January 16, 2018, and that it would address any comments received in a separate final action based on the proposed action published on October 13, 2017 (82 FR 47662). During the reopened comment period from December 14, 2017, until January 16, 2018, EPA received an additional 12 comments, but those comments were not relevant. The 12 additional comments are included in the electronic docket for this action.

V. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Rule 62–297.440, F.A.C., entitled ''Supplementary Test Procedures'' and Rule 62–297.450, F.A.C., entitled ''EPA VOC Capture Efficiency Test Procedures,'' both state effective on July 19, 2014. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and/or at the EPA Region 4 Office (please contact the person identified in the ''For Further Information Contact'' section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally-enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.[2]

VI. Final Action

EPA is finalizing approval of the above mentioned changes to the Florida SIP, as submitted to us in Florida's February 1, 2017, SIP revision. Specifically, EPA is approving the amendments to Rule 62–297.440, F.A.C., and Rule 62–297.450, F.A.C., both state effective on July 19, 2014, as well as the removal of Rule 62–297.401, F.A.C., from Florida's SIP. In addition, EPA is removing Rule 62–297.400, F.A.C., from Florida's SIP as approved in a previous rulemaking.[3] This action is limited to the two rule revisions and two rule removals mentioned above and does not act on the portion of the February 1, 2017, SIP submittal regarding Rule 62–297.310. As mentioned in Section I above, the changes to Rule 62–297.310, were previously approved in a separate rulemaking. *See* 82 FR 46682 (October 6, 2017).

VII. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735,

[1] *See* Docket Identification No. EPA–R04–OAR–2017–0500 at *www.regulations.gov.*

[2] 62 FR 27968 (May 22, 1997).

[3] *See* Section III of this rulemaking for details on Rule 62–297.400.

October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);

• Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.

• Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

• Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under Section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 1, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* Section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: March 15, 2018.

Onis ''Trey'' Glenn, III,

Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart K—Florida

■ 2. In § 52.520 paragraph (c) is amended under ''Chapter 62–297 Stationary Sources—Emissions Monitoring'' by:

■ a. Removing the entries for ''62–297.400'' and ''62–297.401;'' and

■ b. Revising the entries for ''62–297.440'' and ''62–297.450'' to read as follows:

§ 52.520 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED FLORIDA REGULATIONS

State citation (section)	Title/subject	State effective date	EPA approval date	Explanation
* *	*	*	*	* *
Chapter 62–297 Stationary Sources—Emissions Monitoring				
* *	*	*	*	* *
62–297.440	Supplementary Test Procedures.	7/10/2014	4/2/2018 [Insert citation of publication].	
62–297.450	EPA VOC Capture Efficiency Test Procedures.	7/10/2014	4/2/2018, [Insert citation of publication].	
* *	*	*	*	* *

* * * * *

[FR Doc. 2018–06542 Filed 3–30–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R03–OAR–2017–0570; FRL–9976–31—Region 3]

Approval and Promulgation of Air Quality Implementation Plans; State of Maryland; Control of Emissions From Existing Commercial and Industrial Solid Waste Incinerator Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a negative declaration for existing commercial and industrial solid waste incineration (CISWI) units within the State of Maryland. This negative declaration certifies that CISWI units subject to the requirements of sections 111(d) and 129 of the Clean Air Act (CAA) do not exist within the jurisdictional boundaries of the State of Maryland. EPA is accepting the negative declaration in accordance with the requirements of the CAA.

DATES: This rule is effective on May 2, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R03–OAR–2017–0570. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Mike Gordon, (215) 814–2039, or by email at *gordon.mike@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 111(d) and 129 of the CAA require states to submit plans to control certain pollutants (designated pollutants) at existing solid waste combustor facilities (designated facilities) whenever standards of performance have been established under section 111(b) for new sources of the same type, and EPA has established emission guidelines (EG) for such existing sources. CAA section 129 directs EPA to establish standards of performance for new sources and emissions guidelines for existing sources for each category of solid waste incineration unit. CAA section 129(a) and (b). According to section 129(a)(4) of the CAA, EPA also must specify numerical emissions limitations for particulate matter (total and fine), opacity (as appropriate), sulfur dioxide, hydrogen chloride, oxides of nitrogen, carbon monoxide, lead, cadmium, mercury, and dioxins and dibenzofurans.

If a state fails to submit a satisfactory plan, the CAA provides EPA the authority to prescribe a plan for regulating the designated pollutants at the designated facilities. EPA prescribed plan, also known as a federal plan, is often delegated to states with designated facilities but no EPA approved state-specific plan. If no such designated facilities exist within a state's jurisdiction, a state may submit to the EPA a letter of certification to that effect (referred to as a negative declaration) in lieu of a state plan to satisfy the state's obligation. 40 CFR 60.23(b) and 62.06. A negative declaration exempts the state from the requirement to submit a CAA section 111(d)/section 129 plan for that designated pollutant and source category. 40 CFR 60.23(b).

II. State Submittal and EPA Analysis

The Maryland Department of the Environment (MDE) has determined that there are no existing CISWI units subject to the requirements of sections 111(d) and 129 of the CAA in its respective air pollution control jurisdiction. Accordingly, MDE submitted a negative declaration letter to EPA certifying this fact on January 20, 2017. A notice of proposed rulemaking was published in the **Federal Register** on February 1, 2018 (83 FR 4621). EPA received three comments during the public comment that were not specific nor related to this action and thus are not addressed here. The negative declaration letter and EPA's notice of proposed rulemaking are available in the docket for this rulemaking and online at *www.regulations.gov.*

III. Final Action

In this final action, EPA is approving the negative declaration for CISWI units submitted by MDE on January 20, 2017 and amending part 62 to reflect receipt of the negative declaration and subsequent approval by EPA. EPA is accepting the negative declaration in accordance with the requirements of the CAA and 40 CFR 60.23(b) and 62.06.

IV. Statutory and Executive Order Reviews

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely notifies the public of EPA receipt of a negative declaration from an air pollution control agency without any existing CISWI units in their jurisdiction. This action imposes no requirements. Accordingly, EPA certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This action also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves the negative declaration for existing CISWI units from the MDE and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This action also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

With regard to negative declarations for designated facilities received by EPA from states, EPA's role is to notify the public of the receipt of such negative declarations and revise 40 CFR part 62 accordingly. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to approve or disapprove a CAA section 111(d)/129 plan negative declaration submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a CAA section 111(d)/129 negative declaration, to use VCS in place of a section 111(d)/129 negative declaration that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 1, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action approving the negative declaration for existing CISWI units within the State of Maryland may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Waste treatment and disposal.

Dated: March 22, 2018.

Cecil Rodrigues,

Acting Regional Administrator, Region III.

40 CFR part 62 is amended as follows:

PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 1. The authority citation for part 62 continues to read as follows:

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

Subpart V—Maryland

■ 2. Revise § 62.5127 to read as follows:

§ 62.5127 Identification of plan—negative declaration.

(a) May 12, 2005 Maryland Department of the Environment letter certifying that existing CISWI units, subject to 40 CFR part 60, subpart DDDD, have been permanently shut down and have been dismantled in the state.

(b) Letter from the State of Maryland, Department of the Environment, submitted January 20, 2017, certifying that there are no existing commercial/industrial solid waste incineration units within the State of Maryland that are subject to 40 CFR part 60, subpart DDDD.

[FR Doc. 2018–06653 Filed 3–30–18; 8:45 am]

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Proposed Rules

Federal Register
Vol. 83, No. 63
Monday, April 2, 2018

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 325

RIN 3064–AE73

Annual Stress Test—Applicability Transition for Covered Banks With $50 Billion or More in Assets; Technical and Conforming Changes

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Proposed rule.

SUMMARY: The Federal Deposit Insurance Corporation (FDIC) proposes to make several revisions to its stress testing regulation. Consistent with changes already made by the Board of Governors of the Federal Reserve System (Board) and the Office of the Comptroller of the Currency (OCC) to their respective stress testing regulations, the proposed rule would change the transition process for covered banks that become over $50 billion covered banks. Under the proposed rule, a covered bank that becomes an over $50 billion covered bank on or before September 30 would become subject to the requirements applicable to an over $50 billion covered bank beginning on January 1 of the second calendar year after the covered bank becomes an over $50 billion covered bank. A covered bank that becomes an over $50 billion covered bank after September 30 would become subject to the requirements applicable to an over $50 billion covered bank beginning on January 1 of the third calendar year after the covered bank becomes an over $50 billion covered bank. The proposed rule would also change the range of possible ''as-of'' dates used in the trading and counterparty position data stress testing component. Lastly, the proposed rule would make certain technical changes to clarify the requirements of the FDIC's stress testing regulation, and to eliminate obsolete provisions.

DATES: Comments must be received on or before June 1, 2018.

ADDRESSES: Interested parties are encouraged to submit written comments. Commenters are encouraged to use the title ''Annual Stress Test—Applicability Transition for Covered Banks with $50 Billion or More in Assets; Technical and Conforming Changes'' to facilitate the organization and distribution of comments among the Agencies. You may submit comments, identified by RIN number, by any of the following methods:

- *Agency website: https://www.fdic.gov/regulations/laws/publiccomments/.* Follow instructions for submitting comments on the Agency website.
- *Email: Comments@fdic.gov.* Include the RIN number 3064–AE73 on the subject line of the message.
- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.
- *Public Inspection:* All comments received must include the agency name and RIN 3064–AE73 for this rulemaking. All comments received will be posted without change to *https://www.fdic.gov/regulations/laws/publiccomments/,* including any personal information provided. Paper copies of public comments may be ordered from the FDIC Public Information Center, 3501 North Fairfax Drive, Room E–I002, Arlington, VA 22226 by telephone at 1 (877) 275–3342 or 1 (703) 562–2200.

FOR FURTHER INFORMATION CONTACT: Ryan Sheller, Section Chief, (202) 412–4861, Large Bank Supervision, Division of Risk Management Supervision; Annmarie Boyd, Counsel, (202) 898–3714, or Benjamin Klein, Counsel, (202) 898–7027, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC, 20429.

SUPPLEMENTARY INFORMATION:

I. Background

Section 165(i) of the Dodd-Frank Wall Street Reform and Consumer Protection Act [1] (''Dodd-Frank Act'') requires two types of stress tests. Section 165(i)(1) requires the Board to conduct annual stress tests of holding companies with $50 billion or more in assets (''supervisory stress tests''). Section 165(i)(2) requires the federal banking agencies to issue regulations requiring financial companies with more than $10 billion in assets to conduct annual stress tests themselves (''company-run stress tests''). In October 2012, the FDIC, Board, and OCC issued final rules implementing the company-run stress tests.[2] Accordingly, the FDIC regulation at 12 CFR part 325, subpart C, implements the stress test requirements of section 165(i)(2) of the Dodd-Frank Act with respect to covered banks.

The Dodd-Frank Act also requires that the FDIC and other federal financial regulatory agencies issue consistent and comparable regulations to implement the statutory stress testing requirement.[3] In order to fulfill this requirement and minimize regulatory burden, the FDIC is proposing certain changes to 12 CFR part 325, subpart C, as described below, in order to ensure that its stress testing regulation remains consistent and comparable to the regulations enacted by other regulatory agencies, including the Board and the OCC.

II. Description of the Proposed Rule

A. New Terminology and Applicability Transition for Covered Banks With $50 Billion or More in Assets

Although 12 CFR part 325, subpart C applies to all covered banks that exceed $10 billion in average total consolidated assets, the regulation differentiates between ''$10 billion to $50 billion covered banks'' and ''over $50 billion covered banks.'' The proposed rule would change the defined term ''over $50 billion covered bank'' to ''$50 billion or over covered bank.'' This change would not alter the scope of this defined term and would not change the substantive requirements of the regulation. The new defined term would be a more precise description of the entities included within this category, which includes all state nonmember banks and state savings associations ''with average total consolidated assets . . . that are not less than $50 billion.'' [4] While the proposed rule would change

[1] 12 U.S.C. 5365(i).

[2] 77 FR 62417 (Oct. 15, 2012) (FDIC); 77 FR 62380 (Oct. 12, 2012 (Board)); 77 FR 61238 (Oct. 9, 2012) (OCC).

[3] 12 U.S.C. 5365(i)(2)(C).

[4] 12 CFR 325.202(d)(2).

the defined term ''over $50 billion covered bank'' to ''$50 billion or over covered bank,'' this supplementary information section will continue to use the term ''over $50 billion covered bank'' since that is the term used in the current regulatory text.

The proposed rule would also change the transition process for a covered bank that becomes an ''over $50 billion covered bank.'' On February 3, 2017, the Board published a final rule that provided additional time for bank holding companies that cross the $50 billion asset threshold to comply with the stress testing requirements applicable to bank holding companies of such size.[5] On February 23, 2018, the OCC published a final rule making the same change to its stress testing regulation.[6] The proposed rule would make a parallel amendment to the FDIC's stress testing regulation.

Under the existing regulation, a $10 billion to $50 billion covered bank that migrates to an over $50 billion covered bank becomes subject to the requirements applicable to over $50 billion covered banks immediately after satisfying the threshold.[7] Under the proposed rule, a state nonmember bank or state savings association that becomes an over $50 billion covered bank in the first three quarters of a calendar year would not be subject to the stress testing requirements applicable to over $50 billion covered banks until the second calendar year after it crosses the threshold. A state nonmember bank or state savings association that becomes an over $50 billion covered bank in the fourth quarter of a calendar year would not be subject to the stress testing requirements applicable to over $50 billion covered banks until the third year after it crosses the asset threshold. For example, if a state nonmember bank or state savings association becomes an over $50 billion covered bank on September 15, 2018, it would need to comply with the requirements applicable to over $50 billion covered banks beginning in 2020 and file the FDIC DFAST–14A in April 2020. However, if a state nonmember bank or a state savings association becomes an over $50 billion covered bank on October 15, 2018, it would be required to comply with the stress testing requirements applicable to over $50 billion covered banks beginning in 2021 and file the FDIC DFAST–14A in April 2021. The additional time provided to a state nonmember bank or state savings association that becomes an over $50 billion covered bank prior to the enactment of the stress testing requirements is unlikely to change the potential compliance burden for those institutions.

The stress testing timeline and transition process for state nonmember banks and state savings associations that become $10 to $50 billion covered banks would remain unchanged.

B. New Range of Possible As-Of Dates for Trading Scenario Component

Under 12 CFR part 325, subpart C, the FDIC may require a covered bank with significant trading activities to include trading and counterparty components in its adverse and severely adverse scenarios. The trading data to be used in this component is as of a date between January 1 and March 1 of a calendar year.[8] On February 3, 2017 the Board published a final rule that extended this range to run from October 1 of the calendar year preceding the year of the stress test to March 1 of the calendar year of the stress test.[9] On February 23, 2018, the OCC published a final rule making the same change to its stress testing regulation.[10] The proposed rule would make the same change to the FDIC's stress testing regulation. Extending this range would increase the FDIC's flexibility to choose an appropriate as-of date. The FDIC continues to coordinate its stress testing program with the Board and OCC in order to minimize regulatory burden. Presently, no FDIC-supervised institutions are required to comply with this stress testing requirement so the proposed rule is unlikely to have an immediate effect on FDIC-supervised institutions.

C. Removal of Obsolete Transition Language

In 2014 the FDIC, in coordination with the Board and OCC, shifted the dates of the annual stress testing cycle by approximately three months, from October 1 to January 1.[11] The FDIC's stress testing regulation continues to include transition language to facilitate this prior schedule shift. Because the transition to the new schedule is now complete, the proposed rule would remove this obsolete transition language.

III. Request for Comment

The FDIC requests comment on all aspects of the proposal.

IV. Regulatory Analysis and Procedure

Paperwork Reduction Act

Under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3520), the FDIC may not conduct or sponsor, and a person is not required to respond to, an information collection unless the information collection displays a valid Office of Management and Budget (OMB) control number. This notice of proposed rulemaking amends 12 CFR part 325, which has an approved information collection under the PRA (OMB Control No. 3064–0189). The FDIC has determined that the proposed rule does not create any new or revise any existing collection of information under section 3504(h) of title 44. Accordingly, no Paperwork Reduction Act submission will be made to OMB.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* generally requires an agency, in connection with a proposed rule, to prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities.[12] However, a regulatory flexibility analysis is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The Small Business Administration has defined ''small entities'' to include banking organizations with total assets of less than or equal to $550 million.[13] For the reasons described below and pursuant to section 605(b) of the RFA, the FDIC certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

The FDIC supervises 3,637 depository institutions,[14] of which, 2,924 are defined as small banking entities by the terms of the RFA.[15] As discussed in the **SUPPLEMENTARY INFORMATION** above, the proposed changes will only affect institutions with more than $10 billion in total assets. Therefore, the rule will not affect any small entities. As such, no small state nonmember banks and state

[5] 82 FR 9308 (Feb. 3, 2017). These expanded transitional arrangements are codified in the Board's regulations at 12 CFR 252.53(b).

[6] 83 FR 7951 (Feb. 23, 2018).

[7] 12 CFR 325.203(c)(2). A covered bank becomes an over $50 billion covered bank when its average total consolidated assets, as reported on the covered bank's Call Reports, for the four most recent consecutive quarters, equals $50 billion or more.

[8] 12 CFR 325.204(c).

[9] 82 FR 9308 (Feb 3, 2017).

[10] 83 FR 7951 (Feb. 23, 2018).

[11] 79 FR 69365 (Nov. 21, 2014).

[12] 5 U.S.C. 601 *et seq.*

[13] 13 CFR 121.201 (as amended, effective December 2, 2014).

[14] FDIC-supervised institutions are set forth in 12 U.S.C. 1813(q)(2).

[15] FDIC Call Report, December 31, 2017.

savings associations would be affected by the proposal.

The FDIC invites any comments that will further inform the FDIC's consideration of RFA.

Plain Language

Section 722 of the Gramm-Leach-Bliley Act requires the Agencies to use plain language in all proposed and final rules published after January 1, 2000. The Agencies invite comment on how to make this proposed rule easier to understand.

For example:

- Has the FDIC organized the material to suit your needs? If not, how could it present the rule more clearly?
- Have we clearly stated the requirements of the rule? If not, how could the rule be more clearly stated?
- Does the rule contain technical jargon that is not clear? If so, which language requires clarification?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand? If so, what changes would make the regulation easier to understand?
- What else could we do to make the regulation easier to understand?

List of Subjects in 12 CFR Part 325

Administrative practice and procedure, Banks, Banking, Reporting and recordkeeping requirements, State savings associations, Stress tests.

Authority and Issuance

For the reasons set forth in the preamble, the FDIC proposes to amend 12 CFR part 325 as follows:

PART 325—CAPITAL MAINTENANCE

■ 1. The authority citation for part 325 continues to read as follows:

Authority: 12 U.S.C. 5365(i)(2); 12 U.S.C. 5412(b)(2)(C); 12 U.S.C. 1818, 12 U.S.C. 1819(a) (Tenth), 12 U.S.C. 1831o, and 12 U.S.C. 1831p–1.

Subpart C—Annual Stress Test

■ 2. In subpart C, remove the phrase ''over $50 billion covered bank'' from wherever it appears in the subpart, and add in its place the phrase ''$50 billion or over covered bank''.

■ 3. Amend § 325.201(a) by revising paragraph (a) to read as follows:

§ 325.201 Authority, purpose, and reservation of authority.

(a) *Authority.* This subpart is issued by the Federal Deposit Insurance Corporation (the ''Corporation'' or ''FDIC'') under 12 U.S.C. 5365(i)(2); 12 U.S.C. 5412(b)(2)(C); 12 U.S.C. 1818, 12 U.S.C. 1819(a)(Tenth), 12 U.S.C. 1831o, and 12 U.S.C. 1831p–1.

* * * * *

■ 4. Amend § 325.202 by revising paragraphs (d)(2) and (m) to read as follows:

§ 325.202 Definitions.

* * * * *

(d) * * *

(2) *$50 billion or over covered bank.* Any state nonmember bank or state savings association with average total consolidated assets calculated as required under this subpart that are not less than $50 billion.

* * * * *

(m) *Stress test cycle* means the period beginning January 1 of a calendar year and ending on December 31 of that year.

■ 5. Revise § 325.203 to read as follows:

§ 325.203 Applicability.

(a) *Covered banks that become subject to stress testing requirements.* A state nonmember bank or state savings association that becomes a $10 billion to $50 billion covered bank on or before March 31 of a given year shall conduct its first annual stress test under this subpart in the next calendar year after the date the state nonmember bank or state savings association becomes a $10 billion to $50 billion covered bank, unless that time is extended by the Corporation in writing. A state nonmember bank or state savings association that becomes a $10 billion to $50 billion covered bank after March 31 of a given year shall conduct its first annual stress test under this part in the second calendar year after the calendar year in which the state nonmember bank or state savings association becomes a $10 billion to $50 billion covered bank, unless that time is extended by the Corporation in writing.

(b) *Ceasing to be a covered bank or changing categories.* (1) A covered bank shall remain subject to the stress test requirements based on its applicable category, as defined in § 325.202, unless and until total consolidated assets of the covered bank fall below the relevant size threshold for each of four consecutive quarters as reported by the covered bank's most recent Call Reports. The calculation shall be effective on the ''as of'' date of the fourth consecutive Call Report.

(2) Notwithstanding paragraph (b)(1) of this section, a state nonmember bank or state savings association that becomes a $50 billion or over covered bank, whether by migrating from being a $10 billion to $50 billion covered bank or by directly becoming a $50 billion or over covered bank, after September 30 of a calendar year must comply with the requirements applicable to a $50 billion or over covered bank beginning on January 1 of the third calendar year after the state nonmember bank or state savings association becomes a $50 billion or over covered bank, unless that time is extended by the Corporation in writing. A state nonmember bank or state savings association that becomes a $50 billion or over covered bank on or before September 30 of a calendar year must comply with the requirements applicable to a $50 billion or over covered bank beginning on January 1 of the second calendar year after the state nonmember bank or state savings association becomes a $50 billion or over covered bank, unless that time is extended by the Corporation in writing.

(c) *Covered bank subsidiaries of a bank holding company or savings and loan holding company subject to annual stress test requirements.* (1) Notwithstanding the requirements applicable to covered banks under this section, a covered bank that is a consolidated subsidiary of a bank holding company or savings and loan holding company that is required to conduct an annual company-run stress test under applicable regulations of the Board of Governors of the Federal Reserve System may elect to conduct its stress test and report to the FDIC on the same timeline as its parent bank holding company or savings and loan holding company.

(2) A covered bank that elects to conduct its stress test under paragraph (c)(1) of this section will remain subject to the same timeline requirements of its parent company until otherwise approved by the FDIC.

■ 6. Revise § 325.204 to read as follows:

§ 325.204 Annual stress tests required.

Each covered bank must conduct the annual stress test under this part subject to the following requirements:

(a) *Financial data.* A covered bank must use financial data as of December 31 of the previous calendar year.

(b) *Scenarios provided by the Corporation.* In conducting the stress test under this part, each covered bank must use the scenarios provided by the Corporation. The scenarios provided by the Corporation will reflect a minimum of three sets of economic and financial conditions, including baseline, adverse, and severely adverse scenarios. The Corporation will provide a description of the scenarios required to be used by each covered bank no later than February 15 of that calendar year.

(c) *Significant trading activities.* The Corporation may require a covered bank with significant trading activities, as determined by the Corporation, to

include trading and counterparty components in its adverse and severely adverse scenarios. The trading and counterparty position data to be used in this component will be as of a date between October 1 of the previous calendar year and March 1 of that calendar year in which the stress test is performed, and the Corporation will communicate a description of the component to the covered bank no later than March 1 of that calendar year.

■ 7. Amend § 325.206 by revising paragraph (a) to read as follows:

§ 325.206 Required reports of stress test results to the FDIC and the Board of Governors of the Federal Reserve System.

(a) *Report required for annual stress test results—(1) $10 billion to $50 billion covered bank.* A $10 billion to $50 billion covered bank must report to the FDIC and to the Board of Governors of the Federal Reserve System, on or before July 31, the results of the stress test in the manner and form specified by the FDIC.

(2) *$50 billion or over covered bank.* A $50 billion or over covered bank must report to the FDIC and to the Board of Governors of the Federal Reserve System, on or before April 5, the results of the stress test in the manner and form specified by the FDIC.

* * * * *

■ 8. Amend § 325.207 by revising paragraph (a) to read as follows:

§ 325.207 Publication of disclosures.

(a) *Publication date*—(1) *$10 billion to $50 billion covered bank.* A $10 billion to $50 billion covered bank must publish a summary of the results of its annual stress test in the period starting October 15 and ending October 31.

(2) *$50 billion or over covered bank.* A $50 billion or over covered bank must publish a summary of the results of its annual stress tests in the period starting June 15 and ending July 15, provided:

(i) Unless the Corporation determines otherwise, if the $50 billion or over covered bank is a consolidated subsidiary of a bank holding company or savings and loan holding company subject to supervisory stress tests conducted by the Board of Governors of the Federal Reserve System under 12 CFR part 252, then within the June 15 to July 15 period, such covered bank may not publish the required summary of its annual stress test earlier than the date that the Board of Governors of the Federal Reserve System publishes the supervisory stress test results of the covered bank's parent holding company.

(ii) If the Board of Governors of the Federal Reserve System publishes the supervisory stress test results of the covered bank's parent holding company prior to June 15, then such covered bank may publish its stress test results prior to June 15, but no later than July 15, through actual publication by the covered bank or through publication by the parent holding company pursuant to paragraph (b) of this section.

* * * * *

Dated at Washington, DC, on March 20, 2018.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 2018–06162 Filed 3–30–18; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0446; Product Identifier 2010–SW–007–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH (Previously Eurocopter Deutschland GmbH) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to revise Airworthiness Directive (AD) 2013–21–05 for Eurocopter Deutschland GmbH (now Airbus Helicopters Deutschland GmbH) (Airbus Helicopters) Model EC135 P1, P2, P2+, T1, T2, and T2+ helicopters. AD 2013–21–05 requires an initial and repetitive inspections of certain bearings and modifying the floor and a rod. Since we issued AD 2013–21–05, we have determined that modifying the floor and rod removes the unsafe condition. This proposed AD would retain the requirements of AD 2013–21–05 but remove the repetitive inspections. The actions of this proposed AD are intended to prevent an unsafe condition on these products.

DATES: We must receive comments on this proposed AD by June 1, 2018.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov*. Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2013–0446; or in person at the Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received and other information. The street address for the Docket Operations (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt. For service information identified in this proposed rule, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.airbushelicopters.com/website/technical-expert/*. You may review service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *matthew.fuller@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. 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.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive

public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

We issued AD 2013–21–05, Amendment 39–17629 (78 FR 65169, October 31, 2013) (AD 2013–21–05) for Eurocopter Deutschland GmbH (now Airbus Helicopters) Model EC135 P1, P2, P2+, T1, T2, and T2+ helicopters with bearing part number (P/N) LN9367GE6N2; rod P/N L671M5040205; lever P/N L671M5040101; and floor P/N L533M1014101, L533M1014102, L533M1014103, L533M1014104, L533M1014105 or L533M1014106 installed. AD 2013–21–05 requires inspecting each bearing for freedom of movement within 100 hours time-in-service (TIS) and thereafter at intervals not to exceed 800 hours TIS. AD 2013–21–05 also requires modifying the floor and modifying and re-identifying the rod with a new P/N. AD 2013–21–05 was prompted by an incident involving limited control of a tail rotor because of the binding of a bearing. Those actions are intended to detect and prevent the binding of a bearing, which could lead to loss of helicopter control.

AD 2013–21–05 was also prompted by AD 2006–0318 R1, dated October 27, 2006, issued by EASA, which is the Technical Agent for the Member States of the European Union, issued to correct an unsafe condition for all Eurocopter Model EC 135 helicopters. EASA advised of an incident of impaired control of an EC 135 tail rotor. EASA stated that according to examinations, the bearing of the linear transducer was subject to binding, which limited the control range.

Actions Since AD 2013–21–05 Was Issued

After we issued AD 2013–21–05, EASA determined, based on a review of data and operator feedback, that repetitive inspections are not required for helicopters with the modified rod and floor. EASA accordingly revised its AD and issued AD No. 2006–0318R2, dated April 25, 2017, to remove the repetitive inspections.

Also since we issued AD 2013–21–05, Eurocopter Deutschland GmbH Helicopters changed its name to Airbus Helicopters Deutschland GmbH. This proposed AD reflects that change and updates the contact information to obtain service documentation. Additionally, the FAA's Aircraft Certification Service has changed its organizational structure. The new structure replaces product directorates with functional divisions. We have revised some of the office titles and nomenclature throughout this proposed AD to reflect the new organizational changes. Additional information about the new structure can be found in the Notice published on July 25, 2017 (82 FR 34564).

FAA's Determination

These helicopters have been approved by the aviation authority of Germany and are approved for operation in the United States. Pursuant to our bilateral agreement with Germany, EASA, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

We reviewed Eurocopter Alert Service Bulletin EC135–67A–012, Revision 1, dated October 18, 2006 (ASB Rev 1), which specifies repetitively inspecting the bearing of the linear transducer for freedom of movement and the lower side of the floor for chafing or damage. If there is binding, ASB Rev 1 specifies replacing the bearing. If there is chafing or damage on the floor, ASB Rev 1 specifies replacing the bearing and repairing the floor. ASB Rev 1 also specifies modifying and re-identifying a certain rod.

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.

Other Related Service Information

We also reviewed Airbus Helicopters Alert Service Bulletin EC135–67A–012, Revision 2, dated April 3, 2017 (ASB Rev 2). ASB Rev 2 states that the repetitive inspection has been added to the helicopter maintenance manual. The repetitive inspection is therefore removed, and ASB Rev 2 requires no action. ASB Rev 1 is attached to ASB Rev 2 as an Appendix.

Proposed AD Requirements

This proposed AD would remove the repetitive 800-hour TIS bearing inspection that is currently required. This proposed AD would continue to require inspecting each bearing for freedom of movement within 100 hours TIS, and replacing the bearing before further flight if there is binding or rough turning. If there is chafing or damage on the lower side of the floor, this proposed AD would require, before further flight, replacing the bearing and repairing the floor, and thereafter installing a Teflon strip. This proposed AD would also require modifying and re-identifying the rod and lever with a new part number.

Differences Between This Proposed AD and the EASA AD

The EASA AD sets compliance times from its original effective date of October 20, 2006, and this proposed AD would not. This proposed AD would require modifying each rod within 100 hours TIS, rather than within 800 hours TIS as specified in the EASA AD. This proposed AD would not require contacting Eurocopter customer support, unlike the EASA AD. Finally, this proposed AD would not apply to Airbus Helicopters Model EC635 T1, EC635 P2+, and EC635 T2+ helicopters because they have no FAA type certificate.

Costs of Compliance

We estimate that this proposed AD would affect 304 helicopters of U.S. Registry and that labor costs average $85 a work hour. We estimate it would take about 10 work-hours to inspect the bearing and no parts or materials would be required, for a cost of $850 per helicopter and $258,400 for the U.S. fleet. If necessary, replacing the bearing would require 3 additional work-hours, and parts would cost $50, for a cost of $305 per helicopter. Repairing the floor would require 3 additional work hours and minimal cost for materials, for a cost of $255 per helicopter.

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.

We are 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

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

For the reasons discussed, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and
4. 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.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

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 removing Airworthiness Directive (AD) 2013–21–05, Amendment 39–17629 (78 FR 65169, October 31, 2013), and adding the following new AD:

Airbus Helicopters Deutschland GmbH (Previously Eurocopter Deutschland GmbH): Docket No. FAA–2013–0446; Product Identifier 2010–SW–007–AD.

(a) Applicability

This AD applies to Model EC135 P1, P2, P2+, T1, T2, and T2+ helicopters, with bearing, part number (P/N) LN9367GE6N2; rod, P/N L671M5040205; lever, P/N L671M5040101; and floor, P/N L533M1014101, L533M1014102, L533M1014103, L533M1014104, L533M1014105 or L533M1014106, installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as limited control of a tail rotor because of the binding of a bearing. This condition could result in subsequent loss of control of the helicopter.

(c) Affected ADs

This AD replaces AD 2013–21–05, Amendment 39–17629 (78 FR 65169, October 31, 2013).

(d) Comments Due Date

We must receive comments by June 1, 2018.

(e) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(f) Required Actions

(1) Within 100 hours time-in-service (TIS), inspect each bearing for freedom of movement by turning and tilting the bearing as depicted in Figure 2 of Eurocopter Alert Service Bulletin No. EC135–67A–012, Revision 1, dated October 18, 2006 (ASB). During any inspection:

(i) If there is binding or rough turning, before further flight, replace the bearing with an airworthy bearing.

(ii) If there is chafing on the lower side of the floor that does not extend through the panel outer layer, before further flight, replace the bearing with an airworthy bearing.

(iii) If there is damage on the lower side of the floor in the area of the assembly opening that extends through the panel outer layer (revealing an open honeycomb cell or layer), before further flight, replace the bearing with an airworthy bearing and repair the floor.

(2) After performing the actions in paragraphs (f)(1)(i) through (iii) of this AD, before further flight, install a Teflon strip and identify the floor by following the Accomplishment Instructions, paragraphs 3.E.(1) through 3.E.(4), of the ASB.

(3) Within 100 hours TIS, modify and re-identify the rod as depicted in Figure 1 of the ASB and by following the Accomplishment Instructions, paragraphs 3.H.(1) through 3.H.(3)(f), of the ASB.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, 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, we suggest that you 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.

(h) Additional Information

(1) Airbus Helicopters Alert Service Bulletin No. EC135–67A–012, Revision 2, dated April 3, 2017, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.helicopters.airbus.com/website/en/ref/Technical-Support__73.html*. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2006–0318R2, dated April 25, 2017. You may view the EASA AD on the internet at *http://www.regulations.gov* in the AD Docket.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 6720, Tail Rotor Control System.

Issued in Fort Worth, Texas, on March 23, 2018.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2018–06448 Filed 3–30–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0168; Product Identifier 2017–NM–135–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Airbus Model A318, A319, and A320 series airplanes, and Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –253N, and –271N airplanes. This proposed AD was prompted by a revision of an airworthiness limitations document that specifies more restrictive maintenance requirements and airworthiness limitations. This proposed AD would require revising the maintenance or inspection program, as applicable, to

incorporate the specified maintenance requirements and airworthiness limitations. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by May 17, 2018.

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 *http://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 service information identified in this NPRM, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0168; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0168; Product Identifier 2017–NM–135–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2017–0170, dated September 7, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus Model A318, A319, and A320 series airplanes, and Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –253N, and –271N airplanes. The MCAI states:

> The System Equipment Maintenance Requirements (SEMR) for Airbus A320 family aeroplanes, which are approved by EASA, are currently defined and published in the Airbus A318/A319/A320/A321 Airworthiness Limitations Section (ALS) Part 4 document. These instructions have been identified as mandatory for continued airworthiness.
>
> Failure to accomplish these instructions could result in an unsafe condition.
>
> Previously, EASA issued AD 2016–0093 [which corresponds to FAA AD 2017–19–24, Amendment 39–19054 (82 FR 44900, September 27, 2017) (''AD 2017–19–24'')] to require accomplishment of all maintenance tasks as described in ALS Part 4 at Revision 03. ALS Part 4 Revision 04 was not mandated because no significant changes were introduced with this Revision. The new ALS Part 4 Revision 05 (hereafter referred to as 'the ALS' in this [EASA] AD) includes new and/or more restrictive requirements and extends the applicability to model A320–251N, A320–271N, A321–251N, A321–253N and A321–271N aeroplanes.
>
> For the reason described above, this [EASA] AD retains the requirements of EASA AD 2016–0093, which is superseded, and requires accomplishment of all tasks as described in the ALS.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0168.

Relationship of Proposed AD to AD 2017–19–24

This NPRM would not supersede AD 2017–19–24. Rather, we have determined that a stand-alone AD would be more appropriate to address the changes in the MCAI. This NPRM would require revising the maintenance or inspection program to incorporate the new maintenance requirements and airworthiness limitations. Accomplishment of the proposed actions would then terminate all of the requirements of AD 2017–19–24.

Related Service Information Under 1 CFR Part 51

Airbus has issued Airbus A318/A319/A320/A321 Airworthiness Limitations Section (ALS) Part 4, ''System Equipment Maintenance Requirements (SEMR),'' Revision 05, dated April 6, 2017. This service information describes preventive maintenance requirements and includes updated inspections and intervals to be incorporated into the maintenance or inspection program. 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 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, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (j)(1) of this proposed AD. The request should include a description of changes to the required actions that will ensure the continued operational safety of the airplane.

Differences Between This Proposed AD and the MCAI or Service Information

The MCAI specifies that if there are findings from the ALS inspection tasks, corrective actions must be accomplished in accordance with Airbus maintenance documentation. However, this proposed AD does not include that requirement. Operators of U.S.-registered airplanes are required by general airworthiness and operational regulations to perform maintenance using methods that are acceptable to the FAA. We consider those methods to be adequate to address any corrective actions necessitated by the findings of ALS inspections required by this proposed AD.

Airworthiness Limitations Based on Type Design

The FAA recently became aware of an issue related to the applicability of ADs that require incorporation of an ALS revision into an operator's maintenance or inspection program.

Typically, when these types of ADs are issued by civil aviation authorities of other countries, they apply to all airplanes covered under an identified type certificate (TC). The corresponding FAA AD typically retains applicability to all of those airplanes.

In addition, U.S. operators must operate their airplanes in an airworthy condition, in accordance with 14 CFR 91.7(a). Included in this obligation is the requirement to perform any maintenance or inspections specified in the ALS, and in accordance with the ALS as specified in 14 CFR 43.16 and 91.403(c), unless an alternative has been approved by the FAA.

When a type certificate is issued for a type design, the specific ALS, including revisions, is a part of that type design, as specified in 14 CFR 21.31(c).

The sum effect of these operational and maintenance requirements is an obligation to comply with the ALS defined in the type design referenced in the manufacturer's conformity statement. This obligation may introduce a conflict with an AD that requires a specific ALS revision if new airplanes are delivered with a later revision as part of their type design.

To address this conflict, the FAA has approved alternative methods of compliance (AMOCs) that allow operators to incorporate the most recent ALS revision into their maintenance/inspection programs, in lieu of the ALS revision required by the AD. This eliminates the conflict and enables the operator to comply with both the AD and the type design.

However, compliance with AMOCs is normally optional, and we recently became aware that some operators choose to retain the AD-mandated ALS revision in their fleet-wide maintenance/inspection programs, including those for new airplanes delivered with later ALS revisions, to help standardize the maintenance of the fleet. To ensure that operators comply with the applicable ALS revision for newly delivered airplanes containing a later revision than that specified in an AD, we plan to limit the applicability of ADs that mandate ALS revisions to those airplanes that are subject to an earlier revision of the ALS, either as part of the type design or as mandated by an earlier AD. This proposed AD therefore would apply to Airbus Model A318, A319, and A320 series airplanes, and Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –253N, and –271N airplanes with an original certificate of airworthiness or original export certificate of airworthiness that was issued on or before the date of approval of the ALS revision identified in this proposed AD. Operators of airplanes with an original certificate of airworthiness or original export certificate of airworthiness issued after that date must comply with the airworthiness limitations specified as part of the approved type design and referenced on the type certificate data sheet.

Costs of Compliance

We estimate that this proposed AD affects 1,133 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

We have determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although this figure may vary from operator to operator. In the past, we have estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), we have determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, we estimate the total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

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.

We are 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.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

Regulatory Findings

We 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. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. 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):

Airbus: Docket No. FAA–2018–0168; Product Identifier 2017–NM–135–AD.

(a) Comments Due Date

We must receive comments by May 17, 2018.

(b) Affected ADs

This AD affects AD 2017–19–24, Amendment 39–19054 (82 FR 44900, September 27, 2017) (''AD 2017–19–24'').

(c) Applicability

This AD applies to the Airbus airplanes identified in paragraphs (c)(1) through (c)(4) of this AD, certificated in any category, with an original certificate of airworthiness or original export certificate of airworthiness issued on or before April 6, 2017.

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, –233, –251N, and –271N airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –253N, and –271N airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Reason

This AD was prompted by a revision of an airworthiness limitations document that specifies more restrictive maintenance requirements and airworthiness limitations. We are issuing this AD to mitigate the risks associated with the effects of aging on airplane systems. Such effects could change system characteristics, leading to an increased potential for failure of certain life-limited parts, and reduced structural integrity or controllability of the airplane.

(f) Compliance

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

(g) Revision of Maintenance or Inspection Program

Within 90 days after the effective date of this AD, revise the maintenance or inspection program, as applicable, to incorporate Airbus A318/A319/A320/A321 Airworthiness Limitations Section (ALS) Part 4, ''System Equipment Maintenance Requirements (SEMR),'' Revision 05, dated April 6, 2017. The initial compliance time for doing the revised actions is at the applicable time specified in Airbus A318/A319/A320/A321 Airworthiness Limitations Section (ALS) Part 4, ''System Equipment Maintenance Requirements (SEMR),'' Revision 05, dated April 6, 2017.

(h) No Alternative Actions or Intervals

After the maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (j)(1) of this AD.

(i) Terminating Action for AD 2017–19–24

Accomplishing the actions required by this AD terminates all requirements of AD 2017–19–24.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@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 corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2017–0170, dated September 7, 2017, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0168.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

(3) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on March 22, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–06590 Filed 3–30–18; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 2, 5, 15, and 101

[GN Docket No. 18–21, RM–11795; FCC 18–17]

Spectrum Horizons

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) seeks comment on proposed rules to permit licensed fixed point-to-point operations in a total of 102.2 gigahertz of spectrum; on making 15.2 gigahertz of spectrum available for unlicensed use; and on creating a new category of experimental licenses to increase opportunities for entities to develop new services and technologies from 95 GHz to 3 THz with no limits on geography or technology. The Commission also granted, in part, two petitions for rulemaking and denied two requests for waiver.

DATES: Comments are due May 2, 2018. Reply comments are due May 17, 2018.

FOR FURTHER INFORMATION CONTACT: Michael Ha, Office of Engineering and Technology, 202–418–2099, *Michael.Ha@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking, ET Docket No. 18–21, RM–11795, FCC 18–17, adopted February 22, 2018, and released February 28, 2018. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street SW, Washington, DC 20554. The full text may also be downloaded at: *https://transition.fcc.gov/Daily_Releases/Daily_Business/2018/db0228/FCC-18-17A1.pdf.* People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Synopsis

1. *Background.* The Commission focuses the *Notice* on providing licensed and unlicensed spectrum use opportunities in the 95 GHz to 275 GHz range, with additional provisions for experimental licensing up to 3000 GHz in a manner that would not foreclose future federal and non-federal access to opportunities and technologies. The frequencies in the 95 GHz to 275 GHz range are allocated for federal government and non-federal government use across multiple services on a co-primary basis, while the frequencies above 275 GHz are not allocated. Because the Commission presently has no licensed service rules in these bands, and these bands are currently ''restricted'' under the part 15 rules for unlicensed devices, there is limited Commission-authorized use above 95 GHz, other than for experimental and amateur radio operations. In developing our proposals, the Commission therefore draws from many inputs, including the present use of the band, our prior inquiries seeking information on potential use of this spectrum (including adjacent and nearby frequencies that can serve as useful comparisons), recent technical and international developments, our analysis of the engineering issues and propagation characteristics associated with the use of these frequencies, and applications for experimental licenses and rulemaking petitions that the Commission has received. Our proposed approach is intended to provide incentives and opportunities for investment in the development of innovative new technologies and services while remaining cognizant of the flexible international, federal and non-federal allocations, and the already extensive and planned passive uses of these bands. Developing rules in these bands serves the public interest; not only can it lead to new and novel communications opportunities in an uncrowded frequency range, it could also pay dividends by reducing pressures in lower parts of the spectrum. The Commission also recognizes that all the potential services and devices that might be developed in this spectrum are not yet known. Thus, while the Commission proposes a wide range of expanded licensed, unlicensed and experimental use opportunities now, the Commission also leaves room to enable future federal and non-federal access opportunities and technologies.

2. Several parties filed comments in the Spectrum Frontiers docket regarding the spectrum above 95 GHz. Commenters nevertheless offered little in the way of specific proposed rules or technical analyses, likely due to the general nature of the questions about these bands posed by the Further Notice. While parties are welcome to reprise their observations and recommendations to the extent that they remain relevant, the Commission also encourages commenters to react to the specific objectives, proposals, and draft rules that the Commission describes in greater detail herein.

3. *Experimental licenses, petitions and other requests.* A review of our licensing database indicates that there are currently eleven active experimental licenses for spectrum above 95 GHz. The Commission has also received petitions and waiver requests to enable spectrum use above 95 GHz on a non-experimental basis. Battelle Memorial Institute, Inc. (Battelle) filed a petition for rulemaking in February 2014 asking the Commission to adopt service rules for non-federal fixed use of the 102–109.5 GHz band. McKay Brothers, LLC, which holds a nationwide, non-exclusive license in the 70/80/90 GHz bands, seeks a waiver to enable its Geneva Communications subsidiary to operate in the band. Additionally, ZenFi Networks, Inc. (ZenFi), which also holds a 70/80/90 GHz license, seeks a waiver of our part 101 rules to permit use of the 102–109.5 GHz band in a number of cities under the 70/80/90 GHz band rules.

4. IEEE–USA submitted a request for the Commission to make a declaratory ruling that any application for use of technology above 95 GHz is presumed to be a ''new technology'' under section 7 of the Communications Act of 1934, and is thus subject to the one-year timeframe for determining whether the proposal is in the public interest. IEEE–USA also requests that the Commission declare that, if it finds a proposal to use above 95 GHz spectrum is in the public interest, it will adopt rules that enable provisioning of that new technology or service within a one-year period. James Whedbee, in a petition for rulemaking, asks us to create a rule for operation of unlicensed intentional radiator devices in the 95–1,000 GHz band. Whedbee states that his proposed rule is identical in most respects to those used for other Extremely High Frequency (30–300 GHz) bands regulated under part 15. The Commission has yet to take action on these various petitions or waiver requests.

5. *Discussion.* Given the growth in interest in millimeter wave spectrum, the Commission believes it is now appropriate to make spectrum above 95 GHz more readily available for the deployment of fixed and mobile wireless technologies. The Commission tentatively concludes that finding new ways to promote the development of bands above 95 GHz will also serve the public interest. Moreover, a review of academic publications indicates that the demand for wireless data will continue to expand.

6. *Licensed service.* The Commission seeks comment on whether to adopt rules for fixed point-to-point operations in the 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands based on the rules currently in place for the 70/80/90 GHz band. In addition, the Commission also seeks comment on applying these rules to several other frequency bands above 95 GHz that may be suitable for licensed fixed operations, including 158.5–164 GHz, 167–174.5 GHz, 191.8–200 GHz, 209–226 GHz, 232–235 GHz, 238–240 GHz, and 252–275 GHz. The Commission also inquires into whether mobile operations may be appropriate for any bands above 95 GHz with mobile allocations.

7. *Fixed Point-to-Point Services:* Based on the propagation properties of the spectrum the Commission believes that large portions of the spectrum in the 95–275 GHz range are potentially suitable for deploying fixed point-to-point links. While the Commission has no intention of changing the current allocations of any of this spectrum, the Commission notes that there are numerous bands below 275 GHz that are already allocated for the fixed service. Consequently, the Commission seeks comment on proposed rules for fixed point-to-point operations in 36 gigahertz of spectrum in the 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands based on the 70/80/90 GHz rules. These ''proposed fixed bands'' are all the bands below 275 GHz with a fixed service allocation that are not shared with either the FSS or MSS. Below, the Commission seeks comment on whether it should also include the bands shared with the FSS or MSS in our proposal. The Commission also believes that the 70/80/90 GHz rules in place since 2003, which have proven effective in efficiently providing access to spectrum in that frequency range, provide a useful model for the rules contemplated here. The propagation characteristics and technical rules associated with the 70/80/90 GHz frequencies allow for the sharing of spectrum by multiple users in close geographic proximity, as the Commission contemplates would be the

case with the above 95 GHz frequencies proposed here. The 70/80/90 GHz rules also allow for sharing with federal users and the protection of radio astronomy that shares many of these bands, which the Commission anticipates would also be important for the use of the bands contemplated in this proceeding.

8. The Commission seeks comment on draft rules for the proposed fixed bands, which would be mostly identical to the rules for the 70/80/90 GHz bands contained in part 101. Briefly summarizing, both sets of rules provide that:

- The Commission will issue non-exclusive nationwide licenses for ten-year terms.
- Each fixed point-to-point link must be registered through a link registration system maintained by a database manager. An interference analysis for the link must be submitted to the database manager when registering the link.
- The licensee must apply to the Commission for coordination of a link if: (1) The link receives a ''yellow light'' from NTIA's automated mechanism as part of the registration process; (2) it requires an environmental assessment; (3) it requires international coordination; or (4) it operates in a quiet zone.
- An applicant may request a license for any portion of any band.
- Interference protection is granted to the first-in-time registered non-federal link. Existing digital links are protected to a threshold-to-interference ratio (T/I) level of 1.0 dB of degradation to the static threshold. Existing analog links shall not experience more than a 1.0 dB degradation of the baseband signal-to-noise ratio required to produce an acceptable signal in the receiver.
- Construction of links must be completed within 12 months of link registration.
- Transmitters may operate at a maximum Equivalent Isotropically Radiated Power (EIRP) of 25 decibel watts per megahertz (dBW/MHz).
- Transmitters must have a minimum antenna gain of 43 decibels (isotropic) (dBi) with a half-power beamwidth of 1.2 degrees, but the maximum EIRP is reduced by 2 decibels for each decibel the antenna gain is less than 50 dBi.
- Out-of-band emissions are limited as specified in § 101.111 of our rules for signals above 24 GHz with the value of B (bandwidth) set for 500 megahertz.
- Systems using digital modulation must have a minimum bit rate of 0.125 bits/second/Hz.
- Licensees may provide service on either a common carrier or non-common carrier basis and are subject to the eligibility requirements of § 101.7 (foreign ownership).
- Coordination with Mexico or Canada is required for certain stations located near the borders.

The Commission seeks comment generally on adopting these rules for the identified fixed bands and discusses in more detail below some aspects of these proposed rules. Should identical rules be adopted for each of the individual bands or should the rules be adjusted for the characteristics of each band?

9. Certain rules for the 70/80/90 GHz band contained in part 101 are different for the 70/80 GHz bands as opposed to the 90 GHz band. For example, transmitters in the 90 GHz band are required to have an antenna gain of 50 dBi while in the 70/80 GHz band the limit is only 43 dBi. The 90 GHz band also has an additional interference protection requirement that a new link must not decrease an existing link's desired to undesired signal ratio below 36 dB. Digital systems in the 90 GHz band are required to have a bit rate of 1 bit/second/Hz instead of 0.125 bits/second/Hz in the 70/80 GHz bands. In these instances where the current rules vary, the Commission seeks comment on whether to adopt the 70/80 GHz rules

10. Under the 70/80/90 GHz rules, the transmitted power is limited to 55 dBW irrespective of the bandwidth of the signal. Under the Commission's proposal, licensees will be limited to a maximum EIRP of 25 dBW/MHz, which is equivalent to the 75 decibel milliwatts per 100 megahertz (75 dBm/100 MHz) EIRP limit the Commission recently adopted for base stations in our part 30 rules. The Commission seeks comment on this proposal; would another EIRP be more appropriate?

11. Can and should the Commission require or invite the current 70/80/90 GHz database managers to extend their duties to additional bands above 95 GHz or should WTB identify one or more database managers for these bands through an independent process? Is the requirement that licensees submit an interference analysis to the database manager when registering a link necessary to prevent interference given the propagation characteristics above 95 GHz?

12. The Commission seeks comment generally on extending the 70/80/90 GHz service and technical rules to the proposed fixed bands. Should any of the proposed rules be modified for bands above 95 GHz based on licensees' experiences with the 70/80/90 GHz rules or for other reasons? Are modifications to the rules needed to encourage more efficient use of spectrum or to avoid harmful interference? Should a higher EIRP be permitted to compensate for the atmospheric attenuation at these higher frequencies? The Commission notes that Battelle has suggested an EIRP of 70 dBW in their rulemaking petition, which would be 31.25 dBW/MHz if spread evenly across the 102–109.5 GHz band, claiming that the 70/80/90 GHz bands suffers from limited range and operating availability during severe weather and that there will be additional atmospheric attenuation in the 102–109.5 GHz band. Should the Commission segment any of the proposed bands as the Commission did for the 90 GHz band? What segmentation would be appropriate? Would a specific channel plan be appropriate in any of the bands? Do the rules provide a workable framework for protecting radio astronomy facilities and federal operations in the band? Are there any modifications to the proposed rules that would be necessary to address any of the characteristics of the proposed fixed bands?

13. Do the antenna gain requirements for the 70/80/90 GHz bands strike an appropriate balance between facilitating sharing of the spectrum and providing flexibility? Do the proposed rules need to be modified to allow for the use of small planar or phased array antennas?

14. Should the Commission make provisions in the rules for fixed point-to-multipoint systems in addition to point-to-point links? For example, could the Commission allow licensees to register operations in an area around a fixed location instead of requiring registration of individual links as required by the 70/80/90 GHz rules? This would enable a licensee to establish an access point/base station that serves a number of fixed customer locations in the surrounding area. The access point/base station would be permitted to operate with multiple beams where each beam must abide by the power limits the Commission is adopting, but the sum of the power of all the beams could be higher. What are the advantages or disadvantages of such a proposal? The Commission envisions that the area served by an access/point base station would be small. What size area could an access point/base station serve given the propagation properties of these bands? Would allowing such point-to-multipoint systems require a higher degree of coordination with other licensees or Federal operations to prevent harmful interference from occurring? Should the area that is reserved around a particular access point/base station depend on the technical parameters of the access point

such its transmit power and antenna height and characteristics of the surrounding environment such as terrain and structures? Because the access point/base station may use dynamically steerable antenna arrays to point at particular customer locations as needed, would it make sense to allow licensees to specify their coverage areas as a probability density function that describes the relative likelihood of pointing in a particular direction? By specifying coverage areas in terms of probably density functions, the coverage areas of different licensees could overlap to allow a means of sharing the spectrum on a statistical basis. Do commenters agree with this assessment?

15. While the Commission did not include the above 95 GHz bands that are allocated for the FSS or MSS in the above discussion, the Commission notes that satellite services successfully share spectrum with terrestrial services in many bands. Therefore, the Commission seeks comment on extending our above proposal based on the 70/80/90 GHz rules to permit fixed operations in one or more of the following additional bands that are allocated for either the FSS or the MSS in addition to the fixed and mobile services: 158.5–164 GHz, 167–174.5 GHz, 191.8–200 GHz, 209–226 GHz, 232–235 GHz, 238–240 GHz, and 252–275 GHz. What changes, if any, to our proposed rules would be necessary to permit fixed operations in these bands?

16. Alternatively, should the Commission instead adopt the licensing and prior coordination requirement used in many bands subject to our part 101 rules. Under such an approach, links would be individually licensed and the Commission would require that the links be coordinated with the licensee of other potentially affected links prior to application for a license? Are there any other models for licensing that the Commission should consider for these bands?

17. *Mobile Services:* The Commission seeks comment generally on the deployment of mobile services in this spectrum. Would there be significant interest in implementing mobile services here? Given the propagation characteristics of these bands, what type of systems could feasibly be deployed? What type of licensing and technical rules should the Commission consider adopting for mobile services in this spectrum?

18. *Sharing Considerations:* With the exception of passive services (EESS, RAS, and SRS) that collectively have exclusive primary allocations in some of the bands between 95 GHz and 275 GHz, all other services in the 95–275 GHz bands have shared allocations. Sometimes, without specific guidance, such allocations convey a perception that when two or more primary services are listed in the U.S. Table, later-licensed or authorized federal or non-federal operations would be expected to protect the earlier-licensed or authorized operations. However, to avoid any mistaken perceptions and in light of the unique physical characteristics in these bands, the Commission seeks comment below on adopting a new U.S. footnote in the table of allocations that would clarify that, among co-primary federal and non-federal services, first-in-time does not necessarily mean priority relative to other current or future licensed or unlicensed uses.

19. *Sharing with the RAS.* RAS operations in this region of the spectrum are limited to certain locations. For this reason, the Commission believes that excluding fixed and mobile stations from these localities would provide adequate protection for incumbent operations. U.S. footnote 161 includes a list of RAS locations operating in the bands 81–86 GHz, 92–94 GHz, and 94.1–95 GHz that are protected from fixed stations by the use of coordination distances. The Commission seeks comment as to whether a similar approach would adequately protect RAS operations in the bands above 95 GHz. Does this list reflect RAS operations that currently exist or are anticipated above 95 GHz, or should the Commission modify it to add or eliminate certain locations? Given that the propagation losses in the bands above 95 GHz are higher than the bands identified in US161, should the coordination distances be adjusted accordingly?

20. The Commission notes that footnote US246 prohibits all transmissions in a number of bands above 95 GHz to protect passive services such as the RAS and EESS (passive). Footnote US74 specifies that radio astronomy observatories operating in most of the frequency bands listed in US246 will be protected from unwanted emissions from other stations only to the extent the emissions exceed what would be permitted under the technical standards or criteria applicable to the service in which the station operates. However, US74 omits the 182–185 GHz and 226–231.5 GHz bands even though they are included in US246 and have RAS allocations. The Commission seeks comment on whether these two bands should be added to US74.

21. *Sharing services with the EESS and SRS.* The Commission seeks comments on the appropriate methodology for modelling potential interference to the EESS and SRS. Limitations on power or the number and locations of devices may be appropriate mitigation techniques that would not necessarily restrict the transmission ranges of services such as terahertz WLANs or fixed backhaul links to the point they are unworkable. Are there specific environmental propagation models the Commission should consider when contemplating allowing shared services with EESS and SRS? Should additional environmental characteristics, for example via building or other forms of clutter model, be considered? The Commission seeks comment on the harmful interference criteria for satellite passive remote sensing, as well as any published studies or recommendations that may be relevant in assessing sharing with satellite passive remote sensors. Are there methodologies the Commission should adopt into its rules that could mitigate interference to EESS and SRS services caused by new users of above 95 GHz spectrum? What is the best way of predicting atmospheric attenuation (including losses from rain, etc.), particularly in the bands beyond the 1 THz limit of the International Telecommunication Union (ITU) recommendation on attenuation by atmospheric gases, ITU–R P676–11? Are there other assumptions that must be considered in ensuring interference protected operation for passive sensors in the EESS and SRS?

22. *Sharing with the FSS, MSS, and ISS.* The 158.5–164 GHz, 167–174.5 GHz, 209–226 GHz, 232–235 GHz, 238–240 GHz, and 265–275 GHz bands have shared allocations with the FSS. The Commission expects that sharing between the MS service and the FSS service would be similar to the lower frequency bands under the new part 30 rules. The Commission seeks comment on how the Upper Microwave Flexible Use Service (UMFUS) rules could be used to facilitate sharing between the MS and FSS in the above 95 GHz bands. How can interference be avoided between mobile stations and satellite operations? Could exclusion zones or coordination be used to prevent interference? Would designating portions of the shared spectrum where satellite or terrestrial services have priority be an appropriate means for sharing the spectrum?

23. The Commission also seeks comment on how sharing could be accomplished between the FS and FSS in the bands under discussion. Would the use of a narrow-beam antenna requirement in our proposed rules for FS operations avoid harmful interference to the FSS? Sharing

between the FS and the FSS in the lower frequency bands under our part 101 of our rules uses first-in-time coordination. Would this be an appropriate method for sharing between the FS and FSS? Could the registration of fixed links with the database manager required under our proposed rules be extended to also apply to satellite earth stations?

24. The 158.5–164 GHz, 191.8–200 GHz, 232–235 GHz, and 252–265 GHz bands have shared allocations with the MSS. The Commission believes sharing between FS and MSS is technically feasible, and seeks comment on possible sharing mechanisms between these services. The Commission seeks comment on possible sharing mechanisms between the MS and MSS services. Would geographical partitioning between services, for example between urban/rural markets, serve as a possible sharing mechanism? If so, how should such markets be defined? Could dual MS/MSS user equipment, if available, resolve possible interference conditions by switching to terrestrial service when a terrestrial network is detected? Could requiring operators of terrestrial MS networks to adopt a method of registration and tracking of MSS user equipment reduce the possibility of interference by limiting emissions in the direction of MSS user equipment?

25. The 122.25–123 GHz, 130–134 GHz, 167–174.8 GHz, and 191.8–200 GHz bands have a shared allocation with the inter-satellite service (ISS). Is there a need to make provisions in the Commission's rules to prevent harmful interference to and from the ISS? Should there be specific antenna performance requirements for FS and MS stations to limit potential interference to the ISS? If so, should there be separate requirements for each of the shared bands? Commenters who support antenna performance requirements for FS and MS stations should provide specific technical information and proposals showing the need for such requirements. Similarly, should there be specific antenna performance requirements for aeronautical use of MS stations or should such use be prohibited entirely to protect the ISS? The Commission seeks comment on whether NGSO satellites can be accommodated in the 116–122.25 GHz band.

26. *Other shared services.* The 95–100 GHz, 141–148.5 GHz, 151.5–155.5 GHz, 191–200 GHz, 238–241 GHz, and 252–265 GHz bands have shared allocations for radar use (radionavigation service or radiolocation service). The 95–100 GHz, 238–240 GHz, and 252–265 GHz bands are also allocated for the radio navigation satellite service. How likely is it that these allocations will be used in the future by non-federal users? The Commission seeks comment generally on how stations in the fixed and/or mobile service could share the bands with the radar allocated services. Can the sharing mechanism be based on geographical separation? Could a database of locations where radar operations occur or the locations of transmitters or receivers of other licensed services be used to facilitate sharing in these bands? Such a database could be a relatively simple record of the locations of fixed facilities or the geographic areas where mobile operations may occur or it could be more sophisticated. Could the use of sensing technologies to determine when radars are in operation be used to share the bands between radars and other licensed services?

27. *Federal/non-federal sharing:* As the Commission notes above, the 95–275 GHz spectrum is allocated on a co-primary basis for federal and non-federal use. In developing rules for this spectrum, the Commission will work closely with the NTIA with the objective of developing a framework that both encourages private sector investment in new technologies and services and preserves the ability of federal users to research, develop, test, and deploy new technologies and services to meet their needs. While this notice considers the possibility of granting nationwide licenses, access to the band by both federal and non-federal users would be on a shared basis where access by users would not preclude federal and non-federal users from deploying systems where no authorized facilities have been registered or deployed. Specific sharing and coordination terms to ensure federal and non-federal co-primary access will be addressed through a future framework to be jointly developed by NTIA and FCC as part of follow-on proceedings. The Commission seeks comment on adding the following footnote to the Table of Frequency Allocations that reflects this approach:

> USxxx: Federal and non-federal users shall have equal rights to access the spectrum in the 95–275 GHz band. Use of the band by non-federal users on a licensed or unlicensed basis shall not preclude or impair co-primary use of the bands by federal users and shall not establish non-federal priority in bands allocated for shared federal and non-federal use.

28. *Unlicensed operations under parts 15.* Part 15 of the Commission's rules permits the operation of RF devices without issuing individual licenses to operators of these devices. The Commission's part 15 rules are designed to ensure that there is a low probability that these devices will cause harmful interference to authorized users of the same or nearby spectrum. Should harmful interference occur, the operator is required to immediately correct the interference problem or cease operation.

29. Apart from a few specified frequency bands, spectrum above 38.6 GHz is designated as ''restricted'' in § 15.205 of the rules. Unless expressly permitted by rule or waiver, unlicensed devices are not allowed to intentionally radiate energy into a restricted band. The Commission proposes to allow unlicensed operation in additional frequency bands where the Commission believes it will not cause harmful interference to authorized services, and to remove those specific bands from the list of restricted bands.

30. The Commission seeks comment on whether to make 15.2 gigahertz of spectrum above 95 GHz available for unlicensed use in four frequency bands. First, the Commission seeks comment on allowing unlicensed operation in the 122–123 GHz and the 244–246 GHz bands, which are already designated industrial, scientific, and medical (ISM) bands. The Commission would remove these bands from the list of restricted bands in § 15.205. The Commission seeks comment on these proposals.

31. The Commission also seeks comment on whether to allow unlicensed operation in two frequency bands near 183 GHz. The Commission believes that the frequency bands located around a sharp peak in the atmospheric attenuation curve at 183 GHz may be appropriate for unlicensed use. However, no transmissions are permitted in the frequency band at the peak due to Allocations Table footnote US246 stating that no station shall be authorized to transmit in a number of bands including the 182–185 GHz band. The Commission would make spectrum available for unlicensed use on both sides of the attenuation peak, specifically, the 174.8–182 GHz and 185–190 GHz bands. The Commission would remove these bands from the list of restricted bands in § 15.205. The Commission seeks comment on this approach.

32. The Commission also seeks comment on what technical rules should apply to unlicensed operation within the 122–123 GHz, 174.8–182 GHz, 185–190 GHz and 244–246 GHz frequency bands. In particular, the Commission seeks comment on whether the requirements that apply to the operation of unlicensed devices in the 57–71 GHz band under § 15.255 of the rules are appropriate in these bands. Would the power levels provided in that

rule section be high enough for unlicensed equipment to function as intended in the bands under consideration here? If not, what would be a reasonable power level that provides for a practical operational range that would also provide adequate protection to authorized services in the same and nearby spectrum? Could the Commission permit higher power levels in the 174.8–182 GHz and 185–190 GHz bands since they are close to a peak in atmospheric attenuation that is greater than the peak at 60 GHz? The Commission recognizes that the primary allocations for the 174.8–182 GHz and 185–190 GHz bands are for the ISS and for the EESS and the SRS (passive) and that footnote 5.562H limits ISS emissions to levels below the EESS (passive) protection criteria. The Commission also notes that the rules applying to unlicensed use of the 57–71 GHz band do not allow the use of devices on satellites or allow for the use of field disturbance sensors unless the sensors are part of fixed equipment. In addition, these rules permit the use of devices on aircraft only under certain specific circumstances. Therefore, the Commission seeks comment on whether any of these restrictions should apply to unlicensed devices in any or all of the four proposed bands to protect the existing authorized services in these bands, and if so, why? Is there a need to prohibit all operation of devices on aircraft in any of the proposed bands? Would any other modifications to the requirements of § 15.255 be needed to permit unlicensed operation in these bands?

33. The Commission further seeks comment on whether there are any other bands above 95 GHz that would be suitable for unlicensed use in addition to the 15.2 gigahertz of spectrum identified above. In particular, the Commission seeks comment on allowing unlicensed use of the 116–122 GHz band. The 116–122.25 GHz band is allocated to passive services such as the EESS and SRS (passive) as well as the ISS which is used for communications between satellites with footnote 5.562C limiting ISS emission levels below the EESS (passive) protection criteria. The passive services would likely be compatible only with low density deployments and low power unlicensed uses because of the high sensitivity of these types of passive receivers. Because devices operating under our part 15 rules are limited to transmission at low power levels, and given the increased propagation attenuation from high atmospheric absorption, the Commission believes that part 15 devices may be able to share spectrum with these passive services without causing interference. However, the Commission notes that while this band is close to a peak in the atmospheric attenuation curve, this peak is smaller than the peaks at 60 GHz and 183 GHz. Also, the Commission notes that RAS observations at 115.27 GHz may necessitate geographic restrictions to protect RAS facilities. Accordingly, the Commission seeks comment on whether unlicensed operation should be permitted in the 116–122 GHz band. If so, what technical and other requirements should apply to prevent interference to authorized services in the band? The Commission also seeks comment on any other bands above 95 GHz that may be suitable for unlicensed use and the technical requirements that would be necessary to allow operation in them while protecting authorized services. In particular, the Commission seeks comment on how such use would relate to current and planned passive services.

34. Potential future applications in these bands includes ultra-high definition video, and high-speed data transmission, such as temporary fiber optic line replacement, chip-to-chip communication within computer equipment, and replacement of computer data cables in data centers with wireless links. Would the rules proposed above for unlicensed devices allow for applications such as these? With respect to non-federal users, the Commission seeks comment on whether the unlicensed spectrum access model is most appropriate for the types of devices that could be operated in the proposed frequency bands, or whether some other spectrum access model would be more appropriate, *e.g.,* licensed or licensed by rule.

35. As mentioned above, James Whedbee has filed a rulemaking petition requesting that the Commission adopt rules to permit unlicensed device operation in the 95–1000 GHz range. Whedbee advocates that the Commission apply the same technical rules to these unlicensed operations as currently apply in the 57–71 GHz band with a few differences. Whedbee proposes unlicensed devices in 95–1000 GHz be limited to a bandwidth of 500 megahertz. Whedbee also specifies that unlicensed operations be limited to indoors only and that transmitters not be deliberately pointed at windows in a number of bands used by the RAS, EESS (passive), and SRS (passive). According to Whedbee, licensing of transmissions over the range 95–1000 GHz may hinder the technological developments that his proposed rule would permit without licensing. The Commission is reluctant to open such a wide swath of spectrum for unlicensed use because the Commission believes it represents an inefficient use of the spectrum, provides no focus for development of technologies in specific bands and the Commission's proposals would already provide considerable opportunities for unlicensed devices. Nevertheless, in seeking comment on making 15.2 gigahertz of spectrum above 95 GHz available for unlicensed use the Commission grants his petition in part. The Commission also seeks comment broadly on Whedbee's rulemaking petition to the extent his proposal goes beyond what the Commission is seeking comment on and on any costs or benefits that could arise from making the 95–1000 GHz band available for unlicensed use in accordance with his proposal.

36. The Commission also seeks comment on what rules might be most appropriate for ISM operations in the above 95 GHz band. Part 18 of the rules contains the regulations for ISM equipment.

37. The Commission has historically treated RF devices that transmit a radio signal for purposes such as measuring the level of a fluid in a container or for measuring some quantifiable property of a material as part 15 devices. The Commission is aware of interest in using the spectrum above 95 GHz for devices that use terahertz spectroscopy to analyze material properties and for imaging applications, which could possibly be considered ISM applications. The Commission seeks comment on whether it should establish a more certain regulatory approach for devices that use the frequencies above 95 GHz. Is the lack of provisions under part 15 for equipment that operates in these higher frequency bands hampering the ability of these new technologies to be approved and, if so should the Commission modify the part 15 rules to allow them? Or would it be more appropriate to routinely treat these terahertz applications as part 18 ISM equipment for which there are already power and field strength limits specified in the rules?

38. The Commission recognizes that the radiated emission limits in part 18 were originally developed for devices operating at significantly lower frequencies than the Commission is considering here, and seeks comment on how that should affect its analysis. Accordingly, the Commission seeks comment on whether changes to these limits are necessary for operation above 95 GHz. Are the limits in § 18.305 appropriate for these devices? If not,

what are the appropriate limits, and in what terms should they be expressed, *e.g.,* field strength, power density, EIRP or some other power-related terms? In addition, the Commission notes that the rules currently specify that radiated emissions from most ISM equipment must be measured at a distance of 300 meters from the equipment. Due to the rapid attenuation of signals and the limitations in measurement devices at frequencies above 95 GHz, measurements at this distance are likely not practical. The Commission therefore seeks comment on the appropriate measurement distance and procedures for determining compliance with the rules. The Commission also seeks comment on whether any other changes to the rules may be required to prevent harmful interference to authorized services. For example, should the Commission restrict operation in certain frequency bands to indoor locations only, and if so, in which frequency bands should such a restriction apply and how could it be enforced?

39. *Experimental Radio service.* In this section, the Commission seeks comment on whether to create a new subpart of our part 5 Experimental Radio Service (ERS) rules to better encourage experiments in the spectrum range between 95 GHz and 3 THz. The Commission's part 5 ERS rules prescribe the requirements for authorizing a variety of entities to experiment with new radio technologies, equipment designs, characteristics of radio wave propagation, or service concepts related to the use of the radio spectrum. Experimental operations are not entitled to exclusive use protected from harmful interference from allocated services, and ERS licensees must not cause harmful interference to stations of authorized services, including secondary services.

40. *Proposal for ''Spectrum Horizons Experimental Radio Licenses.''* Because of the potential for innovation above 95 GHz, and the unique nature of this spectrum (*e.g.,* limited propagation and virtually no existing operations), the Commission believes that certain experimental requirements can be relaxed or modified without creating an unacceptable risk of interference or undermining our longstanding general policies related to the marketing and authorization of equipment. Accordingly, the Commission seeks comment on a proposal to create an experimental radio license for authorizing operation on frequencies from 95 GHz to 3 THz. In keeping with the current structure of part 5, the Commission proposes to add a new subpart I that would provide specific requirements for ''Spectrum Horizons Experimental Radio Licenses'' and amend subparts A, B, and C, which are generally applicable to all part 5 ERS licenses, as necessary. Since these Spectrum Horizons licensees would be subject to unique requirements that, in many cases, reflect existing or modified versions of the requirements associated with other ERS licensees, the Commission believes this would be the best option for providing prospective licensees with clear requirements, while at the same time maintaining existing rules for the various other forms of ERS authorization. The Commission seeks comment on the assumptions made above and whether a unique subpart of the ERS rules is warranted.

41. The Commission believes that Spectrum Horizons licenses should have a number of characteristics that differ from existing ERS authorizations, although they would also have a number of characteristics in common. Specifically, the Commission seeks comment on the following proposed rules for these Spectrum Horizon licenses.

42. *Marketing.* Marketing of experimental devices or provision of services for hire under product development trial is currently prohibited. While our rules permit market trials under certain circumstances, ERS licensees may sell equipment only to each other under such trials, rather than to market trial participants, and must also ensure that the number of marketed devices is the minimum necessary to conduct the market trial.

43. In the spectrum range above 95 GHz, the Commission believes that marketing of innovative devices at a relatively early stage of experimentation may be particularly important to permit entrepreneurs to gauge consumer acceptance and to determine whether to proceed to the next stage of the experiment. As operations extend further into the spectrum above 95 GHz, the unique technical issues associated with such operations make capable devices more expensive to produce. Further, these same issues also make it less likely that such devices could be easily adapted for use in the lower spectrum. Thus, entrepreneurs will be reluctant to proceed without a clear signal from consumers that they are interested in purchasing such devices.

44. The Commission proposes to allow experimental devices used in market trials in these bands to be sold directly to participants to encourage experimentation, as well as to help innovators share device manufacturing costs with potential early adopters who are willing to bear the risks associated with experimental licensing in this range. As a safeguard against such devices causing harmful interference, the Commission will maintain a requirement that the Spectrum Horizons licensee must adhere to the conditions specified in § 5.602(e) of our rules, which states that ''trial devices are either rendered inoperable or retrieved . . . at the conclusion of the trial.'' The Commission also proposes that the Spectrum Horizons licensee must provide market trial participants with a written disclosure clearly stating that the equipment being purchased is part of an experiment that may be terminated at any time by the licensee or the Commission. Thus, only those individuals who are willing to accept the risk that their devices could be rendered unusable on short notice would be candidates for participating in such market trials. The Commission seeks comment on these proposals.

45. In this connection, the Commission proposes to require that Spectrum Horizons licensees who choose to market equipment must label any such equipment as ''Experimental—Not Authorized for Permanent Use'' and carry with it an equipment ID number registered as part of the experimental license process. The Commission notes that a Spectrum Horizons license should have no expectation that an experiment will always lead to the establishment of a permanent service. Thus, a Spectrum Horizons licensee who chooses to market a substantial—rather than a limited—amount of equipment would be increasing its financial risk. The Commission seeks comment on these marketing proposals, and on any alternatives to them.

46. *Eligibility and filing requirements.* The Commission seeks comment on whether Spectrum Horizons licenses should be broadly available to qualified persons as generally defined under existing ERS rules. However, to obtain a Spectrum Horizons license, the Commission proposes that a qualified applicant be required to include a narrative statement that sufficiently explains the proposed new technology/potential new service and that incorporates an interference analysis that explains why the proposed experiment would not cause harmful interference to any other spectrum user. The statement should include technical details, including the requested frequency band(s), maximum power, emission designators, area(s) of operation, type(s) of device(s) to be used, and the maximum number of each type of device to be used. The Commission seeks comment on these and any other issues that it should

require a Spectrum Horizons service applicant to address in its narrative statement.

47. *Available frequencies.* Because all ERS licenses are authorized on a non-interfering basis, and such applications must be coordinated with federal users via NTIA, the Commission proposes that subpart I specify that Spectrum Horizons licenses be permitted on any frequency in the range of 95 GHz-3 THz, provided there are no objections raised in the coordination process. Applicants would be expected to address any allocation footnotes and any known use(s) of the requested frequency or frequencies in the spectrum analysis that they would be required to provide in their narrative statements discussed above. Additionally, applicants must ensure that the significant number of passive services that use spectrum above 95 GHz are protected from harmful interference and, if proposing to use spectrum that is exclusively allocated for passive use(s), they must explain why nearby bands that have non-passive allocations are not adequate for the experiment. The Commission seeks comment on this proposal. Commenters who propose limitations on available frequencies should identify specific bands where they believe that Spectrum Horizons experiments should be prohibited or restricted, including references to pertinent footnotes listed in the Table of Frequency Allocations. The Commission proposes to list in subpart I all bands that the Commission concludes should be prohibited or restricted for Spectrum Horizons experimental use.

48. *Scope of license grant.* The Commission proposes to provide Spectrum Horizons licensees with substantial flexibility to conduct long-term experiments over a wide geographic area and frequency range, market equipment if necessary, and adapt their program of experimentation as needed. In making these proposals, the Commission emphasizes the overriding considerations that Spectrum Horizons licensees—like all ERS licensees—would have to accept to operate: (1) Licensees would be prohibited from causing harmful interference to any established radio service, and would be solely responsible for promptly remedying any such interference; (2) licenses would be non-exclusive; and (3) there would be no assurance that experimentation would lead to the establishment of an authorized service. Otherwise, the Commission asks for comment on what specific technical rules in subpart C should or should not be applicable to Spectrum Horizons stations.

49. *License term and interim reporting requirement.* The Commission seeks comment on whether to extend the experimental license term for Spectrum Horizons licenses and, if so, for how long. Would a longer license term, such as 10 years, encourage entrepreneurs to make investments in this portion of the spectrum where there has been relatively minimal experimentation and, thus, limited ''real world'' experiences to guide the experimental planning process? If the Commission provides longer license terms, the Commission proposes to require an interim report be submitted to the Commission at the half-way point of the license term to provide the public with information about the progress of the experiment. The Commission also seeks comment on whether a longer Spectrum Horizons license would be eligible for renewal.

50. *Other aspects.* The Commission seeks comment on how best to handle geographic, frequency, or technical limits on experiments, and limits on the number of devices or their type, including whether these limits should be decided on a case-by-case basis. The Commission also seeks comment on how applicants should be required to justify their proposed parameters in their narrative statements. In order to avoid the filing of subsequent requests to modify those parameters during the license term, the Commission proposes that applicants request the maximum parameters that they may ultimately use, even if their initial plans do not require those maximums. The Commission acknowledges that circumstances may change, however, and would still consider granting applications to modify Spectrum Horizons licenses.

51. To better ensure that Spectrum Horizons experiments do not cause harmful interference, the Commission proposes to adopt rules for such experiments similar to our existing ''station identification,'' ''responsible party,'' and ''stop buzzer'' rules. However, consistent with our rules for conventional experimental licenses, the Commission proposes to permit Spectrum Horizons licenses to be transferred, if the Commission finds that to be in the public interest and gives its consent in writing. Comments are requested on each of these proposals.

52. *RF Exposure Limits.* RF devices must comply with the Commission's RF exposure limits that are currently specified up to 100 GHz. The power density limits specified for general population and occupational exposure at 100 GHz are 1 mW/cm^2 and 5 mW/cm^2 respectively for whole-body continuous exposure. The Commission notes that these limits could in principle be applied up to infrared wavelengths, although the Commission does not suggest that there should be any particular changes to our rules at this time. The Commission also notes that the issues of averaging area and averaging time for localized and time varying exposure are the subject of ongoing consideration at lower frequencies in the context of developing laboratory test procedures for specific devices. However, the Commission has an open proceeding in which it is broadly examining its RF exposure rules and policies, which could potentially influence how such devices are authorized in the future. In the *RF Inquiry* of that separate open proceeding, the Commission specifically asks whether it should expand the frequency scope of its exposure rules above the present maximum of 100 GHz. The Commission proposes that it make no changes to its present rules limiting human exposure to RF energy until it considers the broader issues brought forth in its *RF Inquiry.*

53. *Equipment Authorization Matters.* As the Commission has noted previously in the Spectrum Frontiers proceeding, there are unique technical challenges specific to demonstrating compliance with our rules for the purpose of equipment authorization of millimeter-wave devices. As technology evolves to address the technical challenges related to perform compliance measurements above 95 GHz (with respect to propagation, interference protection, modulation techniques, transmission security, etc.), the Commission expects that OET, in its capacity as the technical administrator of the Commission's part 2, 5, 15, and 18 rules, will provide guidance on appropriate measurement techniques through its knowledge database publications as products are developed, seeking notice and comment as appropriate. To inform this guidance, the Commission generally requests information on relevant research as it addresses measurement techniques to verify that devices meet the electromagnetic compatibility (EMC) technical rules; the Commission discusses specific concerns in more detail below.

54. *EMC measurements.* In this Notice, the Commission seeks comment on what technical rules should apply to operation in spectrum above 95 GHz. At this time, the FCC laboratory has offered generally limited guidance related to the technical procedures that could be used to demonstrate the compliance of millimeter-wave devices with such rules. The Commission recognizes that

radiated field strength measurements at frequencies above 1 GHz present challenges due to the relatively high values of cable loss and antenna factor. Similarly, a conducted method of measurement would only be effective if the device and other mixer waveguides are both accessible. The Commission seeks information on fundamental aspects of measurements of radiated and conducted emissions at these frequencies. What are ways to demonstrate compliance with procedures which are practical, repeatable, and do not have large margins of error? Specifically, §§ 15.255 and 15.257 of our rules apply to the use of an RF detector that has been specified to make millimeter-wave measurements. Is the use of an RF detector an appropriate method for measuring the frequencies above 95 GHz? Are there industry measurement standards available for RF devices operating above 95 GHz? The Commission seeks further comment on whether and how present procedures can be adapted or modified to appropriately address the specific technical challenges presented by millimeter-wave devices.

55. *Out-of-band and spurious emissions measurement.* At the present time, the FCC laboratory guidance does offer a procedure to measure the out-of-band and spurious emissions from devices with multiple antennas. The measurement challenges discussed above are often accentuated in the case of out-of-band and spurious emissions due to the low levels of these emissions relative to the fundamental emissions. The Commission seeks comment on what other measurement procedures, such as those in ANSI C63.10–2013, may be used and whether the Commission needs to provide additional guidance (*e.g.,* appropriate measurement bandwidth, cut-off frequency, etc.) to determine compliance with the out-of-band and spurious emission limits for millimeter-wave devices considering the technical challenges of such measurements.

56. *Equipment authorization procedures.* The Commission proposes to parallel the existing 70/80/90 GHz service rules for the bands the Commission proposes for fixed services and similarly adapt our UMFUS rules for the bands the Commission proposes for mobile services. Transmitters used for operation in accordance with the Commission's part 101 Fixed Microwave Services rules are generally authorized via our Suppliers Declaration of Conformity (SDoC) procedure. Transmitters used for part 30 UMFUS mobile operations are required to be authorized via the certification procedure. The Commission seeks comment on which equipment authorization procedure would be most appropriate for any fixed or mobile service adopted under the proposals set forth herein, or whether some other authorization procedure would be more appropriate.

57. *Rulemaking and Waiver Petitions. Battelle Petition.* Battelle Memorial Institute, Inc. (Battelle) filed a petition for rulemaking in February 2014 asking the Commission to commence a rulemaking to propose service rules for fixed use of the 102–109.5 GHz band. Battelle's proposed rules draw extensively from the 70/80/90 GHz rules. Because the rules the Commission is proposing for the 102–109.5 GHz band are similar to what Battelle has proposed, the Commission considers their rulemaking petition granted in part. Battelle and other interested parties are able to participate in this rulemaking and will have ample opportunity to comment on the rules the Commission is proposing and therefore the Commission dismisses Battelle's petition from further consideration.

58. *ZenFi Waiver.* ZenFi Networks, Inc. (ZenFi), which holds a nationwide, non-exclusive license under call sign WQUN758 in the 71–76 GHz, 81–86 GHz, and 92–95 GHz bands, seeks a waiver of the applicable part 1 and subpart Q of part 101 rules to permit use of the 102–109.5 GHz band under its existing license and to register individual point-to-point links at locations within the New York City, Chicago, Washington, DC, and San Francisco metropolitan markets using the regulatory framework established for registering links in the 70/80/90 GHz bands. ZenFi states that it understands that grant of its waiver request will serve as a pre-requisite for coordinating and registering individual point-to-point links in the 102–109.5 GHz band in the four identified markets and that its use of the 102–109.5 GHz band would continue pending resolution of the Battelle rulemaking proceeding.

59. On October 13, 2015, the Commission's Wireless Telecommunications Bureau released a public notice seeking comment on the ZenFi Waiver Request. Battelle and SMG Holdings, LLC (SMG) support grant of the ZenFi Waiver Request, and SMG asks that the Commission extend to it any relief granted to ZenFi.

60. The Commission denies the ZenFi Waiver Request and SMG's informal request seeking waiver to use the 102–109.5 GHz band because ZenFi and SMG have not met the standard for a waiver and grant of a waiver would improperly judge the outcome of the rulemaking proceeding the Commission has begun with this NPRM. First, ZenFi has failed to justify a waiver based on special circumstances because there is nothing unique or unusual about its situation. It is no different than any other operator who has potential interest in using the above 95 GHz bands, and has not demonstrated a need to use this band that cannot be met by deployment in another band. Second, ZenFi has not shown that a deviation from the general rule would be in the public interest. Although ZenFi generally discusses its intent to address the growing demand for wireless links capable of delivering 10GE, it fails to reference a specific proposed deployment that would require a waiver, or discuss the extent to which its proposed deployments could not be reasonably achieved on other spectrum. ZenFi has also failed to distinguish itself from any other party who would potentially be interested in using the 102–109.5 GHz band. ZenFi also fails to satisfy the third prong, because a waiver grant here would essentially replace the current rulemaking process, undermining the validity of that final rule. This is particularly true in this band where the Commission lacks any actual service, licensing, or technical rules. What ZenFi is requesting is not a waiver of the existing rules, but the authority to operate absent any established rules governing the operations. As noted above, there are a series of issues that the Commission must decide before it authorizes service in the 102–109.5 GHz band and develops service rules for that band, including whether to adopt the existing 70/80/90 GHz licensing regime for this band. The Commission does not believe that it would be a prudent policy to subject licensees and their customers to this potential disruption, particularly in the absence of any specific, demonstrated need for interim operation in the band. While the Commission may ultimately adopt rules similar to what Battelle has proposed, ZenFi (and SMG) have not justified the need for a waiver prior to our developing a full record on the proposed changes.

61. *McKay Brothers Waiver.* McKay Brothers has requested that if the Commission were not to issue a notice of proposed rulemaking regarding Battelle's petition, the Commission should consider granting a waiver of the Commission's rules to permit operations similar to ZenFi's waiver request. Because the Commission has deemed Battelle's rulemaking petition granted-in-part, the Commission shall likewise consider McKay Brothers request

granted-in-part and dismiss it from further considerations.

62. *Procedural Matters. Ex Parte Rules—Permit-but-disclose.* Pursuant to § 1.1200(a) of the Commission's rules, this NPRM shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

63. *Comment period and procedures.* Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://fjallfoss.fcc.gov/ecfs2/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW, Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington DC 20554.

64. *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

65. Availability of Documents. Comments, reply comments, and *ex parte* submissions will be publicly available online via ECFS. These documents will also be available for public inspection during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW, CY–A257, Washington, DC, 20554. The Reference Information Center is open to the public Monday through Thursday from 8:00 a.m. to 4:30 p.m. and Friday from 8:00 a.m. to 11:30 a.m.

66. *Initial Regulatory Flexibility Analysis.* As required by the Regulatory Flexibility Act of 1980 (RFA), as amended, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) regarding the possible significant economic impact on small entities of the policies and rules adopted in the *NPRM,* which is found below. The Commission request written public comment on the IRFA. Comments must be filed in accordance with the same deadlines as comments filed in response to the *NRPM* and must have a separate and distinct heading designating them as responses to the IRFA. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of the *Notice,* including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

67. *Paperwork Reduction Analysis.* This document contains proposed new information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), the Commission sought specific comment on how they might further reduce the information collection burden for small business concerns with fewer than 25 employees.

I. ORDERING CLAUSES

68. *It is ordered,* pursuant to the authority found in sections 1, 2, 4, 7, 201, 301, 302a, 303, 307, 310, and 332 of the Communications Act of 1934, 47 U.S.C. 151, 152, 154, 157, 201, 301, 302a, 303, 307, 310, 332, section 706 of the Telecommunications Act of 1996, as amended, 47 U.S.C. 1302, and § 1.411 of the Commission's rules, 47 CFR 1.411, that this *NPRM is hereby adopted.*

69. *It is further ordered*, pursuant to section 4(i) of the Communications Act of 1934, 47 U.S.C. 154(i), and § 1.925 of the Commission's rules, that the Requests for Waivers filed by ZenFi Networks, Inc. on July 22, 2015, McKay Brothers, LLC on August 10, 2015, and SMG Holdings, LLC on November 12, 2015 *are denied.*

70. *It is ordered,* pursuant to section 4(i) of the Communications Act of 1934, 47 U.S.C. 154(i), and § 1.407 of the Commission's rules, that the Petition for Rulemaking of Battelle Memorial Institute, Inc. filed on February 6, 2014 is *granted-in-part* as described herein and *is otherwise denied.*

71. *It is ordered,* pursuant to section 4(i) of the Communications Act of 1934, 47 U.S.C. 154(i), and § 1.407 of the Commission's rules, that the Petition for Rulemaking of James Edwin Whedbee

filed on November 5, 2013 is *granted-in-part* as described herein.

72. *It is ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this *NPRM,* including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects

47 CFR Part 1

Environmental impact statements.

47 CFR Part 2

Radio.

47 CFR Part 5

Reporting and recordkeeping requirements and Radio.

47 CFR Part 15

Communications equipment and Radio.

47 CFR Part 101

Communications equipment and Radio.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR parts 1, 2, 5, 15, and 101 as follows:

PART 1—PRACTICE AND PROCEDURE

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

Authority: 47 U.S.C. 34–39, 151, 154(i), 154(j), 155, 157, 160, 201, 225, 227, 303, 309, 310, 332, 1403, 1404, 1451, 1452, 1455; 28 U.S.C. 2461 note.

■ 2. Amend § 1.1307 by revising the last entry of Table 1 in paragraph (b)(1) to read as follows:

§ 1.1307 Actions that may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared.

* * * * *

(b) * * *

(1) * * *

Service (title 47 CFR rule part)	Evaluation required if:
* *	* * * * *
70/80/90 GHz and above 95 GHz Bands (subpart Q of part 101).	Non-building–mounted antennas: height above ground level to lowest point of antenna < 10 m and power > 1640 W EIRP. Building-mounted antennas: power > 1640 W EIRP, licensees are required to attach a label to transceiver antennas that: (1) provides adequate notice regarding potential radiofrequency safety hazards, e. g., information regarding the safe minimum separation distance required between users and transceiver antennas; and (2) references the applicable FCC-adopted limits for radio-frequency exposure specified in § 1.1310.

* * * * *

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

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

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

■ 4. Amend § 2.803 by revising paragraph (c)(1) to read as follows:

§ 2.803 Marketing of radio frequency devices prior to equipment authorization.

* * * * *

(c) * * *

(1) Activities conducted under market trials pursuant to subpart H of part 5 or in accordance with a Spectrum Horizons experimental radio license issued pursuant to subpart I of part 5.

* * * * *

PART 5—EXPERIMENTAL RADIO SERVICE

■ 5. The authority citation for part 5 continues to read as follows:

Authority: Secs. 4, 302, 303, 307, 336 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 302, 303, 307, 336. Interpret or apply sec. 301, 48 Stat. 1081, as amended; 47 U.S.C. 301.

■ 6. Amend § 5.1 by revising paragraph (b) to read as follows:

§ 5.1 Basis and purpose.

* * * * *

(b) *Purpose.* The rules in this part provide the conditions by which portions of the radio frequency spectrum may be used for the purposes of experimentation and innovation, product development, and market trials.

■ 7. Amend § 5.3 by revising paragraph (l) and adding paragraph (m) to read as follows:

§ 5.3 Scope of service.

* * * * *

(l) Experimentation in innovative new devices and services that operate on frequencies above 95 GHz.

(m) Types of experiments that are not specifically covered under paragraphs (a) through (l) of this section will be considered upon demonstration of need for such additional types of experiments.

■ 8. Amend § 5.54 by redesignating paragraph (f) as paragraph (g) and adding a new paragraph (f) to read as follows:

§ 5.54 Types of authorizations available.

* * * * *

(f) *Spectrum Horizons experimental radio license.* This type of license is issued for the purpose of testing potentially innovative devices and services on frequencies above 95 GHz, where there are no existing service rules.

* * * * *

■ 9. Amend § 5.55 by revising paragraphs (c) and (d) to read as follows:

§ 5.55 Filing of applications.

* * * * *

(c) Each application for station authorization shall be specific and complete with regard to the information required by the application form and this part.

(1) Conventional and Spectrum Horizons license and STA applications shall be specific as to station location, proposed equipment, power, antenna height, and operating frequencies.

(2) Broadcast license applicants shall comply with the requirements in subpart D of this part; Program license applicants shall comply with the requirements in subpart E of this part; Medical Testing license applicants shall comply with the requirements in subpart F of this part; Compliance Testing license applicants shall comply with the requirements in subpart G of this part; and Spectrum Horizons license applicants shall comply with the requirements in subpart I of this part.

(d) Filing conventional, program, medical, compliance testing, and Spectrum Horizons experimental radio license applications:

(1) Applications for radio station authorization shall be submitted electronically through the Office of Engineering and Technology website *http://www.fcc.gov/els.*

(2) Applications for special temporary authorization shall be filed in accordance with the procedures of § 5.61.

(3) Any correspondence relating thereto that cannot be submitted electronically shall instead be submitted to the Commission's Office of Engineering and Technology, Washington, DC 20554.

* * * * *

■ 10. Amend § 5.59 by revising the paragraph (a) subject heading and paragraph (a)(1) to read as follows:

§ 5.59 Forms to be used.

(a) *Application for conventional, program, medical, compliance testing, and Spectrum Horizons experimental radio licenses—(1) Application for new authorization or modification of existing authorization.* Entities must submit FCC Form 442.

* * * * *

■ 12. Amend § 5.71 by adding paragraph (d) to read as follows:

§ 5.71 License period.

* * * * *

(d) *Spectrum Horizons experimental radio license.* Licenses are issued for a term of 10 years.

■ 13. Amend § 5.79 by revising the section heading and adding paragraph (c) to read as follows:

§ 5.79 Transfer and assignment of station authorization for conventional, program, medical testing, Spectrum Horizons, and compliance testing experimental radio licenses.

* * * * *

(c) A station authorization for a Spectrum Horizons experimental radio license, the frequencies authorized to be used by the grantee of such authorization, and the rights therein granted by such authorization shall be transferred, assigned, or in any manner either voluntarily or involuntarily disposed of, if the Commission decides that such a transfer is in the public interest and gives its consent in writing.

■ 14. Amend § 5.107 by adding paragraph (f) to read as follows:

§ 5.107 Transmitter control requirements.

* * * * *

(f) *Spectrum Horizons experimental radio licenses.* The licensee shall ensure that transmissions are in conformance with the requirements in subpart I of this part and that the station is operated only by persons duly authorized by the licensee.

■ 15. Amend § 5.115 by adding paragraph (d) to read as follows:

§ 5.115 Station identification.

* * * * *

(d) *Spectrum Horizons experimental radio licenses.* Spectrum Horizons experimental radio licenses shall transmit identifying information sufficient to identify the license holder and the geographic coordinates of the station. This information shall be transmitted at the end of each complete transmission except that: this information is not required at the end of each transmission for projects requiring continuous, frequent, or extended use of the transmitting apparatus, if, during such periods and in connection with such use, the information is transmitted at least once every thirty minutes. The station identification shall be transmitted in clear voice or Morse code. All digital encoding and digital modulation shall be disabled during station identification.

■ 16. Amend § 5.121 by revising paragraph (a) to read as follows:

§ 5.121 Station record requirements.

(a) For conventional, program, medical testing, compliance testing, and Spectrum Horizons experimental radio stations, the current original authorization or a clearly legible photocopy for each station shall be retained as a permanent part of the station records, but need not be posted. Station records are required to be kept for a period of at least one year after license expiration.

* * * * *

■ 17. Add subpart I, consisting of §§ 5.701 through 5.705, to read as follows:

Subpart I—Spectrum Horizons Experimental Radio Licenses

Sec.

5.701 Applicable rules.
5.702 Licensing requirement—necessary showing.
5.703 Responsible party.
5.704 Marketing of devices under Spectrum Horizons experimental radio licenses.
5.705 Interim report.

Subpart I—Spectrum Horizons Experimental Radio Licenses

§ 5.701 Applicable rules.

In addition to the rules in this subpart, Spectrum Horizons experimental radio station applicants and licensees shall follow the rules in subparts B and C of this part. In case of any conflict between the rules set forth in this subpart and the rules set forth in subparts B and C of this part, the rules in this subpart shall govern.

§ 5.702 Licensing requirement—necessary showing.

Each application must include a narrative statement describing in detail how its experiment could lead to the development of innovative devices and/or services on frequencies above 95 GHz. This statement must sufficiently explain the proposed new technology/potential new service and incorporate an interference analysis that explains why the proposed experiment would not cause harmful interference to any other spectrum user. The statement should include technical details, including the requested frequency band(s), maximum power, emission designators, area(s) of operation, type(s) of device(s) to be used, and the maximum number of each type of device to be used.

§ 5.703 Responsible party.

(a) Each program experimental radio applicant must identify a single point of contact responsible for all experiments conducted under the license and ensuring compliance with all applicable FCC rules.

(b) The responsible individual will serve as the initial point of contact for all matters involving interference resolution and must have the authority to discontinue any and all experiments being conducted under the license, if necessary.

(c) The license application must include the name of the responsible individual and contact information at which the person can be reached at any time of the day; this information will be listed on the license. Licensees are required to keep this information current.

§ 5.704 Marketing of devices under Spectrum Horizons experimental radio licenses.

Unless otherwise stated in the instrument of authorization, devices operating in accordance with a Spectrum Horizons experimental radio license may be marketed subject to the following conditions:

(a) Marketing of devices (as defined in § 2.803 of this chapter) and provision of services for hire is permitted before the radio frequency device has been authorized by the Commission, provided that the number of devices to be marketed shall be the minimum quantity of devices necessary to conduct the experiment as approved by the Commission.

(b) Licensees are required to ensure that trial devices are either rendered inoperable or retrieved by them from trial participants at the conclusion of the trial. Licensees are required to notify

trial participants in advance that operation of the trial device is subject to this condition.

(c) The size and scope of the experiment are subject to limitations as the Commission shall establish on a case-by-case basis. If the Commission subsequently determines that the experiment is not so limited, authorization shall be immediately terminated.

§ 5.705 Interim report.

Licensee must submit to the Commission an interim progress report 5 years after grant of its license.

PART 15—RADIO FREQUENCY DEVICES

■ 18. The authority citation for part 15 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, 304, 307, 336, 544a, and 549.

■ 19. Amend § 15.205 by revising paragraph (d)(4) to read as follows:

§ 15.205 Restricted bands of operation.

* * * * *

(d) * * *

(4) Any equipment operated under the provisions of § 15.255, § 15.256 in the frequency band 75–85 GHz, § 15.257, or § 15.258 of this part.

* * * * *

■ 20. Add § 15.258 to subpart C to read as follows:

§ 15.258 Operation in the bands 122–123 GHz, 174.8–182 GHz, 185–190 GHz and 244–246 GHz.

(a)(1) Operation under the provisions of this section is not permitted for equipment used on satellites.

(2) Operation on aircraft is permitted under the following conditions:

(i) When the aircraft is on the ground.

(ii) While airborne, only in closed exclusive on-board communication networks within the aircraft, with the following exceptions:

(A) Equipment shall not be used in wireless avionics intra-communication (WAIC) applications where external structural sensors or external cameras are mounted on the outside of the aircraft structure.

(B) Equipment shall not be used on aircraft where there is little attenuation of RF signals by the body/fuselage of the aircraft. These aircraft include, but are not limited to, toy/model aircraft, unmanned aircraft, crop-spraying aircraft, aerostats, etc.

(b) Emission levels within the 122–123 GHz, 174.8–182 GHz, 185–190 GHz and 244–246 GHz bands shall not exceed the following equivalent isotropically radiated power (EIRP) as measured during the transmit interval:

(1) The average power of any emission shall not exceed 40 dBm and the peak power of any emission shall not exceed 43 dBm; or

(2) For fixed point-to-point transmitters located outdoors, the average power of any emission shall not exceed 82 dBm, and shall be reduced by 2 dB for every dB that the antenna gain is less than 51 dBi. The peak power of any emission shall not exceed 85 dBm, and shall be reduced by 2 dB for every dB that the antenna gain is less than 51 dBi.

(i) The provisions in this paragraph for reducing transmit power based on antenna gain shall not require that the power levels be reduced below the limits specified in paragraph (b)(1) of this section.

(ii) The provisions of § 15.204(c)(2) and (4) that permit the use of different antennas of the same type and of equal or less directional gain do not apply to intentional radiator systems operating under this provision. In lieu thereof, intentional radiator systems shall be certified using the specific antenna(s) with which the system will be marketed and operated. Compliance testing shall be performed using the highest gain and the lowest gain antennas for which certification is sought and with the intentional radiator operated at its maximum available output power level. The responsible party, as defined in § 2.909 of this chapter, shall supply a list of acceptable antennas with the application for certification.

(3) The peak power shall be measured with an RF detector that has a detection bandwidth that encompasses the band of operation, *e.g.,* 122–123 GHz, 174.8–182 GHz, 185–190 GHz or 244–246 GHz, and that has a video bandwidth of at least 10 MHz. The average emission levels shall be measured over the actual time period during which transmission occurs.

(c) Limits on spurious emissions:

(1) The power density of any emissions outside the band of operation, *e.g.,* 122–123 GHz, 174.8–182 GHz, 185–190 GHz or 244–246 GHz, shall consist solely of spurious emissions.

(2) Radiated emissions below 40 GHz shall not exceed the general limits in § 15.209.

(3) Between 40 GHz and 200 GHz, the level of these emissions shall not exceed 90 pW/cm^2 at a distance of 3 meters.

(4) The levels of the spurious emissions shall not exceed the level of the fundamental emission.

(d) Except as specified paragraph (d)(1) of this section, the peak transmitter conducted output power shall not exceed 500 mW. Depending on the gain of the antenna, it may be necessary to operate the intentional radiator using a lower peak transmitter output power in order to comply with the EIRP limits specified in paragraph (b) of this section.

(1) Transmitters with an emission bandwidth of less than 100 MHz must limit their peak transmitter conducted output power to the product of 500 mW times their emission bandwidth divided by 100 MHz. For the purposes of this paragraph, emission bandwidth is defined as the instantaneous frequency range occupied by a steady state radiated signal with modulation, outside which the radiated power spectral density never exceeds 6 dB below the maximum radiated power spectral density in the band, as measured with a 100 kHz resolution bandwidth spectrum analyzer. The center frequency must be stationary during the measurement interval, even if not stationary during normal operation (*e.g.,* for frequency hopping devices).

(2) Peak transmitter conducted output power shall be measured with an RF detector that has a detection bandwidth that encompasses the band of operation, *e.g.,* 122–123 GHz, 174.8–182 GHz, 185–190 GHz or 244–246 GHz, and that has a video bandwidth of at least 10 MHz.

(3) For purposes of demonstrating compliance with this paragraph, corrections to the transmitter conducted output power may be made due to the antenna and circuit loss.

(e) Frequency stability: Fundamental emissions must be contained within the frequency bands specified in this section during all conditions of operation. Equipment is presumed to operate over the temperature range −20 to + 50 degrees Celsius with an input voltage variation of 85% to 115% of rated input voltage, unless justification is presented to demonstrate otherwise.

(f) Regardless of the power density levels permitted under this section, devices operating under the provisions of this section are subject to the radiofrequency radiation exposure requirements specified in §§ 1.1307(b), 2.1091 and 2.1093 of this chapter, as appropriate. Applications for equipment authorization of devices operating under this section must contain a statement confirming compliance with these requirements for both fundamental emissions and unwanted emissions. Technical information showing the basis for this statement must be submitted to the Commission upon request.

(g) Any transmitter that has received the necessary FCC equipment authorization under the rules of this chapter may be mounted in a group

installation for simultaneous operation with one or more other transmitter(s) that have received the necessary FCC equipment authorization, without any additional equipment authorization. However, no transmitter operating under the provisions of this section may be equipped with external phase-locking inputs that permit beam-forming arrays to be realized.

(h) Measurement procedures that have been found to be acceptable to the Commission in accordance with § 2.947 of this chapter may be used to demonstrate compliance.

PART 101—FIXED MICROWAVE SERVICES

■ 21. The authority citation for part 101 continues to read as follows:

Authority: 47 U.S.C. 154 and 303.

■ 22. Amend § 101.63 by revising paragraph (b) to read as follows:

§ 101.63 Period of construction; certification of completion of construction.

* * * * *

(b) For the 71–76 GHz, 81–86 GHz, 92–95 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands, the 12-month construction period will commence on the date of each registration of each individual link; adding links will not change the overall renewal period of the license.

* * * * *

■ 23. § 101.101 is amended by adding ten entries in numerical order to read as follows:

§ 101.101 Frequency availability.

Frequency band (MHz)	Radio service					
	Common carrier (part 101)	Private radio (part 101)	Broadcast auxiliary (part 74)	Other (parts 15, 21, 22, 24, 25, 74, 78 & 100)		Notes
*	*	*	*	*	*	*
95,000–100,000	CC	OFS			25	F/M/TF.
102,000–109,500	CC	OFS			25	F/M/TF.
111,800–114,250	CC	OFS			25	F/M/TF.
122,250–123,000	CC	OFS			25	F/M/TF.
130,000–134,000	CC	OFS			25	F/M/TF.
141,000–148,500	CC	OFS			25	F/M/TF.
151,500–158,500	CC	OFS			25	F/M/TF.
174,500–174,800	CC	OFS			25	F/M/TF.
231,500–232,000	CC	OFS			25	F/M/TF.
240,000–241,000	CC	OFS			25	F/M/TF.

* * * * *

■ 24. § 101.105 is amended by revising paragraphs (a)(5) introductory text and (c)(2)(i) and (ii) to read as follows:

§ 101.105 Interference protection criteria.

(a) * * *

(5) *71,000–76,000 MHz, 81,000–86,000 MHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands.* In these bands the following interference criteria shall apply:

* * * * *

(c) * * *

(2) * * *

(i) *Co-Channel Interference.* Both side band and carrier-beat, applicable to all bands; the existing or previously authorized system must be afforded a carrier to interfering signal protection ratio of at least 90 dB, except in the 952–960 MHz band where it must be 75 dB, and in the 71–76 GHz, 81–86 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands where the criteria in paragraph (a)(5) of this section applies, and in the 92,000–94,000 MHz and 94,100–95,000 MHz bands, where the criteria in paragraph (a)(6) of this section applies; or

(ii) *Adjacent Channel Interference.* Applicable to all bands; the existing or previously authorized system must be afforded a carrier to interfering signal protection ratio of at least 56 dB, except in the 71–76 GHz, 81–86 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands where the criteria in paragraph (a)(5) of this section applies, and in the 92–94 GHz and 94–95 GHz bands, where the criteria in paragraph (a)(6) of this section applies.

* * * * *

■ 25. Amend § 101.107 by adding ten entries to the table in paragraph (a) in numerical order and revising footnote 8 to read as follows:

§ 101.107 Frequency tolerance.

(a) * * *

Frequency (MHz)	Frequency tolerance (percent)
*	*
95,000–100,000 [8]	
102,000–109,500 [8]	
111,800–114,250 [8]	
122,250–123,000 [8]	
130,000–134,000 [8]	
141,000–148,500 [8]	
151,500–158,500 [8]	
174,500–174,800 [8]	
231,500–232,000 [8]	
240,000–241,000 [8]	

* * * * *

[8] Equipment authorized to be operated in the 71–76 GHz, 81–86 GHz, 92–95 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands is exempt from the frequency tolerance requirement noted in the table of paragraph (a) of this section.

* * * * *

■ 26. Amend § 101.109 by adding ten entries to the table in paragraph (c) in numerical order to read as follows:

§ 101.109 Bandwidth.

* * * * *

(c) * * *

Frequency band (MHz)	Maximum authorized bandwidth
*	*
95,000 to 100,000	5 GHz

Frequency band (MHz)	Maximum authorized bandwidth
102,000 to 109,500	7.5 GHz
111,800 to 114,250	2.45 GHz
122,250 to 123,000	750 MHz
130,000 to 134,000	4 GHz
141,000 to 148,500	7.5 GHz
151,500 to 158,500	7.5 GHz
174,500 to 174,800	300 MHz
231,500 to 232,000	500 MHz
240,000 to 241,000	1 GHz

* * * * *

■ 27. Amend § 101.111 by revising paragraph (a)(2)(v) to read as follows:

§ 101.111 Emission limitations.

(a) * * *

(2) * * *

(v) The emission mask for the 71–76 GHz, 81–86 GHz, 92–95 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands used in the equation in paragraph (a)(2)(ii) of this section applies only to the edge of each channel, but not to sub-channels established by licensees. The value of P in the equation is for the percentage removed from the carrier frequency and assumes that the carrier frequency is the center of the actual bandwidth used. The value of B will always be 500 MHz. In the case where a narrower sub-channel is used within the assigned bandwidth, such sub-carrier will be located sufficiently far from the channel edges to satisfy the emission levels of the mask. The mean output power used in the calculation is the sum of the output power of a fully populated channel.

* * * * *

■ 28. Amend § 101.113 by adding ten entries to the table in paragraph (a) in numerical order to read as follows:

§ 101.113 Transmitter power limitations.

(a) * * *

Frequency band (MHz)	Maximum allowable EIRP [1 2]	
	Fixed [1 2] (dBW)	Mobile (dBW)
*	*	*
95,000–100,000	25 dBW/MHz	25 dBW/MHz.
102,000–109,500	25 dBW/MHz	25 dBW/MHz.
111,800–114,250	25 dBW/MHz	25 dBW/MHz.
122,250–123,000	25 dBW/MHz	25 dBW/MHz.
130,000–134,000	25 dBW/MHz	25 dBW/MHz.
141,000–148,500	25 dBW/MHz	25 dBW/MHz.
151,500–158,500	25 dBW/MHz	25 dBW/MHz.
174,500–174,800	25 dBW/MHz	25 dBW/MHz.
231,500–232,000	25 dBW/MHz	25 dBW/MHz.
240,000–241,000	25 dBW/MHz	25 dBW/MHz.

* * * * *

■ 29. Amend § 101.115 by adding twenty entries to the table in paragraph (b) in numerical order and revising footnote 15 to read as follows:

§ 101.115 Directional antennas.

* * * * *

(b) * * *

Frequency (MHz)	Category	Maximum beam width to 3 dB points [1] (included angle in degrees)	Minimum antenna gain (dBi)	Minimum radiation suppression to angle in degrees from centerline of main beam in decibels						
				5° to 10°	10° to 15°	15° to 20°	20° to 30°	30° to 100°	100° to 140°	140° to 180°
*	*	*	*	*	*	*	*	*	*	*
95,000 to 100,000 (co-polar) [15]	N/A	1.2	43	35	40	45	50	50	55	55
95,000 to 100,000 (cross-polar) [15]	N/A	1.2	43	45	50	50	55	55	55	55
102,000 to 109,500 (co-polar) [15]	N/A	1.2	43	35	40	45	50	50	55	55
102,000 to 109,500 (cross-polar) [15]	N/A	1.2	43	45	50	50	55	55	55	55
111,800 to 114,250 (co-polar) [15]	N/A	1.2	43	35	40	45	50	50	55	55
111,800 to 114,250 (cross-polar) [15]	N/A	1.2	43	45	50	50	55	55	55	55
122,250 to 123,000 (co-polar) [15]	N/A	1.2	43	35	40	45	50	50	55	55
122,250 to 123,000 (cross-polar) [15]	N/A	1.2	43	45	50	50	55	55	55	55
130,000 to 134,000 (co-polar) [15]	N/A	1.2	43	35	40	45	50	50	55	55
130,000 to 134,000 (cross-polar) [15]	N/A	1.2	43	45	50	50	55	55	55	55
141,000 to 148,500 (co-polar) [15]	N/A	1.2	43	35	40	45	50	50	55	55
141,000 to 148,500 (cross-polar) [15]	N/A	1.2	43	45	50	50	55	55	55	55
151,500 to 158,500 (co-polar) [15]	N/A	1.2	43	35	40	45	50	50	55	55
151,500 to 158,500 (cross-polar) [15]	N/A	1.2	43	45	50	50	55	55	55	55
174,500 to 174,800 (co-polar) [15]	N/A	1.2	43	35	40	45	50	50	55	55
174,500 to 174,800 (cross-polar) [15]	N/A	1.2	43	45	50	50	55	55	55	55
231,500 to 232,000 (co-polar) [15]	N/A	1.2	43	35	40	45	50	50	55	55
231,500 to 232,000 (cross-polar) [15]	N/A	1.2	43	45	50	50	55	55	55	55
240,000 to 241,000 (co-polar) [15]	N/A	1.2	43	35	40	45	50	50	55	55
240,000 to 241,000 (cross-polar) [15]	N/A	1.2	43	45	50	50	55	55	55	55

* * * * * * *

[15] Antenna gain less than 50 dBi (but greater than or equal to 43 dBi) is permitted only with a proportional reduction in maximum authorized EIRP in a ratio of 2 dB of power per 1 dB of gain, so that the maximum allowable EIRP (in dBW/MHz) for antennas of less than 50 dBi gain becomes 25 − 2(50–G), where G is the antenna gain in dBi. In addition, antennas in these bands must meet two additional standards for minimum radiation suppression: At angles between 1.2 and 5 degrees from the centerline of the main beam, co-polar discrimination must be G − 28, where G is the antenna gain in dBi; and at angles of less than 5 degrees from the centerline of main beam, cross-polar discrimination must be at least 25 dB.

* * * * * * *

■ 30. Amend § 101.139 by revising paragraph (h) to read as follows:

§ 101.139 Authorization of transmitters.

* * * * *

(h) *71–76 GHz; 81–86 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz.* For equipment employing digital modulation techniques, the minimum bit rate requirement is 0.125 bit per second per Hz.

* * * * *

■ 31. Amend § 101.147 by adding ten entries to the list of frequency bands in paragraph (a) and revising the paragraph (z) subject heading and paragraph (z)(2) to read as follows:

§ 101.147 Frequency assignments.

(a) * * *

95,000,100,000 MHz
102,000–109,500 MHz
111,800–114,250 MHz
122,250–123,000 MHz
130,000–134,000 MHz
141,000–148,500 MHz
151,500–158,500 MHz
174,500–174,800 MHz
231,500–232,000 MHz
240,000–241,000 MHz

* * * * *

(z) *71–76 GHz, 81–86 GHz, 92–94 GHz, 94.1–95 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz.*

* * * * *

(2) Prior links shall be protected using the interference protection criteria set forth in § 101.105. For transmitters employing digital modulation techniques and operating in the 71–76 GHz, 81–86 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands, the licensee must construct a system that meets a minimum bit rate of 0.125 bits per second per Hertz of bandwidth. For transmitters that operate in the 92,000–94,000 MHz or 94,100–95,000 MHz bands, licensees must construct a system that meets a minimum bit rate of 1.0 bit per second per Hertz of bandwidth. If it is determined that a licensee has not met these loading requirements, then the database will be modified to limit coordination rights to the spectrum that is loaded and the licensee will lose protection rights on spectrum that has not been loaded.

Subpart Q—Service and technical rules for the 70/80/90 GHz and above 95 GHz Bands

■ 32. Amend subpart Q by revising the subpart heading to read as set forth above.

■ 33. Revise § 101.1501 to read as follows:

§ 101.1501 Service areas.

The 71–76 GHz, 81–86 GHz, 92–95 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands are licensed on the basis of non-exclusive nationwide licenses. There is no limit to the number of non-exclusive nationwide licenses that may be granted for these bands, and these licenses will serve as a prerequisite for registering individual links.

■ 34. Amend § 101.1505 by adding paragraph (c) to read as follows:

§ 101.1505 Segmentation plan.

* * * * *

(c) An entity may request any portion of the 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands.

■ 35. Revise § 101.1507 to read as follows:

§ 101.1507 Permissible operations.

Licensees may use the 71–76 GHz, 81–86 GHz, 92–95 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands for any point-to-point, non-broadcast service. The segments may be unpaired or paired, but pairing will be permitted only in a standardized manner (*e.g.,* 71–72.25 GHz may be paired only with 81–82.25 GHz, and so on). The segments may be aggregated without limit.

■ 36. Amend § 101.1523 by revising paragraph (a) to read as follows:

§ 101.1523 Sharing and coordination among non-Government licensees and between non-Government and Government services.

(a) Registration of each link in the 71–76 GHz, 81–86 GHz, 92–95 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands will be in the Universal Licensing System until the Wireless Telecommunications Bureau announces by public notice the implementation of a third-party database.

* * * * *

■ 37. Revise § 101.1525 to read as follows:

§ 101.1525 RF safety.

Licensees in the 71–76 GHz, 81–86 GHz, 92–95 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz bands are subject to the exposure requirements found in §§ 1.1307(b), 2.1091 and 2.1093 of this chapter, and will use the parameters found therein.

■ 38. Amend § 101.1527 by revising paragraph (a) and paragraph (b) introductory text to read as follows:

§ 101.1527 Canadian and Mexican coordination.

(a) A licensee of bands 71–76 GHz, 81–86 GHz, 92–95 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz must comply with § 1.928(f) of this chapter, which pertains to coordination with Canada.

(b) A licensee of bands 71–76 GHz, 81–86 GHz, 92–95 GHz, 95–100 GHz, 102–109.5 GHz, 111.8–114.25 GHz, 122.25–123 GHz, 130–134 GHz, 141–148.5 GHz, 151.5–158.5 GHz, 174.5–174.8 GHz, 231.5–232 GHz, and 240–241 GHz must coordinate with Mexico in the following situations:

* * * * *

[FR Doc. 2018–06179 Filed 3–30–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 18–23; FCC 18–20]

Elimination of Obligation To File Broadcast Mid-Term Report (Form 397) Under Section 73.2080(f)(2)

AGENCY: Federal Communications Commission.

ACTION: Propose rule; correction.

SUMMARY: This document corrects the preamble to a proposed rule published in the **Federal Register** on March 21, 2018 regarding the EEO Broadcast Mid-Term Report. The comment periods in

the **DATES** section of the proposed rule published on March 21, 2018, inaccurately reflected a 60-day comment period and 90-day reply comment period, instead of the 30-day comment, 45-day reply comment deadline stated in the proposed rule. Any comments made before this correction is published will be considered.

DATES: Comments are due on or before April 30, 2018; reply comments are due on or before May 15, 2018.

ADDRESSES: You may submit comments, identified by MB Docket No. 18–20, by any of the following methods:

• *Federal Communications Commission's website: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.

• *Mail:* Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's

• Secretary, Office of the Secretary, Federal Communications Commission.

• *People With Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: (202) 418–0530 or TTY: (202) 418–0432. For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Jonathan Mark, *Jonathan.Mark@fcc.gov,* of the Media Bureau, Policy Division, (202) 418–3634. Direct press inquiries to Janice Wise at (202) 418–8165.

Correction: In the **Federal Register** of March 21, 2018, in FR Doc. 2018–05726, on page 12313, in the third column, correct the **DATES** caption to read:

DATES: Comments are due on or before April 30, 2018; reply comments are due on or before May 15, 2018.

Dated: March 28, 2018.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2018–06599 Filed 3–30–18; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 578

[Docket No. NHTSA–2018–0017]

RIN 2127–AL94

Civil Penalties

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes a civil penalty rate applicable to automobile manufacturers that fail to meet applicable corporate average fuel economy (CAFE) standards and are unable to offset such a deficit with compliance credits. The agency is proposing this civil penalty rate based on a tentative determination regarding the applicability of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, and in accordance with the Energy Policy and Conservation Act of 1975 (EPCA) and the Energy Independence and Security Act of 2007 (EISA).

DATES: *Comments:* Comments must be received by May 2, 2018.

ADDRESSES: You may submit comments to the docket number identified in the heading of this document by any of the following methods:

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

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

• *Hand Delivery or Courier:* U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m. Eastern time, Monday through Friday, except Federal holidays.

• Fax: 202–493–2251

FOR FURTHER INFORMATION CONTACT: Kerry Kolodziej, Office of Chief Counsel, NHTSA, telephone (202) 366–2992, facsimile (202) 366–3820, 1200 New Jersey Ave, SE, Washington, DC 20590.

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A. Executive Summary

NHTSA has almost forty years of experience in implementing the corporate average fuel economy (CAFE) program and its civil penalty component. This includes oversight and administration of the program's operation, how the automobile manufacturers respond to CAFE standards and increases, and the role of civil penalties in achieving the CAFE program's objectives. NHTSA has carefully considered these objectives in reconsidering the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Inflation Adjustment Act or 2015 Act) and its application to the CAFE civil penalty statute NHTSA administers.

As a result of this review, NHTSA is proposing to retain the current civil penalty rate in 49 U.S.C. 32912(b) of $5.50 per tenth of a mile per gallon for automobile manufacturers that do not meet applicable CAFE standards and are unable to offset such a deficit with compliance credits. NHTSA's proposal is based on its tentative determination that the CAFE civil penalty rate is not a ''civil monetary penalty,'' as defined by the 2015 Act, that must be adjusted for inflation. NHTSA's previous **Federal Register** notices on its inflation adjustments under the 2015 Act did not consider whether the CAFE civil penalty rate fit the definition of a ''civil monetary penalty'' subject to adjustment under the 2015 Act, instead

proceeding—without analysis—as if the 2015 Act applied to the CAFE civil penalty rate. After taking the opportunity to fully analyze the issue, NHTSA tentatively concludes that the CAFE civil penalty rate is not covered by the 2015 Act and seeks comment on four ways that the provisions of the 2015 Act could be best approached.

First, civil penalties assessed for CAFE violations under Section 32912(b) are not a ''penalty, fine, or other sanction that'' is either ''a maximum amount'' or ''a specific monetary amount.'' Rather, the civil penalties under consideration here are part of a complicated market-based enforcement mechanism. Any potential civil penalties for failing to satisfy fuel economy requirements, unlike other civil penalties, are not determined until the conclusion of a complex formula, credit-earning arrangement, and credit transfer and trading program. In fact, the ultimate penalty assessed is based on the noncompliant *manufacturer's* decision, not NHTSA's, on whether and how to acquire and apply any credits that may be available to the manufacturer, and on the decisions of *other* manufacturers to earn and sell credits to a potentially liable manufacturer. In other words, what the noncompliant manufacturer pays is as much a function of market forces as it is the CAFE penalty rate.

Moreover, NHTSA tentatively concludes that Congress did not intend for the 2015 Act to apply to this specialized civil penalty rate, which has longstanding, strict procedures previously enacted by Congress that limit NHTSA's ability to increase the rate. Congress specifically contemplated that increases to the CAFE civil penalty rate for manufacturer non-compliance with CAFE standards may be appropriate and necessary and included a mechanism in the statute for such increases. Critically, this mechanism requires the Secretary of Transportation to determine specifically that any such increase will not lead to certain specific negative economic effects. In addition, Congress explicitly limited any such increase to $10 per tenth of a mile per gallon.[1] These restrictions have been in place since the statute was amended in 1978. Though Congress later amended the CAFE civil penalty provision in 2007, Congress did not amend either the mechanism for increases or the upper limit of an increased civil penalty under the statute. NHTSA seeks comment on this analysis.

Second, in the alternative, NHTSA is proposing to keep the civil penalty rate the same in order to comply with EPCA, which must be read harmoniously with the 2015 Act. The 2015 Act confers discretion to the head of each agency to adjust the amount of a civil monetary penalty by less than the amount otherwise required for the initial adjustment, with the concurrence with the Director of the Office of Management and Budget, upon determining that doing so would have a ''negative economic impact'' In EPCA, Congress previously identified specific factors that NHTSA is required to consider before making a determination about the ''impact on the economy'' as a prerequisite to increasing the applicable civil penalty rate. NHTSA believes that these statutory criteria are appropriate for determining whether an increase in the CAFE civil penalty rate would have a ''negative economic impact'' for purposes of the 2015 Act. Under EPCA, NHTSA faces a heavy burden to demonstrate that increasing the civil penalty rate ''will not have a substantial deleterious impact on the economy of the United States, a State, or a region of a State.'' Specifically, in order to establish that the increase would not have that ''substantial deleterious impact,'' NHTSA would need to affirmatively determine that it is likely that the increase would *not* cause a significant increase in unemployment in a State or a region of a State; adversely affect competition; or cause a significant increase in automobile imports. In light of those statutory factors—and the absence of evidence to the contrary—NHTSA tentatively concludes it is likely that increasing the CAFE civil penalty rate would have a negative economic impact and thus is proposing not to adjust the rate under the 2015 Act. NHTSA is soliciting comments on this proposal, including whether the inflation adjustment would have a ''negative economic impact,'' and if so, how much less than the amount otherwise required should the penalty level be adjusted.

Third, even if EPCA's statutory factors for increasing civil penalties are not applied, NHTSA has tentatively determined that the $14 penalty will lead to a negative economic impact that merits leaving the CAFE civil penalty rate at $5.50. Based on available information, including information provided by commenters, the effect of applying the 2015 Act to the CAFE civil penalty could potentially drastically increase manufacturers' costs of compliance beyond those contemplated when NHTSA established the current CAFE standards in 2012. NHTSA is soliciting comments on this tentative conclusion, including the level at which the CAFE civil penalty rate should be set.

Fourth, even if the CAFE civil penalty rate is a ''civil monetary penalty'' under the 2015 Act and regardless of whether increasing it would have a ''negative economic impact,'' the increase is capped by statute at $10 by EPCA. NHTSA seeks comment on this alternative, including whether the $10 cap is itself a ''civil monetary penalty'' that is required to be adjusted under the 2015 Act.

NHTSA is also proposing an inflationary adjustment to the general penalty for other violations of EPCA, as amended.

B. Statutory and Regulatory Background

NHTSA sets [2] and enforces [3] corporate average fuel economy (CAFE) standards for the United States light-duty vehicle fleet, and in doing so, assesses civil penalties against vehicle manufacturers that fall short of their compliance obligations and are unable to make up the shortfall with credits.[4] The civil penalty amount for CAFE non-compliance was originally set by statute in 1975, and since 1997, has included a rate of $5.50 per each tenth of a mile per gallon (0.1) that a manufacturer's fleet average CAFE level falls short of its compliance obligation. This shortfall amount is then multiplied by the number of vehicles in that manufacturer's fleet.[5] The basic equation for calculating a manufacturer's civil penalty amount before accounting for credits, is as follows:

(penalty rate, in $ per 0.1 mpg per vehicle) × (amount of shortfall, in tenths of an mpg) × (# of vehicles in manufacturer's non-compliant fleet).

Without even accounting for costs of generating or purchasing credits, automakers have paid more than $890 million in CAFE civil penalties, up to and including model year (MY) 2014

[1] NHTSA tentatively concludes the 2015 Act also does not apply to the $10 cap.

[2] 49 U.S.C. 32902.

[3] 49 U.S.C. 32911, 32912.

[4] Credits may be either *earned* (for over-compliance by a given manufacturer's fleet, in a given model year), *transferred* (from one fleet to another), or *purchased* (in which case, another manufacturer earned the credits by over-complying and chose to sell that surplus). 49 U.S.C. 32903.

[5] A manufacturer may have up to three fleets of vehicles, for CAFE compliance purposes, in any given model year—a domestic passenger car fleet, an imported passenger car fleet, and a light truck fleet. Each fleet belonging to each manufacturer has its own compliance obligation, with the potential for either over-compliance or under-compliance. There is no overarching CAFE requirement for a manufacturer's total production.

vehicles.[6] Starting with the model year 2011, provisions in the CAFE program provided for credit transfers among a manufacturer's various fleets. Starting with that model year, the law also provided for trading between vehicle manufacturers, which has allowed vehicle manufacturers the opportunity to acquire credits from competitors rather than paying civil penalties for non-compliance. Manufacturers are required to notify NHTSA of the volumes of credits traded or sold, but the agency does not receive any information regarding total cost paid or cost per credit. NHTSA believes it is likely that credit purchases involve significant expenditures and that an increase in the penalty rate would correlate with an increase in such expenditures. The agency currently anticipates many manufacturers will face the possibility of paying larger CAFE penalties or incurring increased costs to acquire credits over the next several years than at present.[7]

NHTSA has long had authority under the Energy Policy and Conservation Act (EPCA) of 1975, Public Law 94–163, 508, 89 Stat. 912 (1975), to raise the amount of the penalty for CAFE shortfalls if it can make certain findings,[8] as well as the authority to compromise and remit such penalties under certain circumstances.[9] If NHTSA were to raise the penalty rate for CAFE shortfalls, the higher amount would apply to *any* manufacturer that owed them; the authority to compromise and remit penalties, however, is extremely limited and on a case-by-case basis. To date, NHTSA has never utilized its ability to compromise or remit a CAFE civil penalty.

Recognizing the economic harm that CAFE civil penalties could have on the automobile industry and the economy as a whole, Congress capped any increase in the original statutory penalty rate at $10 per tenth of a mile per gallon. Further—and significantly—it provided that NHTSA may only raise CAFE penalties under EPCA if it concludes through rulemaking that the increase in the penalty rate both (1) will result in, or substantially further, substantial energy conservation for automobiles in model years in which the increased penalty may be imposed, *and* (2) will not have a substantial deleterious impact on the economy of the United States, a State, or a region of the State. A finding of ''no substantial deleterious impact'' may only be made if NHTSA determines that it is likely that the increase in the penalty (A) will not cause a significant increase in unemployment in a State or a region of a State, (B) adversely affect competition, or (C) cause a significant increase in automobile imports. Nowhere does EPCA define ''substantial'' or ''significant'' in the context of this provision.

If NHTSA seeks to compromise or remit penalties for a given manufacturer, a rulemaking is not necessary, but the amount of a penalty may be compromised or remitted only to the extent (1) necessary to prevent a manufacturer's insolvency or bankruptcy, (2) the manufacturer shows that the violation was caused by an act of God, a strike, or a fire, or (3) the Federal Trade Commission certifies that a reduction in the penalty is necessary to prevent a substantial lessening of competition. NHTSA has never previously attempted to undertake this process.

C. Civil Penalties Inflation Adjustment Act Improvements Act of 2015

On November 2, 2015, the Federal Civil Penalties Inflation Adjustment Act Improvements Act (Inflation Adjustment Act or 2015 Act), Public Law 114–74, Section 701, was signed into law. The 2015 Act required federal agencies to make an initial ''catch-up'' adjustment to the ''civil monetary penalties,'' as defined, they administer through an interim final rule and then to make subsequent annual adjustments for inflation. The amount of increase for any ''catch-up'' adjustment to a civil monetary penalty pursuant to the 2015 Act was limited to 150 percent of the then-current penalty. Agencies were required to issue an interim final rule, without providing the opportunity for public comment ordinarily required under the Administrative Procedure Act, for the initial ''catch-up'' adjustment by July 1, 2016.

The method of calculating inflationary adjustments in the 2015 Act differs substantially from the methods used in past inflationary adjustment rulemakings conducted pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (the 1990 Inflation Adjustment Act), Public Law 101–410. Civil penalty adjustments under the 1990 Inflation Adjustment Act were conducted under rules that sometimes required significant rounding of figures.

The 2015 Act altered these rounding rules. Now, penalties are simply rounded to the nearest $1. Furthermore, the 2015 Act ''resets'' the inflation calculations by excluding prior inflationary adjustments under the 1990 Inflation Adjustment Act. To do this, the 2015 Act requires agencies to identify, for each civil monetary penalty, the year and corresponding amount(s) for which the maximum penalty level or range of minimum and maximum penalties was established (*i.e.,* originally enacted by Congress) or last adjusted other than pursuant to the 1990 Inflation Adjustment Act.

The Director of the Office of Management and Budget (OMB) provided guidance to agencies in a February 24, 2016 memorandum.[10] For those penalties an agency determined to be ''civil monetary penalties,'' the memorandum provided guidance on how to calculate the initial adjustment required by the 2015 Act. The initial catch up adjustment is based on the change between the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October in the year the penalty amount was established or last adjusted by Congress and the October 2015 CPI–U. The February 24, 2016 memorandum contains a table with a multiplier for the change in CPI–U from the year the penalty was established or last adjusted to 2015. To arrive at the adjusted penalty, the agency must multiply the penalty amount when it was established or last adjusted by Congress, excluding adjustments under the 1990 Inflation Adjustment Act, by the multiplier for the increase in CPI–U from the year the penalty was established or adjusted as provided in the February 24, 2016 memorandum. The 2015 Act limits the initial inflationary increase to 150 percent of the current penalty. To determine whether the increase in the adjusted penalty is less than 150 percent, the agency must multiply the current penalty by 250 percent. The adjusted penalty is the lesser of either the adjusted penalty based on the multiplier for CPI–U in Table A of the February 24,

[6] Fine reporting for MY15 and newer vehicles was not reported at the time of this proposal. The highest CAFE penalty paid to date for a shortfall in a single fleet was $30,257,920, paid by DaimlerChrysler for its imported passenger car fleet in MY 2006. Since MY 2012, only Jaguar Land Rover and Volvo have paid civil penalties. *See https://one.nhtsa.gov/cafe_pic/CAFE_PIC_Fines_LIVE.html.*

[7] NHTSA's *Projected Fuel Economy Performance Report*7 indicates that many manufacturers are falling behind the standards for model year 2016 and increasingly so for model year 2017.

[8] 49 U.S.C. 32912.

[9] 49 U.S.C. 32913.

[10] Memorandum from the Director of OMB to Heads of Executive Departments and Agencies, Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Feb. 24, 2016), available online at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2016/m-16-06.pdf* (last accessed December 14, 2017).

2016 memorandum or an amount equal to 250% of the current penalty.

Additionally, the 2015 Act gives agencies discretion to adjust the amount of a civil monetary penalty by less than otherwise required if the agency determines that increasing the civil monetary penalty by the otherwise required amount will have either a negative economic impact or if the social costs of the increased civil monetary penalty will outweigh the benefits.[11] In either instance, the agency must publish a notice, take and consider comments on this finding, and receive concurrence on this determination from the Director of OMB prior to finalizing a lower civil penalty amount.

D. NHTSA's Actions to Date Regarding CAFE Civil Penalties

1. Interim Final Rule

On July 5, 2016, NHTSA published an interim final rule, adopting inflation adjustments for civil penalties under its administration, following the procedure and the formula in the 2015 Act. NHTSA did not analyze at that time whether the 2015 Act applied to all of its civil penalties. One of the adjustments NHTSA made at the time was raising the civil penalty rate for CAFE non-compliance from $5.50 to $14.[12] NHTSA also indicated in that notice that the maximum penalty rate that the Secretary is permitted to establish for such violations would increase from $10 to $25, although this was not codified in the regulatory text.[13] NHTSA also raised the maximum civil penalty for other violations of EPCA, as amended, to $40,000.[14]

In response to the changes to the CAFE penalty provisions issued in the interim final rule, the Alliance of Automobile Manufacturers (Alliance) and the Association of Global Automakers (Global) jointly petitioned NHTSA for reconsideration (the Industry Petition).[15] The Industry Petition raised concerns with the significant impact, which they estimated to be at least $1 billion annually, that the increased penalty rate would have on CAFE compliance costs. Specifically, the Industry Petition raised: The issue of retroactivity (applying the penalty increase associated with model years that have already been completed or for which a company's compliance plan had already been ''set''); which ''base year'' (*i.e.,* the year the penalty was established or last adjusted) NHTSA should use for calculating the adjusted penalty rate; and whether an increase in the penalty rate to $14 would cause a ''negative economic impact.''

2. Final Rule

In response to the Industry Petition, NHTSA issued a final rule on December 28, 2016.[16] In that rule, NHTSA agreed that raising the penalty rate for model years already fully complete would be inappropriate, given how courts generally disfavor the retroactive application of statutes. NHTSA also agreed that raising the rate for model years for which product changes were infeasible due to lack of lead time, did not seem consistent with Congress' intent that the CAFE program be responsive to consumer demand. NHTSA therefore stated that it would not apply the inflation-adjusted penalty rate of $14 until model year 2019, as the agency believed that would be the first year in which product changes could be made in response to the higher penalty rate.

3. Reconsideration and Request for Comments

Before NHTSA's December 2016 final rule became effective, in January 2017, NHTSA took action to delay the effective date of the December 2016 CAFE civil penalties rule.[17] As part of that action, and in light of CAFE compliance data submitted by manufacturers to NHTSA showing that many automakers would begin to fall behind in meeting their applicable CAFE standards beginning in model years 2016 and 2017,[18] the agency requested public comment on the civil penalties—the first opportunity the public had to do so.[19] The comment period closed on October 10, 2017. NHTSA received thirteen comments from various interested parties.

Commenters included industry stakeholders and citizens. The array of commenters also included representatives from environmental groups, academia, and state governments such as attorneys general and environmental quality divisions. Industry stakeholders included comments from trade organizations and vehicle manufacturers.[20]

Generally, commenters from environmental organizations, attorneys general of 10 states, and academia expressed support for upholding the December 2016 final rule. In addition, those supporting the $14 civil penalty generally asserted reconsidering the 2016 final rule was outside of NHTSA's authority. None of the comments received from commenters specifically addressed whether the CAFE civil penalty rate was a ''civil monetary penalty'' as defined by the 2015 Act.

Vehicle manufacturers, either directly or via their respective representing organizations, also expressed support for the reconsideration of the 2016 final rule. These commenters provided an analysis of how increased CAFE civil penalties could potentially impact their efforts to develop and sell vehicles in the marketplace when faced with anticipated increases in CAFE stringencies. These commenters expressed support for using 2007 as the base year for calculating inflation adjusted increases in CAFE civil penalty amounts.

Additionally, some commenters suggested civil penalty amounts of 47 dollars per 0.1 mpg and $8.47 per 0.1 mpg, the latter a 54% increase over the $5.50 per 0.1 mpg value.

The California Air Resources Board (CARB) commented that NHTSA's considerations when adjusting a civil penalty rate under EPCA do not matter for purposes of making an adjustment under the 2015 Act. CARB also stated that in past joint documents, NHTSA did not indicate that the $5.50 civil penalty rate would have a negative economic impact.

The Alliance and Global suggested that NHTSA's considerations when adjusting a civil penalty rate under EPCA are informative for purposes of making a determination of negative economic impact under the 2015 Act.

The December 28, 2016 final rule is not yet effective, and during reconsideration, the applicable civil penalty rate was $5.50 per tenth of a

[11] Public Law 114–74, Sec. 701(c).

[12] 81 FR 43524 (July 5, 2016). This interim final rule also updated the maximum civil penalty amounts for violations of all statutes and regulations administered by NHTSA, and was not limited solely to penalties administered for CAFE violations.

[13] For the reasons described in Section E.1, NHTSA is proposing to leave the maximum penalty rate that the Secretary is permitted to establish for such violations at $10.

[14] 81 FR 43524 (July 5, 2016).

[15] Jaguar Land Rover North America, LLC also filed a petition for reconsideration in response to the July 5, 2016 interim final rule raising the same concerns as those raised in the Industry Petition. Both petitions, along with a supplement to the Industry Petition, can be found in Docket ID NHTSA–2016–0075 at *www.regulations.gov.*

[16] 81 FR 95489 (December 28, 2016).

[17] 82 FR 8694 (January 30, 2017); 82 FR 15302 (March 28, 2017); 82 FR 29009 (June 27, 2017); 82 FR 32139 (July 12, 2017). The portions of the July 5, 2016 interim final rule not dealing with CAFE remain in effect and are expected to be finalized as part of NHTSA's 2018 inflationary adjustments.

[18] ''MYs 2016 and 2017 Projected Fuel Economy Performance Report,'' February 14, 2017, available at *https://one.nhtsa.gov/cafe_pic/AdditionalInfo.htm*

[19] 82 FR 32140 (July 12, 2017).

[20] Comments on this notice of proposed rulemaking can be found at: *https://www.regulations.gov/docket?D=NHTSA-2017-0059.*

mile per gallon, which was the civil penalty rate prior to NHTSA's inflationary adjustment.[21] NHTSA's delay of the final rule pending reconsideration did not affect the amount of any CAFE penalties that would have otherwise applied prior to Model Year 2019.

E. Proposed Revisions to the CAFE Civil Penalty Rate

In this notice of proposed rulemaking (NPRM), NHTSA is announcing that it has tentatively determined, upon reconsideration, that the 2015 Act should not be applied to the CAFE civil penalty formula provision found in 49 U.S.C. 32912 and is proposing to retain the current civil penalty rate of $5.50 per .1 of a mile per gallon.[22] The agency is proposing this based on a legal determination that the CAFE civil penalty rate is not a ''civil monetary penalty'' as contemplated by the 2015 Act and that therefore the 2015 Act should not be applied to the NHTSA CAFE civil penalty formula. Additionally, in the alternative, NHTSA is proposing to maintain the current civil penalty rate based on a tentative finding that—in light of the factors Congress requires NHTSA to analyze in determining whether an increase in the civil penalty rate will have ''a substantial deleterious impact on the economy''—increasing the CAFE civil penalty rate would result in negative economic impact. Pursuant to OMB's guidance, NHTSA has consulted with OMB before proposing this reduced catch-up adjustment determination and submitted this notice of proposed rulemaking (NPRM) to the Office of Information and Regulatory Affairs (OIRA) for review. . In addition, if NHTSA determines that a reduced catch-up adjustment is appropriate in its final rule, it will seek OMB's concurrence before promulgating the rule, as required by the 2015 Act and confirmed by OMB's guidance. Finally, in this NPRM NHTSA has provided a series of tentative interpretations of the 2015 Act. In light of OMB's role in providing agencies guidance about the 2015 Act, NHTSA has requested OMB's views about the 2015 Act.

NHTSA is also proposing to finalize the 2017 and 2018 inflationary adjustments for the maximum penalty for general CAFE violations in 49 U.S.C. 32912(a).

1. NHTSA Is Proposing To Retain the $5.50 CAFE Civil Penalty Rate Because the 2015 Act Is Inapplicable

Upon reconsideration, NHTSA has tentatively determined that the 2015 Act is not applicable to the CAFE civil penalty formula. The penalty in 49 U.S.C. 32912(b) for a manufacturer that violates fuel economy standards is not a ''civil monetary penalty'' subject to inflationary adjustment under the 2015 Act. This reflects a change in NHTSA's position on this issue from when NHTSA previously adjusted the CAFE civil penalty rate from $5 to $5.50.[23] Given that the current penalty figure has been in effect since it was set twenty years ago, NHTSA proposes to apply its new position on a prospective basis only from the effective date of the final rule of this rulemaking. As a result of this change, NHTSA is proposing to retain the $5.50 multiplier in the CAFE civil penalty formula. NHTSA requests comment on this issue.

The 2015 Act requires agencies to adjust ''civil monetary penalties'' for inflation.[24] A '''civil monetary penalty' means any penalty, fine, or other sanction'' that meets three requirements.[25] First, the ''penalty, fine, or other sanction'' must be ''for a specific monetary amount as provided by Federal law'' or have ''a maximum amount provided for by Federal law.''[26] Second, the ''penalty, fine, or other sanction'' must be ''assessed or enforced by an agency pursuant to Federal law.''[27] Third, the ''penalty, fine, or other sanction'' must be ''assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts.''[28]

The 2015 Act required the Office of Management and Budget (OMB) to ''issue guidance to agencies on implementing the inflation adjustments'' under the Act.[29] OMB issued guidance on February 24, 2016 that stated: ''Agencies are responsible for identifying the civil monetary penalties that fall under the statutes and regulations they enforce'' and for determining the ''applicability of the inflation adjustment requirement to an individual penalty . . . .''[30] In none of NHTSA's July 2016 interim final rule, its December final rule, its July 2017 request for comments, nor its earlier adjustment from $5 to $5.50 did NHTSA specifically address whether the penalty for manufacturer violations of fuel economy standards in 49 U.S.C. 32912(b) is a ''civil monetary penalty'' subject to inflationary adjustment under the 2015 Act, or more generally, whether the 2015 Act should be made applicable to the penalty in Section 32912(b). Instead, it applied the 2015 Act without specific analysis of these issues.

Upon evaluation, NHTSA has tentatively concluded the penalty for manufacturer violations of fuel economy standards in 49 U.S.C. 32912(b) is not a ''civil monetary penalty'' subject to adjustment under the 2015 Act. Upon similar evaluation, NHTSA also has tentatively concluded the $10 limit for such violations in 49 U.S.C. 32912(c)(1)(B) is not a ''civil monetary penalty'' subject to adjustment under the 2015 Act either. To be a ''civil monetary penalty,'' a penalty must meet all three criteria in the statutory definition.[31] The penalty for manufacturer violations of fuel economy

[21] 82 FR 32140 (July 12, 2017). If the December 28, 2016 final rule had gone into effect, the penalty rate would have remained $5.50 until MY 2019.

[22] NHTSA chose to reconsider its prior determination consistent with its statutory authority to administer the CAFE standards program and its inherent authority to do so efficiently and in the public interest. *See, e.g., Tokyo Kikai Seisakusho, Ltd.* v. *United States,* 529 F.3d 1352, 1360–61 (Fed. Cir. 2008) (''[A]dministrative agencies possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so.''). OMB's February 2016 guidance confirms that each agency is ''responsible for identifying the civil monetary penalties that fall under the statutes and regulations [it] enforce[s].'' And, as repeatedly confirmed by courts, an agency may reconsider how it previously interpreted a statute, particularly when its updated interpretation ''closely fits the design of the statute as a whole and its object and policy.'' *Good Samaritan Hosp.* v. *Shalala,* 508 U.S. 402, 417–18 (1993) (cleaned up); *see also Nat'l Classification Comm.* v. *United States,* 22 F.3d 1174, 1177 (D.C. Cir. 1994) (''[A]n agency may depart from its past interpretation [of a statute] so long as it provides a reasoned basis for the change.'') (citing *Motor Vehicles Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 42 (1983)); *Torrington Extend-A-Care Employee Ass'n* v. *N.L.R.B.,* 17 F.3d 580, 589 (2d Cir. 1994) (similar). In the 2015 Act specifically, Congress did not prohibit or otherwise restrict agencies from reconsidering whether an initial catch-up adjustment is required or, if so, the magnitude of such an adjustment. Moreover, NHTSA's regulations provide broadly that ''[t]he Administrator may initiate any further rulemaking proceedings that he finds necessary or desirable.'' 49 CFR 553.25.

[23] NHTSA may consider a separate rulemaking to consider whether the CAFE civil penalty rate should be $5.

[24] EPCA's use of the terminology ''civil penalty'' in 49 U.S.C. 32912(b) is not dispositive. The 2015 Act does not apply to all civil penalties, but rather ''civil monetary penalties,'' a defined term.

[25] 28 U.S.C. 2461 note, Federal Civil Penalties Inflation Adjustment § 3(2).

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] *Id.* § 7(a).

[30] OMB Guidance at 2. OMB's guidance included the definition of ''civil monetary penalty'' applicable to the 2015 Act and explained: ''Agencies with questions on the applicability of the inflation adjustment requirement to an individual penalty, should first consult with the Office of General Counsel of the agency for the applicable statute, and then seek clarifying guidance from OMB if necessary.''

[31] The three criteria in the definition are joined by the conjunctive ''and.''

standards, which includes a rate of $5.50 per .1 mile in its formula, does not meet the first set of criteria in the definition. It is not a ''penalty, fine, or other sanction'' that is either ''a specific monetary amount'' or ''a maximum amount.'' Instead, the statute outlines a process that NHTSA uses to determine a proposed penalty and that manufacturers use to assess their specific penalty. In particular, the $5.50 per .1 mile is merely a rate that goes into a complex, statutory formula used to calculate a variable penalty. Other factors, such as the manufacturer's credit earning arrangement and its participation in the credit trading program, are also integral parts of the multifaceted formula used to calculate a manufacturer's penalty for violations of the fuel economy standards in 49 U.S.C. 32912(b). Moreover, the decisions of other manufacturers to generate or not generate and sell or not sell credits will also influence the amount that a potentially liable manufacturer pays. NHTSA does not believe this complex formula and credit trading program generates the kind of simple civil penalty that lends itself to rote application of the 2015 Act.

Unlike other civil penalties under NHTSA's jurisdiction, the penalty for manufacturer violations of fuel economy standards is not for ''a maximum amount.'' One example of a penalty that is for ''a maximum amount'' is the ''general penalty'' in EPCA for violations of 49 U.S.C. 32911(a). That ''general penalty'' is ''a civil penalty of not more than $10,000 for each violation.'' [32] This sets ''a maximum amount'' of $10,000 per violation. In other words, EPCA set ''a maximum amount'' of $10,000 per violation of requirements such as the requirement for manufacturers to submit pre-model year and mid-model year reports to NHTSA on whether they will comply with the average fuel economy standards.[33] Accordingly, this civil penalty level was properly adjusted to $40,000 in NHTSA's interim final rule and is further adjusted here for 2017 and 2018.[34] Violations of the Safety Act are also generally subject to ''a maximum amount'' of $21,000 per violation and $105 million for a related series of violations.[35] The agency determines the appropriate amount of such penalties, up to the statutory maximum. On the other hand, the penalty for manufacturer violations of fuel economy standards in 49 U.S.C. 32912(b) does not provide ''a maximum amount'' of a penalty and instead contains only a complex process for determining a penalty. Setting aside any credits available to the manufacturer, the greater shortfall there is in a manufacturer's corporate average fuel economy, the greater the potential exists for the eventual application of a civil penalty for that shortfall.

The penalty for manufacturer violations of fuel economy standards also does not meet the definition of a ''civil monetary penalty'' because the fuel economy standards statute does not provide a ''specific monetary amount'' for manufacturer violations of fuel economy standards. In contrast to other provisions of the statute that provide for a specific amount on a per violation basis, often in the tens of thousands of dollars, section 32912(b) provides no specific amount. It only provides a $5.50 rate, which is one input in a market-based enforcement mechanism involving the calculation established in 49 U.S.C. 32912(b), the ultimate result of which—the penalty owed—is determined by how a manufacturer decides to use any available credits it has, or can acquire, to make up for the initial shortfall identified by NHTSA which in turn is based on the market price for credits which is dependent on the actions of other manufacturers.

For a manufacturer that does not meet an applicable fuel economy standard, NHTSA sends what is known as a ''shortfall letter'' to the manufacturer. NHTSA can only do so after it knows the average fuel economy ''calculated under section 32904(a)(1)(A) or (B) of this title for automobiles to which the standard applies manufactured by the manufacturer during the model year.'' [36] The fuel economy calculation is conducted by the Environmental Protection Agency (EPA). Following the end of a model year, manufacturers submit final model year reports to EPA. EPA reviews and verifies the information and values manufacturers provide before providing the reports to NHTSA, generally more than six months after the end of a model year.

Once NHTSA receives the average fuel economy calculation from EPA, NHTSA must then determine whether the manufacturer's average fuel economy fails to meet the applicable average fuel economy standard.[37] If so, the manufacturer has a shortfall. NHTSA then prepares a preliminary calculation of the manufacturer's *potential* civil penalty, which, as described above, varies depending on the relationship between the manufacturer's average fuel economy and the average fuel economy standards. NHTSA sends the manufacturer a shortfall letter with the preliminary calculation, which requires the manufacturer to respond by either submitting a plan on how it intends to make up the shortfall or by paying a penalty.

NHTSA's preliminary calculation is determined by multiplying three numbers: (1) $5.50, (2) each tenth of a mile per gallon by which the average fuel economy falls short of the applicable average fuel economy standard, and (3) the number of automobiles manufactured by the manufacturer during the model year.[38] That calculation does not yield a final civil penalty amount because the statute requires that calculation to include a reduction ''by the credits available to the manufacturer under section 32903 of this title for the model year.'' [39]

However, applying the reduction for the number of available credits is not a matter of simple mathematics because manufacturers have control over both the amount of credits available to them and the use of their credits. If a manufacturer's performance for a given fleet does not meet the applicable standard, then the manufacturer must elect how to satisfy its shortfall.

Whether and to what extent the penalty calculation is reduced ''by the credits available to the manufacturer under section 32903 of this title for the model year'' (*i.e.,* how to deal with a non-compliance) is ultimately determined by the manufacturer. Only after this step in the process outlined in section 32912 occurs is the penalty calculation complete. Each manufacturer controls the allocation of its own credits, if credits are available.[40] A manufacturer that earned credits in a compliance category before MY 2008

[32] 49 U.S.C. 32912(a). Since the penalty in 49 U.S.C. 32912(a) is for a maximum amount, it is subject to inflationary adjustment under the 2015 Act. NHTSA's inflationary adjustment of that civil penalty in the July 2016 IFR to a maximum penalty of $40,000 was therefore appropriate. The penalty in 49 U.S.C. 32912(a) is subject to additional inflationary adjustment for 2017 and 2018. Applying the multiplier for 2017 of 1.01636, as specified in OMB's December 16, 2016 guidance, results in an adjusted maximum penalty of $40,654. Applying the multiplier for 2018 of 1.02041, as specified in OMB's December 15, 2017, results in an adjusted maximum penalty of $41,484. NHTSA is proposing to finalize that inflationary adjustment.

[33] *See id.;* 49 U.S.C. 32907(a).

[34] 81 FR 43524, 43526 (July 5, 2016).

[35] 49 U.S.C. 30165(a)(1). These civil penalty amounts were established by Section 24110 of the Fixing America's Surface Transportation Act (FAST Act), Public Law 114–94, after the 2015 Act was enacted, and thus were not adjusted in the interim final rule.

[36] 49 U.S.C. 32912(b)(1).

[37] 49 U.S.C. 32912(b)(1).

[38] 49 U.S.C. 32912(b)(2).

[39] 49 U.S.C. 32912(b)(3).

[40] *See* 49 CFR 536.5(c), (d)(2), (6).

may apply those credits to that same compliance category for the three model years prior to, and three model years after, the year in which the credits were earned.[41] A manufacturer that earned credits in a compliance category during and after MY 2008 may apply those credits to the same compliance category for three model years prior to, and five model years after, the year in which the credits were earned.[42] Manufacturers instruct NHTSA on how they wish to allocate their credits, or account for shortfalls.[43]

Only once NHTSA hears back from the manufacturer on how it wishes to satisfy its shortfall does NHTSA know the specific civil penalty that the manufacturer owes for falling short of the applicable average fuel economy standard. In other words, the manufacturer's decision regarding use of credits is one of the several inputs in the complex formula set forth in the fuel economy standards statute, which ultimately produces the civil penalty for a manufacturer's violation of fuel economy standards. In sum, the statute describes a process to determine a penalty amount, but does not itself provide for a penalty, fine or sanction that is ''for a specific amount.'' Instead,, due to additional flexibilities of credit transfers and trades, a manufacturer determines the amount of the civil penalty that is actually owed.[44] Considering this framework, the formula established under 49 U.S.C. 32912(b) and the variable amounts that result from application of the formula, are not a ''specific monetary amount'' of a penalty for manufacturer violations of fuel economy standards subject to adjustment pursuant to the 2015 Act.

NHTSA must conduct a preliminary calculation for each of the manufacturer's fleets. CAFE standards are fleet-wide standards that apply to the vehicles a manufacturer produced for sale in each of three compliance categories: passenger cars manufactured domestically, imported passenger cars, and light trucks.[45] Within specified limits, EISA permitted manufacturers to transfer credits across fleets. For example, credits earned for a manufacturer's domestic passenger fleet may be transferred to its domestic light-truck fleet. Likewise, EISA permitted manufacturers to sell (*i.e.,* trade) their credits to other manufacturers. The ability to trade credits with another manufacturer, authorized for the first time by EISA in 2007, introduced a new level of complexity that further differentiated civil penalties for violations of fuel economy requirements from other types of civil penalties. This added wrinkle further supports NHTSA's current understanding that the statutory CAFE civil penalty process is not included within the scope of the 2015 Act.

Since manufacturers control the use of their available credits, NHTSA has no way of determining on its own the amount of a penalty that a manufacturer must pay, or even if a manufacturer must pay any penalty at all.[46] The options are plentiful.[47] A manufacturer can choose to use no credits and pay a penalty. A manufacturer can choose to use credits from the same compliance category and pay no penalty. A manufacturer can choose to use some credits from the same compliance category and pay a smaller penalty. A manufacturer can choose to transfer credits from another compliance category and pay no penalty. A manufacturer can choose to transfer some credits from another compliance category and pay a smaller penalty. A manufacturer can choose to purchase credits from another manufacturer and pay no penalty. A manufacturer can choose to purchase some credits from another manufacturer and pay a smaller penalty. A manufacturer can combine credits from the same compliance category and/or transfer credits from another compliance category and/or purchase credits from another manufacturer and pay no penalty or a smaller penalty.

Those are just the options for credits already earned. A manufacturer can also elect not to pay a penalty or pay a smaller penalty by using a ''carryback'' plan, in which the manufacturer applies credits it expects to earn in *future* model years.[48]

There are additional considerations that strongly supports NHTSA's conclusion that the 2015 Act should not be applied to the CAFE civil penalty. Congress already adopted a specific scheme for increasing the civil penalty in 49 U.S.C. 32912(b) that requires a far more intensive and restrictive process than the summary approach in the 2015 Act. First, EPCA placed an absolute limit on such an increase to ''not more than $10 for each .1 of a mile a gallon.'' [49] Moreover, Congress set a high bar for adopting an increase. Specifically:

> The Secretary of Transportation shall prescribe by regulation a higher amount for each .1 of a mile a gallon to be used in calculating a civil penalty under subsection (b) of this section, if the Secretary decides that the increase in the penalty—(i) will result in, or substantially further, substantial energy conservation for automobiles in model years in which the increased penalty may be imposed; and (ii) will not have a substantial deleterious impact on the economy of the United States, a State, or a region of a State.[50]

Further, the Secretary must decide that an increase will not have a substantial deleterious impact ''only when the Secretary decides that it is likely that the increase in the penalty will not—(i) cause a significant increase in unemployment in a State or a region of a State; (ii) adversely affect competition; or (iii) cause a significant increase in automobile imports.'' [51] These factors, which appear to demonstrate Congress' concern that the CAFE civil penalties program could damage the economy, are far more specific and tailored to the CAFE program than any provisions in the 2015 Act. Although it is not specifically identified in the statute, the legislative history indicates that the ''impact'' of concern relates to ''the automobile industry.'' [52] In its report on EPCA's original fuel economy provisions in 1975, the House Commerce Committee recognized:

> The automobile industry has a central role in our national economy and that any regulatory program must be carefully drafted so as to require of the industry what is attainable without either imposing impossible burdens on it or unduly limiting consumer choice as to capacity and performance of motor vehicles.[53]

Notably, Congress was aware that inflation would effectively reduce the real value of the civil penalty rate over time—the CBO Director and NHTSA Administrator recognized that the civil penalty structure under 1975 EPCA

[41] *Id.* 536.6(a).

[42] *Id.* 536.6(b).

[43] *See* 49 CFR 536.5(d)(2), (6).

[44] Public Law 110–140, Title I, 104(a), 121 Stat. 1501 (2007).

[45] *Id.* 32902–04.

[46] NHTSA is able to request supplemental reports and audit a manufacturer's compliance plan, *see, e.g.,* 49 CFR 537.8, but ultimately, it is the manufacturer's decision on how to use the credits available to it.

[47] *See* 49 U.S.C. 32903.

[48] *See* 49 CFR 536.5(d).

[49] 49 U.S.C. 32912(c).

[50] 49 U.S.C. 32912(c)(1)(A).

[51] *Id.* 32912(c)(1)(C).

[52] ''Energy Initiatives of the 95th Congress,'' S. Rep. No. 96–10, at 175–76 (1979) (''Representative Dingell (D-Mich.), concerned that increasing the penalties could lead to layoffs in the automobile industry, insisted that raising the penalties be contingent upon findings by the Secretary of Transportation that increasing the penalties would achieve energy savings and would not be harmful to the economy.'').

[53] H.R. Rep. No. 94–340, at 87 (1975). *See also* 121 Cong. Rec. 18675 (June 12, 1975) (statement of Rep. Sharp) (''[W]e recognize that we have serious unemployment in the American auto industry and we want to preserve this important segment of the economy.'').

''actually become less stringent over time . . . as inflation erodes [the penalties'] effect''—yet chose to require this strict procedure to increase the rate without allowing for inflationary adjustments to the multiplier in the formula. In contrast, Congress expressly purposes of the 2015 Act (and its predecessor) ''to establish a mechanism that shall . . . maintain the deterrent effect of civil monetary penalties . . . .'' The omission of any inflation adjustment procedure makes sense in light of Congress' requirement for NHTSA to continually increase fuel economy standards to maximum feasible levels.[54] Rather than increase the penalty each year, Congress directed NHTSA to determine whether fuel economy standards should be increased, because the goal of the CAFE standards is to increase fuel economy not punish manufacturers, as with other penalties subject to the 2015 Act. Requiring mandatory penalty inflation adjustments *and* continuous fuel standard increases would multiply the amount assessed against manufacturers in a way that does not occur with other types of penalties.

Congress also recognized the need for lead time in increasing the civil penalty for violations of fuel economy standards by specifying that an increase ''is effective for the model year beginning at least 18 months after the regulation stating the higher amount becomes final.'' [55]

Congress additionally recognized the need for extensive input from the public and other parts of the Government before any such increase. It required that:

The Secretary shall publish in the **Federal Register** a proposed regulation under this subsection and a statement of the basis for the regulation and provide each manufacturer of automobiles a copy of the proposed regulation and the statement. The Secretary shall provide a period of at least 45 days for written public comments on the proposed regulation. The Secretary shall submit a copy of the proposed regulation to the Federal Trade Commission and request the Commission to comment on the proposed regulation within that period. After that period, the Secretary shall give interested persons and the Commission an opportunity at a public hearing to present oral information, views, and arguments and to direct questions about disputed issues of material fact to—(A) other interested persons making oral presentations; (B) employees and contractors of the Government that made written comments or an oral presentation or participated in the development or consideration of the proposed regulation; and (C) experts and consultants that provided information to a person that the person includes, or refers to, in an oral presentation.[56]

These extensive, statutorily-mandated procedures specifically applicable to increases in the penalty rate in 49 U.S.C. 32912(b) are in stark contrast to the procedures applicable to the 2015 Act. For the initial catch-up adjustment, the 2015 Act specified that agencies should use an interim final rule.[57] For subsequent annual adjustments, the 2015 Act specified that agencies ''shall make the adjustment notwithstanding section 553 of title 5, United States Code,'' which contain the Administrative Procedure Act's requirements for rulemaking.[58]

Finally, before Congress passed the 2015 Act, the CBO provided an assessment of the revenue that inflation adjustments pursuant to the 2015 Act would provide the Federal government. CBO determined that *all* inflation adjustments pursuant to the 2015 Act (across *every* Federal agency) would provide in total $1.3 billion of revenue across ten years.[59] Commenters indicate that adjusting the civil penalty rate to $14 could cost up to $1 billion *annually* in penalty payments.[60] Across ten years, the penalty payments under this provision of the statute alone could dwarf CBO's contemporaneous estimate of the 2015 Act's effect on revenues from *all* civil monetary penalties across *all* statutes. The drastic difference between CBO's estimate of revenue from *all* inflation adjustments across *ten* years and the potential revenue from this adjustment alone further suggests Congress had not considered the civil penalty rate subject to the 2015 Act's inflation adjustment. This is bolstered by the rounding rule adopted by Congress. The 2015 Act states, ''[a]ny increase determined under this subsection shall be rounded to the nearest multiple of $1.'' [61] This rounding rule suggests the Act was not intended to apply to the small dollar value CAFE civil penalty rate, since it would not serve a *de minimis* rounding function. As a practical matter, if the rounding rule applied to a small dollar penalty rate, it would prevent any annual inflationary increases (absent extraordinary inflation).

NHTSA believes that applying the 2015 Act to the penalty in 49 U.S.C. 32912(b) would evade the statutory safeguards and limitations directly applicable to that penalty, in contrast to Congress's original awareness of penalty rate adjustments, and could result in the imposition of a potentially massive increase in civil penalties, in contrast to contemporaneous, pre-enactment evidence about the effect of the 2015 Act.

NHTSA has previously sought comment on related issues, but NHTSA believes it is important to provide the public with an opportunity to provide additional comments in light of NHTSA's analysis. Accordingly, NHTSA requests comments on this analysis. For these reasons, NHTSA tentatively concludes that it is not appropriate to apply the 2015 Act and is proposing to retain the $5.50 rate in the CAFE civil penalty.

2. The Agency Tentatively Finds That Increasing the CAFE Civil Penalty Rate Will Result in Negative Economic Impact

NHTSA is proposing to retain the CAFE civil penalty rate of $5.50 per tenth of a mile per gallon, even if one were to assume that the penalties are subject to the 2015 Act, because NHTSA tentatively concludes that, in light of the statutory requirements in EPCA for raising the penalty rate, applying the increase would lead to a ''negative economic impact'' under the 2015 Act.

The 2015 Act states, ''[a]ny increase determined under this subsection shall be rounded to the nearest multiple of $1.'' [62] NHTSA requests comment on whether, and if so, how, this rounding rule should apply if NHTSA ultimately concludes that adjusting the $5.50 CAFE civil penalty rate upwards would have a ''negative economic impact.'' Specifically, does the 2015 Act rule require a $5.50 civil penalty rate, if finalized, to be rounded to $6? Commenters should consider the potential application of the rounding rule to the initial catch-up adjustment,

[54] 49 U.S.C. 32902(a).

[55] *Id.* 32912(c)(1)(D).

[56] *Id.* 32912(c)(2).

[57] 28 U.S.C. 2461 note, Federal Civil Penalties Inflation Adjustment § 4(b)(1)(A).

[58] *Id.* § 4(b)(2).

[59] *See* ''Estimate of the Budgetary Effects of H.R. 1314, the Bipartisan Budget Act of 2015, as reported by the House Committee on Rules on October 27, 2015,'' at 4, available at *https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1314.pdf.* Title VII of the Bipartisan Budget Act of 2015 includes three sections and the revenue estimate was for title VII in its entirety. Section 701 is the 2015 Act. The other two sections are the rescission of money deposited or available in two funds which CBO recognized would decrease direct government spending. Therefore, the 2015 Act is likely the only portion of title VII to provide revenue, and the CBO's revenue estimate for title VII can be understood as a revenue estimate for the 2015 Act.

[60] *See, e.g.,* Comment ID NHTSA–2017–0059–0019, available at *https://www.regulations.gov/.*

[61] 28 U.S.C. 2461 note, Federal Civil Penalties Inflation Adjustment § 5(a).

[62] 28 U.S.C. 2461 note, Federal Civil Penalties Inflation Adjustment § 5(a).

as well as the 2017 and 2018 adjustments and future annual adjustments. Commenters should also consider the relationship, if any, between the rounding rule and the criteria required to be met to raise the civil penalty under EPCA.

a. Negative Economic Impact

i. ''Negative Economic Impact'' Is Not Defined

Under the 2015 Inflation Adjustment Act, NHTSA, under authority delegated by the Secretary, may adjust the amount of a civil monetary penalty by the less than the amount otherwise required for the ''catch-up adjustment'' upon determining in a final rule, after notice-and comment, that increasing the civil monetary penalty by the otherwise required amount will have a ''negative economic impact,'' or the social costs of increasing the civil monetary penalty by the otherwise required amount outweigh the benefits.[63] In either case, the Director of the Office of Management and Budget must concur with the agency's determination.

To determine whether increasing the CAFE civil penalty rate by the amount calculated under the inflation adjustment formula would have a ''negative economic impact,'' NHTSA must first establish the meaning of ''negative economic impact.'' The statute does not define ''negative economic impact.'' OMB issued a memorandum providing guidance to the heads of executive departments and agencies on how to implement the Inflation Adjustment Act, but the guidance does not define ''negative economic impact'' either.[64]

ii. How To Interpret ''Negative Economic Impact''

In interpreting ''negative economic impact,'' NHTSA cannot just consider the Inflation Adjustment Act in isolation: statutory interpretation is not conducted in a vacuum.[65] ''It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'' [66]

Accordingly, NHTSA must interpret Congress' Inflation Adjustment Act in light of the longstanding CAFE civil penalty structure previously enacted by Congress. Interpreting the Inflation Adjustment Act in context is particularly important in determining the appropriate adjustment to make to the CAFE civil penalty rate given the unique nature of the CAFE civil penalties program. For example, in contrast to other federal civil penalty programs, the CAFE statute requires a minimum of eighteen months' lead time in advance of a model year before a higher civil penalty amount can become effective.[67] Congress mandated this interval because ''manufacturers' product and compliance plans are difficult to alter significantly for years ahead of a given model year.'' [68] Indeed, ''NHTSA believes that this approach facilitates continued fuel economy improvements over the longer term by accounting for the fact that manufacturers will seek to make improvements when and where they are most cost-effective.'' [69] For similar reasons, when DOT amends a fuel economy standard to make it more stringent, that new standard must be promulgated ''at least 18 months before the beginning of the model year to which the amendment applies.'' [70]

CAFE civil penalties are also atypical in that they follow a prescribed formula that can only be compromised or remitted by NHTSA in exceptionally limited circumstances.[71] In practice, therefore, any increase in the CAFE civil penalty rate would apply to all non-compliant manufacturers, regardless of the circumstances, and in turn, would likely increase the price of credits.[72] Contrast this constrained structure with NHTSA's general civil penalty authority, which allows the Secretary to determine or compromise the amount of a civil penalty and delineates multiple factors for the Secretary to consider in making such a determination, including the nature, circumstances, extent, and gravity of the violation.[73]

The principles underlying other traditional canons of statutory interpretation further support NHTSA's proposed approach. For example, statutes that relate to the same or to similar subjects are *in pari materia.* Such statutes should be construed together, even if they do not expressly reference each other or were passed at different times, unless a contrary intent is clearly expressed by Congress. Here, both the inflationary adjustment statute and the relevant provisions of the CAFE statute involve civil penalties and must be read *in pari materia.*[74] And when one of the statutes is generalized and passed later—like the Inflation Adjustment Act—it cannot be read to implicitly repeal an earlier, more specific statute—like EPCA's establishment of the CAFE civil penalties structure.[75] This approach to statutory interpretation is consistent with NHTSA's past practice.[76]

The principles underlying the rule of lenity also substantiate interpreting the Inflation Adjustment Act narrowly in light of EPCA. This canon instructs that statutes imposing penalties should be construed narrowly in favor of those against whom the penalties will be imposed. Although the rule of lenity is

[63] 28 U.S.C. 2461 note, Federal Civil Penalties Inflation Adjustment § 4(c)(1).

[64] Memorandum from the Director of OMB to Heads of Executive Departments and Agencies, Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Feb. 24, 2016), available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2016/m-16-06.pdf.*

[65] *Davis* v. *Michigan Dep't of Treasury,* 489 U.S. 803, 809 (1989).

[66] *Id.* (citing *United States* v. *Morton,* 467 U.S. 822, 828 (1984)).

[67] 49 U.S.C. 32912(c)(1)(D).

[68] 81 FR 95491 (December 28, 2016).

[69] *Id.*

[70] 49 U.S.C. 32902(a)(2).

[71] 49 U.S.C. 32913 (authorizing the Secretary to ''compromise or remit the amount of civil penalty imposed'' under CAFE ''only to the extent'' (1) necessary to prevent a manufacturer's insolvency or bankruptcy; (2) the manufacturer shows that the violation was caused by an act of God, a strike, or a fire; or (3) the Federal Trade Commission certifies that a reduction is necessary to prevent a substantial lessening of competition). NHTSA has never attempted to utilize this provision to compromise or remit a CAFE civil penalty.

[72] *See* H.R. Rep. No. 95–1751, at 112 (1978) (Conf. Rep.) (''[T]he higher penalty . . . will be the same for all manufacturers when adopted. . ..'').

[73] 49 U.S.C. 30165(b)–(c).

[74] *See Wisconsin Cent. Ltd.* v. *United States,* 194 F. Supp. 3d 728, 738 (N.D. Ill. 2016), *aff'd,* 856 F.3d 490 (7th Cir. 2017) (''[C]onceptual similarity' . . . is precisely the point of the *in pari materia* canon: 'statutes addressing the same subject matter *generally* should be read as if they were one law,' with the traditional tools of statutory interpretation applied accordingly. . . . [A]lthough FICA does not by completely define the RRTA's various contours, examining the former to elucidate related provisions of the latter is an acceptable mode of statutory interpretation given the close linkages between the statutes.'') (internal citation omitted) (emphasis in original); *cf. Pound* v. *Airosol Co.,* 498 F.3d 1089, 1094 n.2 (10th Cir. 2007) (''The penalty provisions of the CAA and the Clean Water Act (CWA) are virtually identical; thus, CWA cases are instructive in analyzing issues arising from the CAA''); *United States* v. *Dell'Aquilla,* 150 F.3d 329, 338 n.9 (3d Cir. 1998) (''[T]he Clean Water Act and the Clean Air Act are *in pari materia,* and courts often rely upon interpretations of the Clean Water Act to assist with an analysis under the Clean Air Act.'') (citations omitted).

[75] *See Crawford Fitting Co.* v. *J. T. Gibbons, Inc.,* 482 U.S. 437, 445 (1987) (''Where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment.'') (cleaned up); *Radzanower* v. *Touche Ross & Co.,* 426 U.S. 148, 153 (1976) (''It is a basic principle of statutory construction that a statute dealing with a narrow, precise, and specific subject is not submerged by a later enacted statute covering a more generalized spectrum.'').

[76] *See, e.g.,* 80 FR 40137, 40171 (Aug. 12, 2015) (interpreting a term in EISA by looking to how the term is defined in the Motor Vehicle Safety Act, ''[g]iven the absence of any apparent contrary intent on the part of Congress in EISA'').

traditionally applied in criminal contexts,[77] the principles underlying the rule are worth considering when there are severe punitive implications of a broad interpretation, as is the case here. Construing the statute strictly is particularly important here because the inflation adjustment essentially acts as a ''one-way ratchet,'' where all subsequent annual adjustments will be based off this ''catch-up'' adjustment with no ensuing opportunity to invoke the ''negative economic impact'' exception.[78]

iii. Reading Section 32912 With the Inflationary Adjustment Act

Under 49 U.S.C. 32912(b), a manufacturer that violates a fuel economy standard is potentially subject to a civil penalty rate for each tenth of a mile per gallon that the manufacturer misses the applicable average fuel economy standard for the number of automobiles manufactured by the manufacturer during the model year, unless the manufacturer is able and willing to apply credits or establish a plan to generate and apply credits in subsequent years, as discussed above. NHTSA has exceptionally limited discretion in whether to impose the penalty or the amount of the preliminary calculation of the penalty when it does indeed apply.

The Secretary is required to increase the applicable civil penalty rate up to $10 per each tenth of a mile per gallon if she decides that the increase in the penalty:

(i) will result in, or substantially further, substantial energy conservation for automobiles in model years in which the increased penalty may be imposed; and

(ii) will not have a substantial deleterious impact on the economy of the United States, a State, or a region of a State.[79]

The Secretary can only decide that the increase ''will not have a substantial deleterious impact on the economy'' if she decides that it is likely that the increase in the penalty will not:

(i) Cause a significant increase in unemployment in a State or a region of a State;

(ii) adversely affect competition; or

(iii) cause a significant increase in automobile imports.[80]

Thus, to increase the civil penalty rate for CAFE violations, the Secretary must affirmatively determine that doing so ''will not have a substantial deleterious impact on the economy of the United States, a State, or a region of a State.'' Critically, if she is unable to make such a determination or, put another way, if she determines that increasing the civil penalty may have ''a substantial deleterious impact on the economy of the United States, a State, or a region of a State,'' she is prohibited by statute from increasing the applicable civil penalty rate.[81] Therefore, in determining whether adjusting the CAFE civil penalty rate for inflation will have a ''negative economic impact,'' it is appropriate to consider the potential negative economic impact the adjustment would have not just on the United States in general, but also, at a minimum, on whether such impact could occur in any particular State or region of a State.

NHTSA also believes it is appropriate to consider the impact raising the CAFE civil penalty rate would have on individual manufacturers who fall short of fuel economy standards, and those affected, such as dealers. Such a broad interpretation is consistent with how other statutory provisions permitting or requiring agencies to consider economic impacts have been interpreted. For example, under the Safety Act, a discretionary factor in determining the amount of a penalty is ''the appropriateness of such penalty in relation to the size of the business of the person charged, including the potential for *undue adverse economic impacts.*'' [82] NHTSA interpreted that factor in its regulation to include consideration of ''financial factors such as liquidity, solvency, and profitability.'' [83] Other federal statutes likewise contemplate consideration of negative economic impacts on individual actors in determining an appropriate civil penalty.[84] NHTSA's proposal, which includes consideration of the ''negative economic impact'' the level would have on individual noncompliant actors, represents a uniform approach with how it determines the appropriate civil penalty level in these other, non-CAFE cases. Moreover, the Senate Conference report on the 1975 version of EPCA directed ''the Secretary [to] weigh the benefits to the nation of a higher average fuel economy standard against the difficulties of individual automobile manufacturers.'' [85]

Note also that ''negative economic impact,'' as used in the Inflation Adjustment Act, need not mean ''*net* negative economic impact.'' Congress expressly utilized the ''net'' concept in the very next provision of the statute, authorizing a lesser increase to a civil penalty if the agency determines that ''the social costs of increasing the civil monetary penalty by the otherwise required amount *outweigh* the benefits.'' [86] The absence of comparable phrasing for the ''negative economic impact'' provision immediately prior implies either that term is ambiguous or that Congress intentionally omitted the word ''net.'' Either way, without any express indications that Congress meant ''net negative economic impact,'' NHTSA proposes that the provision should be interpreted without reference to any potential benefits of increasing the penalty.

a. NHTSA has not Determined That an Increase in the CAFE Civil Penalty Rate Will Not Have a Substantial Deleterious Impact on the Economy

To summarize: The 2015 Act allows an agency to set a lower penalty amount than would otherwise be required if it can show that raising the penalty in accordance with the 2015 Act will lead to a ''negative economic impact,'' which is not defined either in the 2015 Act or OMB's implementing guidance. However, the statute specifically related to penalties for violations of NHTSA's fuel economy standards has a provision allowing for an increase in the penalty rate only if the agency can determine that increasing the rate will not have a ''substantial deleterious impact on the economy.'' To read these two provisions together harmoniously, NHTSA interprets the statutes to mean that the agency must be able to affirmatively show that increasing the penalty as would be required by the 2015 Act will not have the adverse economic effects identified in the definition of ''substantial deleterious impact.'' Since the agency cannot make those affirmative findings, discussed further

[77] Some courts have applied the rule of lenity in civil and administrative contexts as well. *See, e.g., United States* v. *Thompson/Ctr. Arms Co.,* 504 U.S. 505, 518 (1992); *Rand* v. *C.I.R.,* 141 T.C. 376, 393 (2013), overturned on other grounds due to legislative action.

[78] This ''one-way ratchet'' constraint is also imposed by EPCA. H.R. Rep. No. 95–1751, at 113 (1978) (Conf. Rep.) (''No provision [in EPCA] is made for lowering the penalty.'').

[79] 49 U.S.C. 32912(c)(1)(A)–(B).

[80] 49 U.S.C. 32912(c)(1)(C).

[81] In addition to the substantive findings that must be made before the civil penalty rate can be increased, Section 32912 also imposes procedural requirements. For instance, the Secretary must hold a public hearing during which interested persons and the Federal Trade Commission be allowed to make presentations. 49 U.S.C. 32912(c)(2).

[82] 49 U.S.C. 30165(c)(7) (emphasis added).

[83] 49 CFR 578.8.

[84] *See* 15 U.S.C. 2069(b), (c) (Consumer Product Safety Commission); 33 U.S.C. 1232(a)(1) (Coast Guard); 33 U.S.C. 1319(d), 1321(b)(8) (Environmental Protection Agency).

[85] S. Rep. No. 94–516, at 155 (1975) (Conf. Rep.).

[86] 28 U.S.C. 2461 note, Federal Civil Penalties Inflation Adjustment § 4(c)(1)(B) (emphasis added).

below, it is therefore prohibited from raising the penalty rate because doing so would have a ''negative economic impact.''

Since NHTSA does not have sufficient evidence to make the requisite finding under EPCA that an increase in the CAFE penalty rate will not have a substantial deleterious impact on the economy, NHTSA is proposing to retain the $5.50 penalty rate pursuant to the negative economic impact exception to inflationary adjustments. NHTSA invites comments on whether this is the appropriate penalty level, and if not, requests data or other evidence that would support the findings necessary under EPCA that would allow for such an increase.

The comments should take into account that the factors are probabilistic and prospective, that is, to increase the penalty rate, the Secretary must determine that doing so likely would not have the statutorily-enumerated effects in the future.

The comments should also reflect the considerable burdens that must be overcome to make the findings needed to increase the civil penalty under EPCA, in part reflected in the statute's repeated use of ''substantial'' and ''significant.'' Indeed, the burden is so great that NHTSA has been unable to make all of the determinations necessary since the provisions were added in 1978.

The comments should also address the impact of increasingly stringent fuel economy standards established in existing statute and NHTSA regulation, and whether this increasing stringency has a relationship to a ''negative economic impact'' or ''substantial deleterious impact determination.''

b. NHTSA has not Determined That an Increase in the CAFE Civil Penalty Rate Will Not Cause a Significant Increase in Unemployment in a State or Region of a State

NHTSA tentatively concludes that an increase in the CAFE penalty rate could plausibly cause a significant increase in unemployment in a State or a region of a State. For instance, vehicle price increases—resulting from increased penalty payments or compliance costs passed through to customers—could result in customers keeping their current vehicles longer or shifting purchases towards less expensive new vehicles or toward the used vehicle market. Either outcome could lead to fewer jobs with vehicle manufacturers. Losses may be concentrated in particular States and regions within those States where automobile manufacturing plants are located. Some manufacturers who have historically paid civil penalties in lieu of compliance have automobile assembly and parts manufacturing plants located in the Midwest and Southeastern U.S. These plants employing thousands of people could be most adversely impacted by a civil penalty increase resulting in employment losses. In response to substantial increases in potential penalties, some manufacturers could plausibly lose sales due to resulting higher prices, which may result in reduced employment at facilities currently producing vehicles and engines.

Fewer new vehicle sales attributable to price increases resulting from increased penalty payments and/or compliance costs could also plausibly result in fewer jobs within new motor vehicle dealerships franchised to sell vehicles manufactured or distributed by manufacturers subject to penalties and/or increased compliance costs. A manufacturer's decision to change allocation of vehicles distributed to dealers to address increased penalties and/or compliance costs could also result in job losses within the franchised dealer network. For example, one might expect that increased CAFE penalties could lead to a decrease in the number of vehicles with powerful engines being produced or sold. Dealers in States or intra-State regions where these types of vehicles are more popular would be affected disproportionately.

c. NHTSA Has Not Determined That an Increase in the CAFE Civil Penalty Rate Will Not Adversely Affect Competition

Notably, unlike the other two factors, this factor does not require a finding of a ''significant'' effect. The absence of this modifier implies that even a modest adverse effect on competition would suffice to block a civil penalty increase. This phrasing similarly contrasts with the provision in the next section of the Code, describing the compromising or remitting the amount of a CAFE civil penalty. That provision requires the Federal Trade Commission to certify that a reduction in the penalty is ''necessary to prevent a substantial lessening of competition.'' [87]

In establishing CAFE stringency requirements, NHTSA has consistently evaluated risks to competition, including the potential effects on individual automakers. For instance, in the 1985 rulemaking, NHTSA analyzed the potential effect of a 1.5 mpg fuel economy improvement on the domestic auto industry, stating:

> It is always possible that higher levels of fuel economy could be achieved by the domestic manufacturers if they were to restrict severely their product offerings. For example, sales of particular larger light truck models and larger displacement engines could be limited or eliminated entirely. As discussed by the October 1984 notice, Ford submitted an analysis of the potential effects of restricting product offerings in this manner. This analysis showed that to achieve a 1.5 mpg average fuel economy benefit through such restrictions, sales reductions of 100,000 to 180,000 units at Ford could occur, with resulting employment losses of 12,000 to 23,000 positions at Ford, its dealers and suppliers. The agency believes this analysis to be a reasonable projection of the impacts of restricting the availability of larger light trucks in the current market.
>
> Impacts of this magnitude go beyond the realm of ''economic practicability'' as contemplated in the Act. This is particularly true since it is likely that a standard set at a level resulting in impacts of this magnitude would result in little or no net fuel economy benefit. This is because consumers could meet their demand for larger light trucks by merely shifting their purchases to other manufacturers which continue to offer such trucks. The other manufacturers could increase sales of these vehicles without risking noncompliance with the standards. An additional possible negative economic consequence would be reduced competition in the market for larger light trucks. Given the small number of manufacturers producing larger light trucks, a decision by Ford (or GM or [Chrysler]) to significantly reduce its role in this market could have serious consequences for competition.[88]

NHTSA continues to believe that, in the context of CAFE rulemakings, an analysis of the effects of a regulation on competition should be undertaken in a broad manner, similar to the analysis traditionally used in establishing CAFE stringency requirements, and seeks comments on this approach.

NHTSA tentatively concludes that it is reasonable to believe that an increase in the CAFE penalty rate could distort the normal market competition that would be expected in a free market by favoring one group of manufacturers over another. This could adversely impact the affected manufacturers through higher prices for their products (without corresponding benefits to consumers), restricted product offerings, and reduced profitability. An increased CAFE penalty benefits fleets of already-compliant fuel efficient vehicles over fleets of less fuel-efficient vehicles. A manufacturer who is already generating or possesses over-compliance credits will find itself with much more valuable credits to sell and may use this additional capital to invest more heavily in research and development, marketing, add other features to its

[87] 49 U.S.C. 32913(a)(3).

[88] 50 FR 40398, 40400–40401 (Oct. 3, 1985).

vehicles which make them more desirable to consumers, or reduce the price of its vehicles. Through model year 2015, manufacturers with positive credit balances had credits in varying amounts up to nearly 396 million credits.[89] A hypothetical manufacturer with 10 million credits could see the potential value of its credits increase from $55 million to $140 million, while a hypothetical manufacturer with 100 million credits could see the potential value even more dramatically increase from $550 million to $1.4 billion. Meanwhile, a manufacturer who is not compliant and facing increased difficulties in meeting future stringency requirements may be forced to purchase credits at an increased price, invest more heavily in fuel economy improvements, discontinue less fuel-efficient models or configurations, increase vehicle prices, or some combination of these options—instead of investing in other areas to address consumer demands that would have been satisfied if the manufacturer was able to pay a lower penalty. While this result may be beneficial for purposes of fuel savings, it would further diminish the competitiveness of those manufacturers who are least able to comply with CAFE standards.

In addition to the impact on competition an increase in penalties might have on market participants, it could also have an impact on the market itself by limiting consumer choice involving vehicles and vehicle configurations that would otherwise be produced with penalties at their current values. For instance, faced with the prospect of having to pay larger penalties in the future, a manufacturer could decide that it makes financial sense to shift resources from its planned investments in capital towards payment of possible future penalties. If the possibility of paying penalties looms too large, a manufacturer could go out of business, reducing competition even further.

d. NHTSA has not Determined That an Increase in the CAFE Civil Penalty Rate will not Cause a Significant Increase in Automobile Imports

Final model year fuel economy performance reports published by NHTSA indicate import passenger car fleets are performing better than domestic passenger car fleets. The model year 2015 fleet performance report[90], the latest available, indicates the performance of the imported passenger car fleet has a one-tenth of one mpg advantage. While this slight advantage could be viewed as negligible, performance has varied significantly in recent years—the most significant being model year 2010 where the import fleet outpaced the domestic fleet by more than two mpg.

In light of this historical variation, it is unclear whether increasing the civil penalty fine amount would have a significant effect on either the domestic or import passenger cars fleets, and NHTSA seeks comment on potential positive or negative impacts civil penalties may have on the domestic and import passenger car fleets, along with any potential positive or negative impacts to the light truck fleet. Please provide supporting information for your position.

iv. Analysis of Comments Received on ''Negative Economic Impact'' and EPCA Considerations

NHTSA has reviewed the comments it received on the July 2017 notice regarding ''negative economic impact,'' and—from previous requests for comment—on the EPCA considerations. NHTSA did not identify anything persuasive in the submissions that would undermine NHTSA's proposed interpretation of ''negative economic impact.''

In its July 2017 request for comments, NHTSA specifically sought comments on:

- Whether the EPCA considerations for ''substantial deleterious impact'' are relevant to a determination of ''negative economic impact''?
- And if so, whether those considerations must be accounted for in determining negative economic impact, or simply that they are informational, and what is the legal basis for that belief?

Only two commenters submitted comments touching on these questions. But none of the comments addressed whether the EPCA criteria for ''substantial deleterious impact on the economy'' should guide NHTSA's consideration of whether the inflation adjustment would have a ''negative economic impact,'' and if so, how much less than the otherwise required amount should the penalty level be adjusted after analyzing data relevant to the EPCA factors.

CARB observed that the 2016 joint Technical Assessment Report stated that manufacturers ''who have consistently chosen to pay CAFE fines in the past may continue to do so,'' even if the civil penalty rate changes. CARB concluded from that NHTSA saw no reason at the time to think its fines would have a negative economic impact. However, this conclusion does not necessarily follow, as the greatly increased civil penalty rate, in light of longstanding expectations about the steadiness of that rate, could significantly upset manufacturers' expectations about compliance and thus cause operational or other challenges given the lead time necessary to make significant fuel economy improvements in subsequent model years.

The Alliance and Global jointly submitted comments that also relate to these issues. These associations contended that although the EPCA factors ''do not override'' the Inflation Adjustment Act and ''are not binding'' in the inflation adjustment, they provide ''helpful support'' and ''useful guidance'' in deciding whether there would be a ''negative economic impact'' and, if so, how much to adjust the civil penalty amount. In their view, the ''stringent'' factors required by EPCA demonstrate that the CAFE civil penalty amount should not be increased without evidence of ''substantial net benefits'' and evidence that there would be ''no substantial harm to the economy.''[91]

NHTSA has previously sought comment on the EPCA civil penalty criteria in other rulemaking proceedings. In 2009, NHTSA sought comment on whether it should initiate a proceeding to consider raising the CAFE civil penalty under EPCA. Most of the comments on this issue focused on the energy conservation factor, rather than the impact on the economy. But no commenter argued that raising the penalty would have a positive or neutral impact on the economy.[92]

In 2010, NHTSA specifically solicited comments on how raising or not raising the penalty amount under EPCA would impact the economy. Only Ferrari and Daimler commented on this issue. Both manufacturers argued that raising the penalty would have no impact on fuel savings and would simply hurt the manufacturers forced to pay it. Daimler stated further that manufacturers pay fines because they cannot increase energy savings any further. No commenter argued or provided any information supporting the opposing

[89] *See* ''CAFE Public Information Center,'' available at *https://one.nhtsa.gov/cafe_pic/CAFE_PIC_Credit_LIVE.html.*

[90] Available at *https://one.nhtsa.gov/cafe_pic/CAFE_PIC_fleet_LIVE.html* (last accessed December 15, 2017)

[91] The groups go on to claim that the evidence shows that adjusting the penalty to $14 ''will cost society $3.5 billion and will not produce commensurate benefits.''

[92] 74 FR 14195, 14427 (Mar. 30, 2009).

position that raising the penalty amount would have a positive or neutral impact on the economy. Ultimately, NHTSA ''defer[red] consideration of this issue for purposes of this rulemaking.'' [93]

In 2012, NHTSA again solicited comments on how raising or not raising the penalty amount under EPCA would impact the economy. This time, ''no comments specific to this issue were received,'' so NHTSA declared it would ''continue to attempt to evaluate this issue on its own.'' [94]

The public has had multiple opportunities to comment on the EPCA civil penalty provisions and now the Inflation Adjustment Act. NHTSA has considered all the comments it received in generating this proposed rule.

Based on the findings discussed above, NHTSA has tentatively made a determination that negative economic impact will result if the CAFE civil penalty rate is increased. For this reason, NHTSA is proposing to retain the existing CAFE civil penalty rate of $5.50 per .1 of a mile per gallon. NHTSA also seeks comment on whether a modest increase in the CAFE civil penalty rate, less than the amount that would otherwise be required if the 2015 Act applies, would ''result in, or substantially further, substantial energy conservation for automobiles in model years in which the increased penalty may be imposed,'' as expected by EPCA.

3. Increasing the CAFE Civil Penalty Rate to $14 Would Have a ''Negative Economic Impact,'' Even If The EPCA Factors Were Not Mandatory

Even if NHTSA was not required to apply the EPCA factors, NHTSA has tentatively determined that raising the CAFE civil penalty rate to $14 would have a ''negative economic impact.'' NHTSA believes that the economic consequences described above are a reasonable estimate of what would occur if the CAFE civil penalty rate was increased 150 percent, regardless of any effect from EPCA. That is, increasing the penalty rate to $14 would lead to significantly greater costs than the agency had anticipated when it set the CAFE standards because manufacturers who had planned to use penalties as one way to make up their shortfall would now need to pay increased penalty amounts, purchase additional credits at likely higher prices, or make modifications to their vehicles outside of their ordinary redesign cycles. NHTSA believes all of these options would increase manufacturers' compliance costs, many of which would be passed along to consumers. Considering the agency's past analyses of CAFE's impact on vehicle costs, NHTSA tentatively concludes that the estimate provided by industry showing annual costs of at least one billion dollars is a reasonable estimate of this impact. NHTSA requests comments, including any substantive analysis, on this issue. The agency further believes that an increase in costs of this significant magnitude exceeds the range of adjustments Congress intended to cover when it enacted the 2015 Act, as described above.

If NHTSA determines that raising the CAFE civil penalty rate to $14 would have a ''negative economic impact,'' it is permitted to adjust the rate by less than the otherwise required amount. Without any statutory direction or OMB guidance on how much to adjust the rate, if at all, it falls to NHTSA to determine the appropriate adjustment—and NHTSA has wide discretion in making this determination.[95]

In light of the regulatory concerns described above, and in consideration of the unique regulatory structure with non-discretionary penalties tied to standards that increase over time, NHTSA is proposing to keep the CAFE civil penalty rate at $5.50 because it tentatively concludes that retaining the $5.50 rate would avoid the ''negative economic impact'' caused by any adjustment upwards.

Although NHTSA has previously sought comment on these issues, NHTSA believes it is important to provide the public with an opportunity to provide additional information in light of NHTSA's analysis. Therefore, NHTSA requests comment on whether increasing the CAFE civil penalty rate to $14 would have a ''negative economic impact,'' and if so, to what level the rate should be raised, if at all.

4. The CAFE Civil Penalty Rate is Capped At $10

Under 49 U.S.C. 32912(c)(1)(B), if the CAFE civil penalty rate is increased, the rate at which it is set ''may not be more than $10 for each .1 of a mile a gallon.'' This upper limit has been in effect since EPCA was amended in 1978 and was left in place when Congress amended the civil penalty provision in 2007.[96]

The 2015 Act requires adjustments of ''civil monetary penalties,'' which must be penalties that are ''assessed or enforced by an agency pursuant to Federal law.'' [97] NHTSA believes that the $10 cap is not the maximum amount of a penalty that is ''assessed or enforced.'' Rather, it is a limit on the amount NHTSA can set for the CAFE civil penalty rate if the required determinations are made. NHTSA cannot assess or enforce the $10 cap against anyone. In contrast, other penalties in EPCA have a maximum amount that can be ''assessed or enforced.'' One example of such a penalty is the ''general penalty'' in EPCA for violations of 49 U.S.C. 32911(a). That ''general penalty'' is ''a civil penalty of not more than $10,000 for each violation.'' NHTSA has the authority, without any additional rulemakings, to subject the entity committing a violation to the maximum amount—$10,000—for that violation, or a lower amount, in its discretion. By contrast NHTSA has no discretion to enforce anything other than the result of the CAFE formula against a manufacturer, which includes the current $5.50 multiplier. The $10 figure is not part of that formula and could only become so after further rulemaking.

Accordingly, NHTSA is tentatively proposing in the alternative that any potential adjustment NHTSA makes to the CAFE civil penalty rate be capped at $10 and seeks comment on this proposal. Commenters should consider whether the $10 limit is itself a ''civil monetary penalty'' that must be adjusted under the 2015 Act, keeping in mind that the level was kept the same when the previous adjustment was made in 1997. Commenters should also consider the effect of the 2007 amendments in ratifying the $10 level and whether the market-based complexities established by those amendments bear on what Congress meant subsequently by ''civil monetary penalty'' in the 2015 Act.

[93] 75 FR 25323, 25666–67 (May 7, 2010).

[94] 77 FR 62623, 63131 (Oct. 15, 2012).

[95] *Nat'l Shooting Sports Found., Inc.* v. *Jones,* 716 F.3d 200, 214–15 (D.C. Cir. 2013) (''An agency has 'wide discretion' in making line-drawing decisions and '[t]he relevant question is whether the agency's numbers are within a zone of reasonableness, not whether its numbers are precisely right.' . . . An agency 'is not required to identify the optimal threshold with pinpoint precision. It is only required to identify the standard and explain its relationship to the underlying regulatory concerns.'") (quoting *WorldCom, Inc.* v. *FCC,* 238 F.3d 449, 461–62 (D.C. Cir. 2001)).

[96] In the interim final rule required by the 2015 Act, NHTSA announced that the adjusted maximum civil penalty would be increased from $10 to $25. 82 FR 32139 (July 12, 2017). However, this change was never formally codified in the Code of Federal Regulations nor adopted by Congress. Even if the adjustment is considered to have been adopted, however, NHTSA is now reconsidering that decision for the reasons explained above.

[97] 28 U.S.C. 2461 note, Federal Civil Penalties Inflation Adjustment § 3(2)(B), (C).

F. Rulemaking Analyses and Notices

1. Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

NHTSA has considered the impact of this rulemaking action under Executive Order 12866, Executive Order 13563, and the Department of Transportation's regulatory policies and procedures. This rulemaking document has been considered a ''significant regulatory action'' under Executive Order 12866. At this stage, NHTSA believes that this rulemaking could also be ''economically significant,'' but cannot definitively make that determination until the final rule stage, as it depends entirely on the civil penalty rate established in the final rule.

2. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of proposed rulemaking or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions). No regulatory flexibility analysis is required if the head of an agency certifies the proposal will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a proposal will not have a significant economic impact on a substantial number of small entities.

NHTSA has considered the impacts of this notice of proposed rulemaking under the Regulatory Flexibility Act and certifies that this rule would not have a significant economic impact on a substantial number of small entities. The following provides the factual basis for this certification under 5 U.S.C. 605(b).

The Small Business Administration's (SBA) regulations define a small business in part as a ''business entity organized for profit, with a place of business located in the United States, and which operates primarily within the United States or which makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials or labor.'' 13 CFR 121.105(a). SBA's size standards were previously organized according to Standard Industrial Classification (''SIC'') Codes. SIC Code 336211 ''Motor Vehicle Body Manufacturing'' applied a small business size standard of 1,000 employees or fewer. SBA now uses size standards based on the North American Industry Classification System (''NAICS''), Subsector 336—Transportation Equipment Manufacturing. This action is expected to affect manufacturers of motor vehicles. Specifically, this action affects manufacturers from NAICS codes 336111—Automobile Manufacturing, and 336112—Light Truck and Utility Vehicle Manufacturing, which both have a small business size standard threshold of 1,500 employees.

Though civil penalties collected under 49 CFR 578.6(h)(1) and 49 CFR 578.6(h)(2) apply to some small manufacturers, low volume manufacturers can petition for an exemption from the Corporate Average Fuel Economy standards under 49 CFR part 525. This would lessen the impacts of this rulemaking on small business by allowing them to avoid liability for penalties under 49 CFR 578.6(h)(2). Small organizations and governmental jurisdictions will not be significantly affected as the price of motor vehicles and equipment ought not change as the result of this rule.

3. Executive Order 13132 (Federalism)

Executive Order 13132 requires NHTSA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations 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.'' Under Executive Order 13132, the agency may not issue a regulation with Federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, the agency consults with State and local governments, or the agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132.

The reason is that this rule will generally apply to motor vehicle manufacturers. Thus, the requirements of Section 6 of the Executive Order do not apply.

4. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, Public Law 104–4, requires agencies to prepare a written assessment of the cost, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually. Because this rule is not expected to include a Federal mandate, no Unfunded Mandates assessment will be prepared.

5. National Environmental Policy Act

The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4347) requires Federal agencies to analyze the environmental impacts of proposed major Federal actions significantly affecting the quality of the human environment, as well as the impacts of alternatives to the proposed action. 42 U.S.C. 4332(2)(C). When a Federal agency prepares an environmental assessment, the Council on Environmental Quality (CEQ) NEPA implementing regulations (40 CFR parts 1500–1508) require it to ''include brief discussions of the need for the proposal, of alternatives [. . .], of the environmental impacts of the proposed action and alternatives, and a listing of agencies and persons consulted.'' 40 CFR 1508.9(b). This section serves as the agency's Draft Environmental Assessment (Draft EA). NHTSA invites public comments on the contents and tentative conclusions of this Draft EA.

i. Purpose and Need

This notice of proposed rulemaking sets forth the purpose of and need for this action. NHTSA is required to consider whether it is appropriate, pursuant to the Inflation Adjustment Act, to make an initial ''catch-up'' adjustment to the civil monetary penalties it administers for the CAFE program. Further, if the agency determines that the Inflation Adjustment Act applies, it must consider the appropriate approach to undertake pursuant to the legislation. The purpose of this notice of proposed rulemaking is to consider the applicability of the Inflation Adjustment Act and to propose adjustments pursuant to the Act, consistent with its

requirements as well as the agency's responsibilities under EPCA (as amended by EISA).

ii. Alternatives

NHTSA has considered a range of alternatives for the proposed action, including maintaining the civil penalty amount at $5.50 per each tenth of a mile per gallon (the No Action Alternative) and increasing the civil penalty amount to $14.00 per each tenth of a mile per gallon (as previously proposed). This notice of proposed rulemaking also seeks public comment on whether it is required to increase the civil penalty amount to $6.00 per each tenth of a mile per gallon (rounding pursuant to the 2015 Act) or whether the civil penalty amount is capped at $10.00 per each tenth of a mile per gallon (pursuant to EPCA). In this notice of proposed rulemaking, the agency proposes maintaining the civil penalty amount at $5.50 as its preferred alternative, although it may select any value along this range of alternatives, including any civil penalty amount between $5.50 and $14.00. NHTSA is also proposing to increase the ''general penalty'' to a maximum penalty of $41,484,[98] pursuant to the requirements of the Inflation Adjustment Act.

iii. Environmental Impacts of the Proposed Action and Alternatives

Under all of the alternatives under consideration, the agency would maintain or increase the civil penalty amount for a manufacturer's failure to meet its fleet's average fuel economy target (assuming the manufacturer does not have sufficient credits available to cover the shortfall). When deciding whether to add fuel-saving technology to its vehicles, a manufacturer might consider the cost to add the technology, the price and availability of credits, the potential reduction in its civil penalty liability, and the value to the vehicle purchaser of the change in fuel outlays over a specified ''payback period.'' A higher civil penalty amount could encourage manufacturers to improve the average fuel economy of their passenger car and light truck fleets if the benefits of installing fuel-saving technology (*i.e.,* lower civil penalty liability and increased revenue from vehicle sales) outweigh the costs of installing the technology.

However, there are many reasons why this might not occur to the degree anticipated. Apart from the civil penalty rate, as CAFE standards increase in stringency, manufacturers have needed to research and install increasingly less cost-effective technology that may not obtain levels of consumer acceptance necessary to offset the investment. A higher civil penalty amount combined with the value of the potential added fuel economy benefit of new, advanced technology to the vehicle purchaser may not be sufficient to outweigh the added technology costs (including both the financial outlays and the risk that consumers may not value the technology or accept its impact on the driving experience, therefore opting not to purchase those models). This may be especially true when gas prices are low. If the added cost in civil penalty payments is borne by the manufacturer, this may result in reduced investment in fuel saving technology or reduced consumer choice. If the added cost in civil penalty payments is passed on to the consumer, the consumer would see higher vehicle purchase costs without a corresponding fuel economy benefit or other benefits, resulting in fewer purchases of newer, more fuel-efficient vehicles. Based on the foregoing, NHTSA believes that each of the alternatives under consideration in this notice of proposed rulemaking could result, at most, only marginally better levels of compliance with the applicable fuel economy targets.

An increase in a motor vehicle's fuel economy is associated with reductions in fuel consumption and greenhouse gas (GHG) emissions for an equivalent distance of travel. Increased global GHG emissions are associated with climate change, which includes increasing average global temperatures, rising sea levels, changing precipitation patterns, increasing intensity of severe weather events, and increasing impacts on water resources. These, in turn, could affect human health and safety, infrastructure, food and water supplies, and natural ecosystems. Fewer GHG emissions would reduce the likelihood of these impacts. Changes in motor vehicle fuel economy are also associated with impacts on criteria and hazardous air pollutant emissions, safety, life-cycle environmental impacts, and more.

As part of recent rulemaking actions establishing CAFE standards, NHTSA evaluated the impacts of increasing fuel economy standards for passenger cars and light trucks on these and other environmental impact areas.[99] The analyses assumed a civil monetary penalty of $5.50 per each tenth of a mile per gallon. Though particular values reported in its recent Environmental Impact Statements (EISs) may no longer be replicable due to updated assumptions and new information obtained since their publication, the agency believes that the environmental impact trends reported remain adequate and valid. The agency has considered the information and trends presented in those EISs in preparing this proposal. For example, the MY 2017–2025 CAFE EIS showed that the large stringency increases in the fuel economy standards as a result of that rulemaking would result in reductions of global mean surface temperature increases of no more than 0.016°C by 2100. Further, that EIS showed nationwide reductions in most criteria pollutant emissions in 2040 (usually in ranges of 10% or less) and small increases or reductions in most toxic pollutant emissions in 2040 (usually in ranges of 3% or less). NHTSA believes the impacts on fuel economy resulting from this action would be very small compared to the impacts on fuel economy resulting from the stringency increases that were reported in those EISs. Therefore, NHTSA anticipates that the environmental impacts resulting from the proposed action would range from no change (No Action Alternative) to negligible impacts consistent with, but to a much smaller degree than, the trends reported in those EISs (increase in the civil penalty).

NHTSA will prepare a new EIS for its forthcoming proposal for new CAFE standards.[100] The agency's civil penalty rate is an input in the CAFE Model that will inform the development of that EIS and, ultimately, the agency's final decision for setting CAFE standards. The agency does not believe the civil penalty rate being proposed will limit its ability to set ''maximum feasible'' standards pursuant to 49 U.S.C. 32902(b)(2)(B), nor will it unreasonably constrain the potential environmental outcomes associated with future rulemakings. In addition, NHTSA will review the new EIS and the updated CAFE Model as it prepares its final EA for this action, which will ultimately inform the development of the final rule.

NHTSA is also proposing to increase the ''general penalty'' pursuant to the

[98] NHTSA adjusted this penalty to a maximum of $40,000 in its July 2016 IFR. Applying 1.01636 multiplier for 2017 inflationary adjustments, as specified in OMB's December 16, 2016 guidance, results in an adjusted maximum penalty of $40,654. Applying the multiplier for 2018 of 1.02041, as specified in OMB's December 15, 2017, results in an adjusted maximum penalty of $41,484.

[99] *See, e.g.,* NHTSA, *Final Environmental Impact Statement, Corporate Average Fuel Economy Standards, Passenger Cars and Light Trucks, Model Years 2017–2025.* Docket No. NHTSA–2011–0056. July 2012.

[100] NHTSA, *Notice of Intent to Prepare an Environmental Impact Statement for Model Year 2022–2025 Corporate Average Fuel Economy Standards.* 82 FR 34740 (Jul. 26, 2017).

Inflation Adjustment Act. This increase is not anticipated to have impacts on the quality of the human environment. The ''general penalty'' is applicable to other violations, such as a manufacturer's failure to submit pre-model year and mid-model year reports to NHTSA on whether they will comply with the average fuel economy standards. These violations are not directly related to on-road fuel economy, and therefore the penalties are not anticipated to directly or indirectly affect fuel use or emissions.

iv. Agencies and Persons Consulted

NHTSA and DOT have consulted with OMB as described earlier in this proposal. NHTSA and DOT have not consulted with any other agencies in the development of this proposal.

v. Conclusion

NHTSA has reviewed the information presented in this Draft EA and concludes that the proposed action and alternatives would have no impact or a small positive impact on the quality of the human environment. The preferred alternative is anticipated to have no impact on the quality of the human environment, as it would result in no change, as compared to current law, to the civil penalty amount for failure to meet fuel economy targets. Further, the proposed change to the ''general penalty'' is not anticipated to affect on-road emissions. Any of the impacts anticipated to result from the alternatives under consideration are not expected to rise to a level of significance that necessitates the preparation of an Environmental Impact Statement. Based on the information in this Draft EA and assuming no additional information or changed circumstances, NHTSA expects to issue a Finding of No Significant Impact (FONSI). Such a finding will not be made before careful review of all public comments received. A Final EA and a FONSI, if appropriate, will be issued as part of the final rule.

6. Executive Order 12778 (Civil Justice Reform)

This rule does not have a retroactive or preemptive effect. Judicial review of a rule based on this proposal may be obtained pursuant to 5 U.S.C. 702.

7. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980, NHTSA states that there are no requirements for information collection associated with this rulemaking action.

8. Privacy Act

Please note that anyone is able to search the electronic form of all comments received into any of DOT's dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or you may visit *http://dms.dot.gov.*

9. Executive Order 13771

This proposed rule is expected to be a deregulatory action under Executive Order 13771, although NHTSA, at this point, has not been able to quantify potential cost savings.

Proposed Regulatory Text

List of Subjects in 49 CFR Part 578

Imports, Motor vehicle safety, Motor vehicles, Rubber and rubber products, Tires, Penalties.

In consideration of the foregoing, 49 CFR part 578 is proposed to be amended as set forth below.

PART 578—CIVIL AND CRIMINAL PENALTIES

■ 1. The authority citation for 49 CFR part 578 is revised to read as follows:

Authority: Pub. L. 101–410, Pub. L. 104–134, Pub. L. 109–59, Pub. L. 114–74, Pub. L. 114–94, 49 U.S.C. 30165, 30170, 30505, 32308, 32309, 32507, 32709, 32710, 32902, 32912, and 33115; delegation of authority at 49 CFR 1.81, 1.95.

■ 2. Amend § 578.6 by revising paragraph (h) to read as follows:

§ 578.6 Civil penalties for violations of specified provisions of Title 49 of the United States Code.

* * * * *

(h) *Automobile fuel economy.* (1) A person that violates 49 U.S.C. 32911(a) is liable to the United States Government for a civil penalty of not more than $41,484 for each violation. A separate violation occurs for each day the violation continues.

(2) Except as provided in 49 U.S.C. 32912(c), a manufacturer that violates a standard prescribed for a model year under 49 U.S.C. 32902 is liable to the United States Government for a civil penalty of $5.50 multiplied by each .1 of a mile a gallon by which the applicable average fuel economy standard under that section exceeds the average fuel economy—

(i) Calculated under 49 U.S.C. 32904(a)(1)(A) or (B) for automobiles to which the standard applies manufactured by the manufacturer during the model year;

(ii) Multiplied by the number of those automobiles; and

(iii) Reduced by the credits available to the manufacturer under 49 U.S.C. 32903 for the model year.

* * * * *

Issued in Washington, DC, under authority delegated in 49 CFR 1.81, 1.95, and 501.5

Heidi R. King,

Deputy Administrator.

[FR Doc. 2018–06550 Filed 3–30–18; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R1–ES–2017–0050; FXES11130900000C6–189–FF09E42000]

RIN 1018–BC10

Endangered and Threatened Wildlife and Plants; Reclassifying the Hawaiian Goose From Endangered to Threatened With a 4(d) Rule

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: Under the authority of the Endangered Species Act of 1973, as amended (Act), we, the U.S. Fish and Wildlife Service (Service), propose to reclassify the Hawaiian goose (nene) (*Branta* (=*Nesochen*) *sandvicensis*) from endangered to threatened, and we propose a rule under section 4(d) of the Act to enhance conservation of the species through range expansion and management flexibility. This proposal is based on a thorough review of the best available scientific data, which indicate that the species' status has improved such that it is not currently in danger of extinction throughout all or a significant portion of its range. We also propose to correct the Federal List of Endangered and Threatened Wildlife to reflect that *Nesochen* is not currently a scientifically accepted generic name for this species, and to acknowledge the Hawaiian name ''nene'' as an alternative common name. We seek information, data, and comments from the public on this proposal.

DATES: We will accept comments received or postmarked on or before June 1, 2018. Please note that if you are using the Federal eRulemaking Portal (see **ADDRESSES**), the deadline for submitting an electronic comment is 11:59 p.m. Eastern Time on this date.

We must receive requests for public hearings, in writing, at the address shown in the **FOR FURTHER INFORMATION CONTACT** section by May 17, 2018.

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

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R1–ES–2017–0050, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Comment Now!'' Please ensure that you have found the correct rulemaking before submitting your comment.

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R1–ES–2017–0050, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3808.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Document availability: The proposed rule is available on *http://www.regulations.gov.* In addition, the supporting file for this proposed rule will be available for public inspection, by appointment, during normal business hours, at the Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard, Room 3–122, Honolulu, HI 96850; telephone 808–792–9400.

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

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, a species may warrant reclassification from endangered to threatened if it no longer meets the definition of endangered (in danger of extinction). The Hawaiian goose (nene) is listed as endangered, and we are proposing to reclassify nene as threatened because we have determined it is no longer in danger of extinction. Reclassifications can only be made by issuing a rulemaking. Furthermore, changes to the take prohibitions in section 9 of the Act, such as those we are proposing for this species under a section 4(d) rule, can only be made by issuing a rulemaking.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species based on any one or a combination of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that the nene is no longer at risk of extinction and, therefore, does not meet the definition of endangered, but is still affected by the following current and ongoing threats to the extent that the species meets the definition of a threatened species under the Act:

- Habitat destruction and modification due to urbanization, agricultural activities, nonnative ungulates, and nonnative vegetation;
- Predation by nonnative mammals such as mongooses, cats, dogs, rats, and pigs;
- Diseases such as toxoplasmosis, avian pox, avian botulism, avian malaria, omphalitis, West Nile virus, and avian influenza;
- Human activities such as motor vehicle collisions, collisions at wind energy facilities, artificial hazards (*e.g.,* fences, fishing nets, erosion control material), feeding and habituation, and recreational activities (*e.g.,* human visitation at parks and refuges); and
- Stochastic events such as drought and hurricanes.

Environmental effects from climate change are likely to exacerbate the impacts of drought and hurricanes, and flooding of nene habitat due to sea level rise may become a threat in the future. Existing regulatory mechanisms and conservation efforts do not effectively address the introduction and spread of nonnative plants and animals and other threats to the nene.

We are proposing to promulgate a section 4(d) rule. We are proposing to modify the normal take prohibitions to allow certain activities conducted on lands where nene occur or where they would occur if we were to reintroduce them to areas of their historical distribution. Under the proposed 4(d) rule, take of nene caused by actions resulting in intentional harassment that is not likely to cause direct injury or mortality, control of introduced predators, or habitat enhancement beneficial to nene would be not be prohibited. The proposed 4(d) rule identifies these activities to provide protective mechanisms to landowners and their agents so that they may continue with certain activities that are not anticipated to cause direct injury or mortality to nene and that will facilitate the conservation and recovery of nene. Federally implemented, funded, or permitted actions would continue to be subject to the requirements of section 7 of the Act and eligible for an incidental take exemption through section 7(o).

Information Requested

Public Comments

We intend that any final action resulting from this proposal will be based on the best available scientific and commercial data and will be as accurate and as effective as possible. Therefore, we invite governmental agencies, the scientific community, industry, Native Hawaiian organizations, or any other interested parties to submit comments or recommendations concerning any aspect of this proposed rule. Comments should be as specific as possible. We are specifically requesting comments on:

(1) The appropriateness of our proposal to reclassify nene from endangered to threatened.

(2) The factors that are the basis for making a reclassification determination for a species under section 4(a) of the Act (16 U.S.C. 1531 *et seq.*), which are:

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

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

(c) Disease or predation;

(d) The inadequacy of existing regulatory mechanisms; or

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

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to the nene and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of this species, including the locations of any additional populations of this species.

(5) Any information on the biological or ecological requirements of the species and ongoing conservation measures for the species and its habitat.

(6) Any information on foreseeable changes to State land use or County land use planning within the

boundaries of the nene's range that may affect future habitat availability for the nene.

(7) The appropriateness of a rule under section 4(d) of the Act to allow certain actions to take nene, and any additional actions that should be considered for authorization.

(8) The appropriateness of a rule under section 4(d) of the Act to allow interstate commerce for nene in captivity outside Hawaii.

(9) Any additional information pertaining to the promulgation of a rule under section 4(d) of the Act to allow certain actions that may take nene.

(10) Relevant data on climate change and potential impacts to the nene and its habitat.

We will take into consideration all comments and any additional information we receive. Such communications may lead to a final rule that differs from this proposal. All comments, including commenters' names and addresses, if provided to us, will become part of the supporting record. Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include. Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning the proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

We will post all hardcopy submissions on *http://www.regulations.gov.* Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Public Hearing

Section 4(b)(5)(E) of the Act provides for a public hearing on this proposal, if requested. We must receive a request for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by the date specified in **DATES**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** at least 15 days before the hearing.

Peer Review

In accordance with our policy, ''Notice of Interagency Cooperative Policy for Peer Review in Endangered Species Act Activities,'' which published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinion of at least three appropriate independent specialists regarding scientific data and interpretations contained in this proposed rule. We will send copies of this proposed rule to the peer reviewers immediately following publication in the **Federal Register.** This assessment will be completed during the public comment period. The purpose of such review is to ensure that our decisions are based on scientifically sound data, assumptions, and analysis. Accordingly, the final decision may differ from this proposal.

Background

Previous Federal Action

On March 11, 1967, the Secretary of the Interior identified nene as an endangered species (32 FR 4001), under the authority of the Endangered Species Preservation Act of 1966 (80 Stat. 926; 16 U.S.C. 668aa(c)). On March 8, 1969, the Secretary of the Interior again identified nene as an endangered species (34 FR 5034) under section 1(c) of the Endangered Species Preservation Act of 1966. On October 13, 1970, the Director of the Bureau of Sport Fisheries and Wildlife listed nene as an endangered species (35 FR 16047) under the authority of the new regulations implementing the Endangered Species Conservation Act (ESCA) of 1969. Species listed as endangered under the ESCA of 1969 were automatically included in the List of Endangered and Threatened Wildlife when the Endangered Species Act (Act) was enacted in 1973.

On February 14, 1983, the Service released the Nene Recovery Plan (USFWS 1983). On September 24, 2004, the Service published for comment (69 FR 57356) the Draft Revised Recovery Plan for Nene (USFWS 2004). The Draft Revised Recovery Plan presented additional information on the status of the species, factors affecting species recovery, and an updated framework for species recovery.

A 5-year status review of the nene was completed on September 30, 2011 (USFWS 2011a). This review concluded that nene continued to meet the definition of an endangered species under the Act, and recommended no change in the classification of nene as endangered. However, current information indicates the species is not in danger of extinction and may warrant reclassification from endangered to threatened.

Species Information

The original rules identifying nene as an endangered species (32 FR 4001, 34 FR 5034, 35 FR 16047) listed its scientific name as *Branta sandvicensis* and its common name as ''Hawaiian goose (Nene).'' Currently the Federal List of Endangered and Threatened Wildlife (50 CFR 17.11) gives its scientific name as *Branta* (=*Nesochen*) *sandvicensis,* and its common name as ''Hawaiian goose,'' without indicating ''nene'' as an alternative common name. This species was once placed in the genus *Nesochen* by the American Ornithologists' Union (AOU) (1982); however, it was subsequently reassigned to the genus *Branta* (AOU 1993) based on analysis of mitochondrial DNA by Quinn *et al.* (1991). Thus, *Branta sandvicensis* is the only currently accepted scientific name. The common name ''Hawaiian goose'' continues to be accepted by the ornithological community (AOU 1998). However, the Hawaiian common name ''nene'' is also widely familiar to the public and is, for example, frequently referenced in governmental documents within the State of Hawaii (*e.g.,* Hawaii Department of Land and Natural Resources (DLNR) 2005). Therefore, we are including in this document a proposal to return to the scientific and common names that were used in the original listing rules, with ''nene'' as an accepted alternative common name.

The nene is a medium-sized goose with an overall length of approximately 25 to 27 inches (in) (63 to 65 centimeters (cm)) (Banko *et al.* 1999, p. 2). The plumage of both sexes is similar (Banko *et al.* 1999, p. 2). This species is

adapted to a terrestrial and largely non-migratory lifestyle in the Hawaiian Islands with limited freshwater habitat (Banko *et al.* 1999, p. 1). Adaptations to a terrestrial lifestyle include increased hindlimb size, decreased forelimb size, more upright posture, and reduced webbing between the toes compared to other species of *Branta* (Banko *et al.* 1999, p. 1; Olson and James 1991, p. 42). Compared to the related Canada goose (*Branta canadensis*), nene wings are about 16 percent smaller in size and their flight is not as strong (Banko *et al.* 1999, p. 9). Nene are capable of inter-island and high altitude flight, but they do not migrate out of the Hawaiian archipelago (Banko *et al.* 1999, p. 9).

Nene currently use shrublands, grasslands, sparsely vegetated lava flows, and human-altered habitats ranging from coastal to alpine environments (Wilson and Evans 1890–1899, p. 186; Munro 1944, pp. 41–42; Scott *et al.* 1986, p. 77; Banko *et al.* 1999, pp. 4–5). In the grassy shrublands and sparsely vegetated lava flows on the islands of Hawaii and Maui, nene nest, raise their young, forage, and molt (Banko *et al.* 1999, p. 2). Some nene populations on these islands move seasonally from montane foraging grounds to lowland or midelevation nesting areas (Banko *et al.* 1999, p. 2). On the island of Kauai, nene are primarily found using lowland habitats such as coastal wetlands at Hanalei National Wildlife Refuge (NWR), with the exception of the Na Pali Coast (USFWS 2004, pp. 15, 17).

Nene are currently known to occupy various habitat and vegetation community types ranging from coastal dune vegetation and nonnative grasslands (such as golf courses, pastures, and rural areas) to sparsely vegetated low- and high-elevation lava flows, mid-elevation native and nonnative shrubland, cinder deserts, native alpine grasslands and shrublands, and open and nonnative alpine shrubland-woodland community interfaces (Banko *et al.* 1999, pp. 4–6). On the island of Kauai, nene also use a number of coastal wetland areas including taro loi (ponds) (A. Marshall 2017a, pers. comm.). Nene are browsing-grazers; the composition of their diet depends largely on the vegetative composition of their surrounding habitats, and they appear to be opportunistic in their choice of food plants as long as they meet nutritional demands (Banko *et al.* 1999, pp. 6–8; Woog and Black 2001, p. 324). Nene may exhibit seasonal movements to grasslands in periods of low berry production and wet conditions that produce grass with a high water content and resultant higher protein content. The sites currently used by nene for nesting range from coastal lowland to subalpine zones and demonstrate considerable variability in features (Banko *et al.* 1999, pp. 4–5). However, the current distribution of nene nesting sites has been influenced by the location of release sites of captive-bred individuals (Hawaii Division of Forestry and Wildlife (DOFAW) 2012, pp. 9–10). Historical reports from the island of Hawaii indicate that nene bred and molted primarily in the lowlands during winter months and moved upslope in the hotter and drier summer months (Henshaw 1902, p. 105; Munro 1944, pp. 41–42; Banko 1988, p. 35). Reproductive success is relatively low in upland habitats on the islands of Hawaii and Maui, and higher in lowland habitat on Kauai (Banko *et al.* 1999, p. 19).

Nene have an extended breeding season with eggs being laid from August to April (Banko *et al.* 1999, p. 12). Nesting peaks in December, and most goslings hatch from December to January (Banko *et al.* 1999, p.12). On the island of Kauai, nene frequently nest earlier (A. Marshall 2017a, pers. comm.). Nene nest on the ground, in a shallow scrape in the dense shade of a shrub or other vegetation. A clutch typically contains three to five eggs, and incubation lasts for 29 to 32 days (Banko *et al.* 1999, pp. 14–15). Once hatched, the young may remain in the nest for 1 to 2 days; all hatchlings depart the nest after the last egg is hatched (Banko *et al.* 1999, p. 12). Fledging (*i.e.,* development of wing feathers large enough for flight) occurs at 10 to 12 weeks for captive birds, but may be later in the wild (Banko *et al.* 1999, p. 18). During molt, adults are flightless for a period of 4 to 6 weeks and generally attain their flight feathers at about the same time as their offspring. When flightless, goslings and adults are extremely vulnerable to predators such as cats, dogs, and mongoose. After molting and fledging, around June to September, family groups frequently congregate in post-breeding flocks, often far from nesting areas. Nene reach sexual maturity at 1 year of age, but usually do not form pair bonds until the second year. Females are highly philopatric (loyal to their place of birth) and nest near their natal area, while males more often disperse (Banko *et al.* 1999, p. 13).

Nene and one or more now extinct species of *Branta* are thought to have once been widely distributed among the main Hawaiian Islands. Fossil remains of nene have been found on Maui, Molokai, Lanai, and Kauai (Olson and James 1991, p. 43). However, nene fossils have not yet been found on Niihau (USFWS 2004, p. 6). On Oahu, all fossils appear to be of a related but extinct *Branta* form (Olson and James 1991, p. 43). The fossil record indicates the prehistoric (before 1778) range of nene was much greater than the historically observed range (Banko *et al.* 1999, p. 1). However, it is difficult to estimate original nene population numbers because the species composition and even gross structure of the vegetation before Polynesian arrival is poorly understood (USFWS 2004, p. 7). By 1960, fewer than 30 nene remained on Hawaii Island (Smith 1952, p. 1). The release of captive-bred nene, which began in 1960, helped save the species from imminent extinction (USFWS 2004, pp. 2–3). As a result of such programs, wild populations of nene now occur on four of the main Hawaiian Islands. As of 2016, the Statewide population of wild Hawaiian geese was estimated to have reached 2,855 individuals; the wild populations on the islands of Hawaii, Maui, Molokai, Kauai, and Oahu were estimated to have 1,095, 616, 35, 1,107, and 2 individuals, respectively (Nene Recovery Action Group [NRAG] 2017, unpublished). For maps of areas currently used by nene, see USFWS (2017).

Recovery Planning

Section 4(f) of the Act directs us to develop and implement recovery plans for the conservation and survival of endangered and threatened species unless we determine that such a plan will not promote the conservation of the species. Under section 4(f)(1)(B)(ii), recovery plans must, to the maximum extent practicable, include ''objective, measurable criteria which, when met, would result in a determination, in accordance with the provisions of [section 4 of the Act], that the species be removed from the list.'' However, revisions to the Lists of Endangered and Threatened Wildlife and Plants (adding, removing, or reclassifying a species) must be based on determinations made in accordance with sections 4(a)(1) and 4(b) of the Act. Section 4(a)(1) requires that the Secretary determine whether a species is endangered or threatened (or not) because of one or more of five threat factors. Section 4(b) of the Act requires that the determination be made ''solely on the basis of the best scientific and commercial data available.'' While recovery plans provide important guidance to the Service, States, and other partners on methods of enhancing conservation and minimizing threats to listed species, as well as measurable criteria against which to measure

progress towards recovery, they are not regulatory documents and cannot substitute for the determinations and promulgation of regulations required under section 4(a)(1) of the Act. A decision to revise the status of a species on, or to remove a species from, the Federal List of Endangered and Threatened Wildlife (50 CFR 17.11) is ultimately based on an analysis of the best scientific and commercial data then available to determine whether a species is no longer an endangered species or a threatened species, regardless of whether that information differs from the recovery plan.

There are many paths to accomplishing recovery of a species, and recovery may be achieved without all of the criteria in a recovery plan being fully met. For example, one or more criteria may be exceeded while other criteria may not yet be accomplished. In that instance, we may determine that the threats are minimized sufficiently and the species is robust enough to delist. In other cases, recovery opportunities may be discovered that were not known when the recovery plan was finalized. These opportunities may be used instead of methods identified in the recovery plan. Likewise, information on the species may be learned that was not known at the time the recovery plan was finalized. The new information may change the extent to which existing criteria are appropriate for recognizing recovery of the species. Recovery of a species is a dynamic process requiring adaptive management that may, or may not, follow all of the guidance provided in a recovery plan.

In 1983, the Service published the Nene Recovery Plan and concluded that the nene population in the wild was declining; however, the exact causes of the decline were not clearly understood (USFWS 1983, p. 24). The Statewide population was estimated at approximately 600 nene with 390 ± 120 nene on Hawaii Island and 112 nene on Maui. Based on the available data, the plan recommended the primary objective to delist the species was establishing a population of 2,000 nene on Hawaii Island and 250 nene on Maui, well distributed in secure habitat and maintained exclusively by natural reproduction (USFWS 1983, p. 24). The plan focused on maintenance of wild populations through annual releases of captive-reared birds to prevent further population decline, habitat management including control of introduced predators, and conducting research to determine factors preventing nene recovery and appropriate actions to overcome these factors. The plan also acknowledged that more research, biological data, and better population models would lead to a reassessment of recovery efforts and criteria for delisting the species.

On September 24, 2004, the Service published for comment (69 FR 57356) the Draft Revised Recovery Plan for Nene (USFWS 2004). The draft revised recovery plan presented additional information on the status of the species, factors affecting species recovery, and an updated framework for species recovery. At the time, the Statewide population was estimated at 1,300 nene with populations on Hawaii (349), Maui (336), Kauai (564), and Molokai (55). The primary factors affecting the nene recovery in the wild were: (1) Predation by introduced mammalian predators (Factor C), (2) inadequate nutrition (Factor E), (3) lack of lowland habitat (Factor A), (4) human-caused disturbance and mortality (Factor E), (5) behavioral issues (Factor E), (6) genetic issues (Factor E), and (7) disease (Factor C). The draft revised recovery plan recommended the following criteria for downlisting the nene from endangered to threatened: (1) Self-sustaining populations exist on Hawaii, Maui Nui (Maui, Molokai, Lanai, Kahoolawe), and Kauai (target of at least 2,000 birds distributed in 7 populations over 15 years); and (2) sufficient suitable habitat to sustain the target population levels on each island is identified, protected, and managed in perpetuity (USFWS 2004, pp. 50–52). Self-sustaining was defined as maintaining (or increasing) established population levels without additional releases of captive-bred nene, although manipulation such as predator control or pasture management may need to be continued. The draft revised recovery plan stated that consideration for delisting could occur once all of the downlisting criteria had been met, and population levels on Hawaii, Maui Nui, and Kauai had all shown a stable or increasing trend (from downlisting levels) for a minimum of 15 additional years (*i.e.,* for total of 30 years).

As noted above, substantial self-sustaining populations exist and are well distributed in multiple localities on Hawaii Island, Maui, and Kauai (NRAG 2017; USFWS 2017), totaling nearly 3,000 individuals. The species continues to be conservation-reliant (*i.e.,* dependent on long-term management commitments to active predator control and habitat management), but with ongoing management we expect these populations to continue to be self-sustaining without additional releases of captive-bred birds. As discussed below under Factor A, certain habitat stresses continue to exist, but as nene have proven adaptable to diverse native and human-modified habitats, it appears that with active management the extent and quality of existing breeding habitat is sufficient to support robust populations in multiple localities throughout the range. Additional management in seasonally occupied non-breeding habitat would improve population viability.

The 2004 draft revised recovery plan sets forth the general recovery strategy for nene (USFWS 2004, p. 47), as follows. In order for nene populations to survive they should be provided with generally predator-free breeding areas and sufficient food resources. Human-caused disturbance and mortality should be minimized, and genetic and behavioral diversity maximized. The goal of recovery stated in the draft revised recovery plan is to enable the conservation of nene by using a mix of natural and human-altered habitats in such a way that the life-history needs of the species are met and the populations become self-sustaining. While it is important to restore nene as a functioning component of the native ecosystem to ensure long-term species survival, it should be noted that nene currently successfully use a gradient of habitats ranging from highly altered to completely natural. Additionally, some populations exhibit behaviors that differ from what it is believed wild birds historically displayed. Nene are a highly adaptable species, which bodes well for recovery of the species.

Conservation needs and activities to recover nene vary among islands due to differences in factors affecting nene populations both within and among islands. For example, although mongooses occur on Hawaii, Maui, and Molokai, Kauai does not yet have an established mongoose population; thus predator control priorities there are different. In addition, elevations used by nene vary among sites and among islands, and vegetation available to nene also differs between sites and by island.

Implementation of Recovery Actions for the Nene

Nene are now more abundant than when they were federally listed as endangered in 1967, largely due to a captive propagation program that began in 1949 before the species was listed and continued through 2011. The program was initiated prior to Hawaiian statehood in collaboration between Territory of Hawaii biologists and private partners, and was operated by the Division of Fish and Game of the territorial government. The initial site of the captive propagation operation was at

Pohakuloa on Hawaii Island. Operations moved to Olinda, Maui, in 1989. In 1994, a new partnership was established between the DLNR, the Service, and The Peregrine Fund (TPF) to expand facilities and operations for captive propagation to include Hawaiian forest bird species. The Peregrine Fund established captive propagation operations at a newly built propagation facility in Keauhou on Hawaii Island in addition to the operations at Olinda. In 2000, management of the captive propagation program was transferred to the Zoological Society of San Diego. In addition, a number of zoos and private facilities in the United States and abroad continue to maintain and breed nene in captivity (Kear and Berger 1980, pp. 59–77; A. Marshall 2017b, pers. comm.). The existence of privately owned nene outside of Hawaii provides additional insurance against extinction of the species, but due to concerns about disease introduction, they are not currently used as a source for supplementation of the wild population and are not considered a significant contributor of conservation of the species. However, they are still subject to permitting requirements under the Act for interstate commerce.

Smaller operations to breed nene in open-top pens in semi-captive environments were conducted at Hawaii Volcanoes and Haleakala National Parks. In some cases, wild birds were placed into the pens where they could breed protected from predators. The young fledged from the pens to disperse to the surrounding areas. In some cases, birds were released directly into the wild farther from the pens.

In the years between 1960 and 2008, some 2,800 captive-bred nene were released into areas of their former range at more than 20 sites throughout the main Hawaiian Islands. Most releases of captive birds used open-top pens to provide protection from predators. The pens provide protection to the birds as long as they are inside the pens, and the birds frequently returned to breed in the same pens in subsequent years.

Many of the earlier releases were accompanied by little or no management of predators and habitats. Monitoring of released birds showed high mortality and low nesting success, indicating that food availability and predators had a significant impact on wild populations (Banko 1992, pp. 102–104). The highest levels of survival and reproductive success were documented at Hawaii Volcanoes and Haleakala National Parks, where more intensive management of threats was initiated, demonstrating the need and benefits of habitat management and predator control (Black *et al.* 1997, p. 1,171). Recent years have seen an increase in the capacity of conservation agencies and partners to manage habitat and control predators on larger spatial scales. Although not all release sites have supported sustained populations, areas in which predators are low or controlled and habitat is managed for native food plant species have allowed nene to fare better (Hawaii Division of Forestry and Wildlife 2012, p. 19).

Recent studies on movements of nene using satellite telemetry documented the re-establishment of traditional movement patterns in two breeding subpopulations on Hawaii Island (Hess *et al.* 2012, pp. 480–482). Nene spent the breeding and molting seasons at lower elevations from September to April, and moved to higher elevation areas during the non-breeding season in May to August. Hess *et al.* (2012, pp. 479, 482) contend that this movement pattern may be beneficial to nene for the following reasons: (1) Altitudinal migration may allow nene to track availability of food resources not otherwise seasonally available (Black *et al.* 1997, pp. 1,170–1,171); (2) migration may enhance survival during the non-breeding season by avoiding nonnative predators in (lowland) breeding areas; (3) nene may be able to reduce exposure to human activities by occupying high-elevation areas during the non-breeding season; and (4) there may be opportunities for greater genetic exchange if pair bonds are formed between individuals from separate breeding subpopulations at non-breeding locations. This movement pattern is believed to have occurred historically (Banko *et al.* 1999, pp. 3–4).

Population Viability Analyses

Black and Banko (1994) conducted a population viability analysis using the VORTEX software program to model the long-term fate of nene under three different management scenarios: (1) No further releases or management, (2) releases mirroring those of the past 30 years, and (3) increased management without further releases. The report concluded that only under the third scenario could all three populations (Hawaii, Maui, and Kauai) survive for 200 years, and that reintroduction alone as a management tool may continue to be effective in delaying extinction on Hawaii, but will not lead to a self-sustaining population. The study concluded that enhanced management efforts, which include an appropriate predator control effort, would enable nene to reach a self-sustaining level.

Another population viability analysis was conducted for nene in Hawaii Volcanoes National Park to examine management options more specific to that area (Hu 1998). First year mortality was identified as the primary limiting factor for nene in Hawaii Volcanoes National Park. From 1990 to 1996, survival of fledglings averaged 84 percent for females and 95 percent for males, while survival from laying to fledging ranged from 7 to 19.5 percent (mean 12 percent; Hu 1998, pp. 84–85). While predator control had reduced egg predation, fledging success remained low, largely due to inadequate nutrition. The study found that open-top pens cannot sustain a viable nene population in Hawaii Volcanoes National Park. The study suggests that while management techniques such as grassland management, supplemental feeding, and cultivation of native food plants may sustain nene in Hawaii Volcanoes National Park, such approaches require considerable effort and would require increasing resource expenditures. Thus, Hu (1998, pp. 107–114) suggested that nene would be more secure if they were integrated into habitat management instituted on a larger scale that would involve the creation of native-dominated, fire-adapted landscapes at low and mid-elevations in Hawaii Volcanoes National Park and more efficient, widespread predator control techniques, allowing reestablishment of their seasonal movement patterns between various locations.

Black *et al.* (1997) analyzed survival data from 1960 through 1990 for released nene on the island of Hawaii and found that the highest mortality rate was found among newly released goslings during drought years. They also found that nene at Hawaii Volcanoes National Park had the lowest annual mortality rates. The three main factors affecting mortality rates were found to be release method, age at time of release, and year of release. Releasing pre-fledged goslings with parents or foster parents from open-top pens during years with sufficient rainfall was found to be the most successful release method on the island of Hawaii (Black *et al.* 1997, p. 1,170). On Kauai, where mongooses are not yet established, protecting the nesting area from other predators, such as dogs and cats, was found to be extremely successful (T. Telfer 1998, pers. comm., as cited in USFWS 2004).

Amidon (2017) recently conducted a preliminary assessment of the short-term population trends in nene populations on the four main Hawaiian Islands where nene currently occur. This assessment used count-based and demographic models (Morris and Doak 2002, pp. 8–9) developed with readily available information on each

population (Hu 1998; Hu 1999, unpubl. as cited in Banko *et al.;* USFWS 2004; Bailey and Tamayose 2016, *in litt.;* Kendall 2016, *in litt.;* Uyehara 2016a, *in litt.*) projected over a 20-year time period assuming constant management. Count-based models (for Hawaii Volcanoes National Park, the island of Maui, Haleakala National Park, the island of Molokai, and the island of Kauai) showed an increase or leveling off around current population estimates (Amidon 2017, pp. 10–16). Demographic models variously projected level or slightly declining populations (Hakalau Forest NWR and Haleakala National Park) or continued increase (Kauai NWR Complex) (Amidon 2017, pp. 18–21). Available data did not allow modeling of nene populations on lands outside national parks and national wildlife refuges, where management and population trends are likely to differ.

Current Status Summary

In conclusion, the implementation of recovery actions for nene has significantly reduced the risk of extinction for the species. On the brink of extinction, the captive propagation and release program successfully increased the number of individuals and re-established populations throughout the species' range on Kauai, Molokai, Maui, and Hawaii Island. Studies of foraging behavior identified nene food preferences and nutritional value of food resources contributing to a greater understanding of habitat requirements during the breeding and non-breeding seasons. Current populations are sustained by ongoing management (*e.g.,* predator control, habitat management for feral ungulates and nonnative plants). On Hawaii Island, research indicates that traditional movements are being restored, which could be expected to improve survival and breeding, as well as genetic exchange between subpopulations. Recent population modeling data suggest that certain key populations are expected to maintain current levels or increase into the future if the current level of management is continued.

Summary of Factors Affecting the Species

Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for listing species, reclassifying species, or removing species from listed status. ''Species'' is defined by the Act as including any species or subspecies of fish or wildlife or plants, and any distinct vertebrate population segment of vertebrate fish or wildlife that interbreeds when mature (16 U.S.C. 1532(16)). A species may be determined to be an endangered or threatened species because of any of one or a combination of the five factors described in section 4(a)(1) of the Act: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We must consider these same five factors in reclassifying a species from endangered to threatened (*i.e.,* downlisting). We may downlist a species if the best available scientific and commercial data indicate that the species no longer meets the definition of endangered, but instead meets the definition of threatened because the species' status has improved to the point that it is not in danger of extinction throughout all or a significant portion of its range, but the species is not fully recovered.

Determining whether a species has improved to the point that it can be downlisted requires consideration of whether the species is endangered or threatened because of the same five categories of threats specified in section 4(a)(1) of the Act. A species is ''endangered'' for purposes of the Act if it is in danger of extinction throughout all or a ''significant portion of its range'' and is ''threatened'' if it is likely to become endangered within the foreseeable future throughout all or a ''significant portion of its range.''

In considering what factors might constitute threats, we must look beyond the exposure of the species to a particular factor to evaluate whether the species may respond to the factor in a way that causes actual impacts to the species. If there is exposure to a factor and the species responds negatively, the factor may be a threat, and during the five-factor analysis, we attempt to determine how significant a threat it is. The threat is significant if it drives or contributes to the risk of extinction of the species, such that the species warrants listing as endangered or threatened as those terms are defined by the Act. However, the identification of factors that could impact a species negatively may not be sufficient to compel a finding that the species warrants listing. The information must include evidence sufficient to suggest that the potential threat is likely to materialize and that it has the capacity (*i.e.,* it should be of sufficient magnitude and extent) to affect the species' status such that it meets the definition of endangered or threatened under the Act.

In the following analysis, we evaluate the status of the nene throughout all of its range as indicated by the five-factor analysis of threats currently affecting, or that are likely to affect the species within the foreseeable future.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

The draft revised recovery plan identified the lack of lowland habitat and inadequate nutrition as two habitat-related stressors limiting nene recovery (USFWS 2004, pp. 29–30). Nene continue to be affected by historic and ongoing habitat destruction and modification caused by urbanization, agricultural activities, drought, feral ungulates, and nonnative plants. These factors limit suitable breeding and flocking habitat, constraining the recovery of nene populations.

Historical habitat loss was largely a result of human activities such as urban development and land conversion for agricultural activities, particularly in lowland areas. Degradation of lowland habitats used by nene began with Polynesian colonization (around 1,600 years ago) and has continued since European arrival over the past 200 years (Kirch 1982, pp. 7–10). Impacts to lowland habitat included clearing of land for settlements and agriculture; increased frequency of fire; heavy grazing, browsing, and soil disturbance by introduced deer, cattle, goats, sheep, and pigs; and the spread of nonnative plants (Cuddihy and Stone 1990, pp. 103–107).

The threat of destruction and modification of habitat, particularly in lowland areas, by urbanization and land use conversion, including agriculture, is ongoing and expected to continue to limit the amount of nene foraging and nesting habitat. Past land use practices have resulted in great reduction or loss of native vegetation below 2,000 feet (ft) (600 meters (m)) throughout the Hawaiian Islands (TNC 2006). Hawaii's agricultural industries (*e.g.,* sugar cane, pineapple) have been declining in importance, and large tracts of former agricultural lands are being converted into residential areas or left fallow (TNC 2007). In addition, Hawaii's population has increased almost 10 percent in the past 10 years, further increasing demands on limited land and water resources in the islands (Hawaii Department of Business, Economic Development and Tourism 2013, *in litt.*). While breeding habitat has some level of protection in the national parks, national wildlife refuges, and some

State lands, there is little to no protection for habitat that nene use outside the breeding season. Nene are vulnerable at this time as well as during the breeding season as they are moving around to different areas, exposing them to additional predation in unprotected habitat, poor availability of suitable foraging habitat, and interactions with humans and human structures (wind towers, vehicles, etc). Human activities associated with the development and urbanization of lowland habitat will continue to impact nene. For example, nene collide with trees, fences, and particularly motor vehicles (Banko and Elder 1990; Banko *et al.* 1999). Nene are attracted to feeding opportunities provided by mowed grass, weeds, and human handouts. Feeding, in particular, makes nene vulnerable to collisions along roadsides as they frequently become tame and unafraid of human activity (Banko *et al.* 1999). Mortality is high in human-modified habitats due to increased predation, collisions, and human-caused accidents (Banko *et al.* 1999).

The alteration of lowland areas and increasing pressure from human activities (including hunting; see Factor B discussion, below) led to the extirpation of nene on Kauai and Molokai, and the loss of seasonally important lowland breeding habitat in leeward regions of islands with elevations above 5,000 ft (1,524 m) (Maui and Hawaii) (Baldwin 1945). From the time of European arrival (in the late 1700s) until the late 1800s, nene were thought to be all but extirpated, except for a widely distributed population on the island of Hawaii (Baldwin 1945, pp. 27–30). By the 1940s, Baldwin (1945, p. 35) estimated a reduction in the range of nene on Hawaii Island from 2,475 square miles (mi^2) (6,410 square kilometers (km^2)) to 1,150 mi^2 (2,979 km^2), a loss of over half of its remaining range on Hawaii Island since European contact. At the time the captive propagation program began in the late 1950s, the remaining wild nene were restricted to montane habitats in the ''saddle area'' between Mauna Loa and Mauna Kea on Hawaii Island (Baldwin 1945, p. 33).

Feral ungulates and nonnative plants led to further degradation of nene habitat by negatively impacting forage quality, shelter, and potential nest sites. Grazing and browsing by introduced cattle, goats, and sheep converted significant portions of native montane forest and shrubland between 1,640 and 6,562 ft (500 and 2,000 m) to wild grassland and managed pastureland dominated by nonnative species (Cuddihy and Stone 1990, pp. 59–63, 63–67). Effects of nonnative ungulates have been somewhat less severe above 6,562 ft (2,000 m) because nonnative weeds are less prevalent (Banko *et al.* 1999, p. 6). Nonnative plants adversely affect native habitat in Hawaii by: (1) Modifying the availability of light, (2) altering soil-water regimes, (3) modifying nutrient cycling, and (4) altering fire regimes of native plant communities (*i.e.,* the ''grass/fire cycle'' that converts native-dominated plant communities to nonnative plant communities) (Smith 1985, pp. 180–181; Cuddihy and Stone 1990, p. 74; D'Antonio and Vitousek 1992, p. 73; Vitousek *et al.* 1997, p. 6).

Studies indicate that inadequate nutritional quality is a limiting factor on nene reproduction and gosling survival, especially on Hawaii and Maui (USFWS 2004, pp. 29–30). Proper nutrition is critical for successful reproduction. Breeding females require carbohydrates and protein to increase fat reserves for egg laying and incubation; goslings require high-protein foods for growth and development (Ankney 1984, pp. 364–370; Banko *et al.* 1999, p. 7). Banko (1992, pp. 103–104) suggested that low breeding rates (20 to 63 percent) and low nest success (44 percent) at several sites on Maui and Hawaii from 1979 to 1981 were likely attributable to poor quality or low availability of foods. Baker and Baker (1995, p. 2; 1999, p. 12) found that the high rates of gosling mortality (57 to 81 percent) in Haleakala National Park during the mid-1990s were due to starvation and dehydration. Between 1989 and 1999, lack of adequate food or water also appeared to be a factor limiting nene recruitment in Hawaii Volcanoes National Park (Rave *et al.* 2005, p. 14). In many instances of gosling mortality, the actual cause of death may be exposure because goslings are weakened by malnutrition (at hatching) and were unable to keep up with parents, and therefore got chilled or overheated and died (Baker and Baker 1999, p. 13). Emaciation was the most common cause of death diagnosed in 71 out of 300 adult and gosling mortalities submitted to the National Wildlife Health Research Center between 1992 and 2013 for which a cause of death was identified (Work *et al.* 2015, p. 692). More cases of emaciation were diagnosed on Hawaii Island (32), and to a lesser extent Kauai (21) and Maui (13), perhaps reflecting the rates of hatching and fledgling success and nutritional quality of habitats on the respective islands. Habitat also continues to be reduced due to the spread of unpalatable alien grasses (*e.g.,* guinea grass (*Megathyrsus maximus*), sword grass (*Miscanthus floridulus*)) and other weeds (*e.g.,* koa haole (*Leucaena leucocephala*), lantana (*Lantana camara*)), as this spread diminishes foraging opportunities (Banko *et al.* 1999, p. 23). Therefore, inadequate nutritional quality due to the lack of suitable foraging opportunities in and around current breeding areas, particularly at higher elevations on Maui and Hawaii Island, coupled with the loss of lowland breeding areas across its range, is expected to continue as a threat to the nene.

Drought has been identified as a factor contributing to nene mortality. Drought reduces the amount and quality of available forage, thereby increasing the risk of nene mortality due to starvation and dehydration; thus, for example, nene exhibited higher rates of mortality in drought years during the prolonged island-wide drought between 1976 and 1983 on Hawaii Island (Black *et al.* 1997, pp. 1,165–1,169). Drought was also thought to have contributed to the population decline (10 percent) at Hawaii Volcanoes National Park in the late 1990s (Rave *et al.* 2005, p. 12). Numerous and recurrent droughts have been historically documented throughout the Hawaiian Islands (Giambelluca *et al.* 1991, pp. 3–4; Hawaii Civil Defense 2011, ch. 14, pp. 1–12), with the most severe events often associated with the El Niño phenomenon (Hawaii Civil Defense 2011, p. 14–3). Based on the frequency of drought and its population-level impacts to nene, we conclude that the threat of drought is ongoing and likely to continue periodically into the foreseeable future.

Recovery efforts initially focused on the establishment of populations with the majority of releases of captive-bred nene at high-elevation native shrublands (above 5,000 ft (1,524 m)) on Hawaii Island and Maui. High-elevation nesting areas are less modified than lowlands (Banko *et al.* 1999, p. 6), but may provide poorer quality habitat for nene foraging and nesting, due to drier conditions and phenology of food plants, which limit available food resources during critical pre-breeding and breeding periods (Black *et al.* 1994, pp. 101–103; Black *et al.* 1997, p. 1,170). Black *et al.* (1997, p. 1,169) found that nene that remained at high-elevation sites year-round exhibited lower rates of reproductive success and survival than those that dispersed from release sites. Nene survival and breeding success improved by moving away from dry upper montane volcanic scrubland to managed grasslands or managed ranchland, or if they were provided supplemental feed and water,

particularly in drought years (Black *et al.* 1994, p. 103; Black *et al.* 1997, pp. 1,169–1,170). Subsequent reintroductions at low- and mid-elevation sites, first on Kauai and Hawaii Island, and more recently on eastern Molokai and western Maui, demonstrated the ability of nene to successfully become re-established in these areas.

Currently, nene are found in a range of habitats from sea level to subalpine zones on Kauai, Oahu, Molokai, Maui, and Hawaii Island. Populations are centered around release sites and rely on continued land use protections and habitat management (including predator control) to sustain populations in these areas. On Maui Nui and Hawaii Island, the majority of the nene nest in managed areas at mid- to high-elevation habitats, including Haleakala National Park, Hawaii Volcanoes National Park, and Puu Oo Ranch/Puu 6677; and at lower elevation sites, including Hanaula, Piiholo Ranch, Haleakala Ranch (Waiopae), and Puu O Hoku Ranch (Molokai). On Kauai, most nene nest and live year-round in areas below 984 ft (300 m), where large expanses of managed grasslands (including golf courses) and low levels of predation (mostly due to the absence of a mongoose population) have led to a stable and increasing nene population. The majority of the Kauai population is centered in and around the Hanalei and Kilauea Point NWRs.

Many of the areas where nene occur in the wild are afforded some level of habitat enhancement that focuses on increasing the survival and reproduction of nene. Habitat enhancement can include predator control, mowing, outplanting, and supplemental feeding. Hawaii Volcanoes National Park has areas where many of these types of enhancement occur. For instance, park staff maintain two predator-resistant open-topped pens, 4 and 5 hectares (10 and 13 acres) in size, as safe-breeding sites with supplemental feed and occasional mowing. In addition, predator control is conducted at key brooding sites, and some areas may be closed to human use during the nene breeding season. The Hawaii Division of Forestry and Wildlife also provides supplemental food for nene populations on Hawaii Island. Haleakala National Park has controlled ungulate populations and horses intermittently grazing in Paliku pasture. Kauai DOFAW also has predator control programs and may provide supplemental feed during drought years. Mowing, grazing, and irrigating grass can improve its attractiveness to geese by increasing the protein content (Sedinger and Raveling 1986, p. 302; Woog and Black 2001, pp. 324–328).

Highly altered landscapes and nonnative vegetation also can significantly affect nene recovery. For example, nene on Kauai primarily use lowland areas in highly altered, human-impacted habitats such as pastures, agricultural fields, golf courses, and highly degraded waste areas (USFWS 2004, pp. 41–42). Nene have been very successful in these areas, indicating their adaptability to a variety of habitats. Lowlands, however, are often unsuitable because of intense human activity or dense predator populations placing nene at greater risk of predation, and hazardous situations such as habituation to human feeding, vehicle collisions, and golf ball strikes (Natural Resources Conservation Service [NRCS] 2007, p. 7). The recovery of nene is dependent on a variety of habitats ranging from highly altered, managed habitats to habitats consisting of primarily native species, and it may not be feasible to restore habitats to native species in all areas used by nene. It is believed that nene currently require availability of a diverse suite of food resources that may include both nonnative and native vegetation (Baldwin 1947, pp. 108 − 120; Black *et al.* 1994, pp. 103–105; Banko *et al.* 1999, pp. 6–7). However, the current amount and distribution of suitable breeding, foraging, and flocking habitat continues to be a limiting factor for the nene.

Our analyses of Factor A under the Act include consideration of ongoing and projected changes in climate, and the impacts of global climate change and increasing temperatures on Hawaii ecosystems, all of which are the subjects of active research. Analysis of the historical record indicates surface temperature in Hawaii has been increasing since the early 1900s, with relatively rapid warming over the past 30 years. The average increase since 1975 has been 0.48 degrees Fahrenheit (°F) (0.27 degrees Celsius (°C)) per decade for annual mean temperature at elevations above 2,600 ft (800 m) and 0.16 °F (0.09 °C) per decade for elevations below 2,600 ft (800 m) (Giambelluca *et al.* 2008, pp. 3–4). Based on models using climate data downscaled for Hawaii, the ambient temperature is projected to increase by 3.8 to 7.7 °F (2.1 to 4.3 °C) over the 21st century, depending on elevation and the emissions scenario (Liao *et al.* 2015, p. 4344). Environmental conditions in tropical montane habitats can be strongly influenced by changes in sea surface temperature and atmospheric dynamics (Loope and Giambelluca 1998, pp. 504–505; Pounds *et al.* 1999, pp. 611–612; Still *et al.* 1999, p. 610; Benning *et al.* 2002, pp. 14,246–14,248; Giambelluca and Luke 2007, pp. 13–15). On the main Hawaiian Islands, predicted changes associated with increases in temperature include a shift in vegetation zones upslope; a similar shift in animal species' ranges; changes in mean precipitation with unpredictable effects on local environments; increased occurrence of drought cycles; and increases in intensity and numbers of hurricanes (tropical cyclones with winds of 74 miles per hour or higher) (Loope and Giambelluca 1998, pp. 514–515; U.S. Global Change Research Program (US–GCRP) 2009, pp. 10, 12, 17–18, 32–33; Giambelluca 2013, p. 6). The effect on nene of these changes associated with temperature increase is detailed in the following paragraphs.

The forecast of changes in precipitation is highly uncertain because it depends, in part, on how the El Niño–La Niña weather cycle (an episodic feature of the ocean-atmosphere system in the tropical Pacific having important global consequences for weather and climate) might change (State of Hawaii 1998, pp. 2–10). The historical record indicates that Hawaii tends to be dry (relative to a running average) during El Niño phases and wet during La Niña phases (Chu and Chen 2005, pp. 4809–4810). However, over the past century, the Hawaiian Islands have experienced a decrease in precipitation of just over 9 percent (US National Science and Technology Council 2008, p. 61) and a decreasing trend (from the long-term mean) is evident in recent decades (Chu and Chen 2005, pp. 4802–4803; Diaz *et al.* 2005, pp. 1–3). Models of future rainfall downscaled for Hawaii generally project increasingly wet windward slopes and mild to extreme drying of leeward areas in particular during the middle and late 21st century (Timm and Diaz 2009, p. 4262; Elison Timm *et al.* 2015, pp. 95, 103–105). Altered seasonal moisture regimes can have negative impacts on plant growth cycles and overall negative impacts on native ecosystems (US–GCRP 2009, pp. 32–33). Long periods of decline in annual precipitation result in a reduction of moisture availability; an increase in drought frequency and intensity; and a self-perpetuating cycle of nonnative plant invasion, fire, and erosion (US–GCRP 2009, pp. 32–33; Warren 2011, pp. 221–226). Overall, more frequent El Niño events are predicted to produce less precipitation for the Hawaiian Islands. These

projected decreases in precipitation are important stressors for nene because they experience substantially higher mortality from starvation in drought years (Hess 2011, p. 59). In addition, the drying trend, especially on leeward sides of islands, creates suitable conditions for increased invasion by nonnative grasses and enhances the risk of wildfire.

Tropical cyclone frequency and intensity are projected to change as a result of increasing temperature and changing circulation associated with climate change over the next 100 to 200 years (Vecchi and Soden 2007, pp. 1068–1069, Figures 2 and 3; Emanuel *et al.* 2008, p. 360, Figure 8; Yu *et al.* 2010, p. 1371, Figure 14). In the central Pacific, modeling projects an increase of up to two additional tropical cyclones per year in the main Hawaiian Islands by 2100 (Murakami *et al.* 2013, p. 2, Figure 1d). In general, tropical cyclones with the intensities of hurricanes have been an uncommon occurrence in the Hawaiian Islands. From the 1800s until 1949, hurricanes were only rarely reported from ships in the area. Between 1950 and 1997, 22 hurricanes passed near or over the Hawaiian Islands, and 5 of these caused serious damage (Businger 1998, *in litt.*). A recent study shows that, with a projected shift in the path of the subtropical jet stream northward, away from Hawaii, more storms will be able to approach and reach the Hawaiian Islands from an easterly direction, with Hurricane Iselle in 2014 being an example (Murakami *et al.* 2013, p. 751). At high-elevation nesting sites, frequent heavy precipitation may affect gosling survival during the cooler months (Hess *et al.* 2012, p. 483). More frequent and intense tropical storms are likely to increase the number of nest failures and gosling mortalities in mid- and high-elevation habitats on Maui and Hawaii where nene are already at risk of exposure and starvation due to inadequate nutrition (Baker and Baker 1995, p. 13; K. Misajon 2016, pers. comm.; J. Tamayose 2016, pers. comm.). In addition, projected warmer temperatures and increased storm severity resulting from climate change are likely to exacerbate other threats to nene, such as by enhancing the spread of nonnative invasive plants into these species' native ecosystems in Hawaii.

Finally, sea level rise resulting from thermal expansion of warming ocean water; the melting of ice sheets, glaciers, and ice caps; and the addition of water from terrestrial systems (Climate Institute 2011, *in litt.*) has the potential for direct effects on nene habitat. Rise in global mean sea level (GMSL) is ongoing and expected to continue for the foreseeable future (*i.e.,* centuries) (Meehl *et al.* 2012, p. 576; Golledge *et al.* 2015, pp. 421, 424; DeConto and Pollard 2016, pp. 1, 6) due to warming that has already occurred and an uncertain amount of additional warming caused by future greenhouse gas emissions (Sweet *et al.* 2017, p. 1). Six risk-based scenarios describing potential future conditions through 2100 project lower and upper bounds of GMSL rise between 0.3 and 2.5 m (1 and 8 ft) (Sweet *et al.* 2017, pp. vi–vii, 1–55, and Appendices A–D).

Sea level rise is not expected to be uniform throughout the world, due to factors including, but not limited to: (1) Variations in oceanographic factors such as circulation patterns; (2) changes in Earth's gravitational field and rotation, and the flexure of the crust and upper mantle due to melting of land-based ice; and (3) vertical land movement due to postglacial rebound of topographically depressed land, sedimentation compaction, groundwater and fossil fuel withdrawals, and other non-climatic factors (Spada *et al.* 2013, p. 484; Sweet *et al.* 2017, pp. vi–vii, 9, 19). Sea level rise in the Hawaiian Islands is expected to be greater than rise in GMSL (Spada *et al.* 2013, p. 484; Polhemus 2015, p. 7; Sweet *et al.* 2017, p. 9). In Hawaii, long-term sea level rise adds to coastal erosion, impacts from seasonal high waves, coastal inundation due to storm surge and tsunami, and drainage problems due to the convergence of high tide and rainfall run-off (SOEST 2017, *in litt.*). Flooding related to sea level rise would result in the additional loss of lowland habitat occupied by nene in low-lying coastal areas at Huleia NWR on Kauai, Ukumehame on Maui, and Keeau on Hawaii Island.

Thus, although we cannot predict the timing, extent, or magnitude of specific events, we expect effects of climate change (changes in tropical cyclone frequency and intensity, drought frequency, and sea level rise) to exacerbate the current threats to this species such as predation, inadequate nutrition, and habitat loss and degradation.

Summary of Factor A

Habitat destruction and modification from urbanization, agricultural activities, drought, feral ungulates, and invasive plant species remain threats to nene. These factors contribute to an ongoing lack of suitable breeding and flocking habitat, limiting nene population expansion. Historical habitat loss was largely a result of human activities such as urban development and land conversion for agricultural activities, particularly in lowland areas, contributing to the extirpation of nene on Kauai and Molokai, and the loss of seasonally important leeward, lowland breeding areas on islands with elevations above 5,000 ft (1,524 m) (Maui and Hawaii). Feral ungulates and invasive plant species led to further degradation of nene habitat by negatively impacting forage quality, shelter, and potential nest sites.

Recovery efforts initially focused on the establishment of populations with the majority of releases of captive-bred nene at high-elevation sanctuaries (above 5,000 ft (1,524 m)) on Maui and Hawaii Island. Despite supplemental food and water and localized predator control efforts, nene at these sites experienced high rates of adult mortality and low rates of gosling survival attributed to inadequate nutrition caused by habitat factors such as poor forage quality, drought, and exposure. Research showed that access to managed grassland habitats and habitat enhancement during the breeding season improved foraging opportunities and resulted in increased survival and breeding success. Control of feral ungulate populations in areas such as Hawaii Volcanoes National Park and Haleakala National Park reduced their impacts on native vegetation and likely improved nene foraging and breeding habitat. Subsequent reintroductions at low- and mid-elevation sites, first on Kauai and Hawaii Island, and more recently on eastern Molokai and western Maui, demonstrated the ability of nene to successfully become established in these areas.

Currently, nene are found in a range of habitats from sea level to subalpine areas on Kauai, Oahu, Molokai, Maui, and Hawaii Island. Populations are centered around release sites and rely on continued land use protections and habitat management (including predator control) to sustain successful breeding and population numbers in these areas.

Overall, the expansion of existing populations is limited by the lack of suitable breeding and flocking habitat due to continuing urbanization, agricultural activities, and potential conflicts with human activities. Periods of drought are expected to continue and are likely to be exacerbated by the effects of climate change. To minimize the effects of drought on the food availability and adequate nutrition, habitat enhancement activities to provide foraging opportunities, especially during the breeding season, will need to be maintained. The rise in sea level projected by climate change models may threaten any low-lying

habitats used by nene. Although the effects of climate change do not constitute a threat to nene now, we do expect them to exacerbate the effects of drought and tropical storms, and to constitute a threat in the foreseeable future.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Overuse for commercial, recreational, scientific, or educational purposes is not a threat to the nene. The exploitation of nene for food by Hawaiians and non-Polynesian settlers is believed to have been responsible for substantial population declines in lowland areas, and hunting was a major limiting factor until a hunting ban was passed and enforced in 1907 (Banko *et al.* 1999, p. 23). Human visitation for recreational activities at parks and refuges where nene occur often results in human interactions with nene. Habituation to humans and feeding of nene at these recreational areas create the potential for injury or mortality of nene by attracting nene to hazardous areas where collisions, predation, and accidents frequently occur (Banko *et al.* 1999, p. 24). For discussion and analysis of the population-level impacts to nene caused by direct and indirect human impacts, see our discussion under Factor E, below. While the historical effects of overuse were factors that led to the original listing of nene as federally endangered in 1967, current regulations and enforcement are in place to protect nene from overuse. Therefore, overuse does not constitute a threat to nene now or in the foreseeable future.

Factor C. Disease or Predation

Disease

Numerous parasites and diseases have been documented in captive and wild nene (van Riper and van Riper 1985, pp. 308, 312, 333; Bailey and Black 1995, p. 62; Work *et al.* 2002, p. 1,040). Recent data attributing the primary causes of death in nene to disease have identified parasites, bacterial and fungal infection, and, less commonly, avian pox (virus) and avian botulism (Work *et al.* 2015, pp. 690–694). Avian influenza and West Nile Virus (WNV), if established, also have the potential to affect the nene population.

Toxoplasma gondii is a protozoan parasite transmitted by domestic cats (*Felis catus*) that has historically caused mortality in native Hawaiian birds, and is the most commonly encountered infectious disease in nene, primarily affecting adult birds (Work *et al.* 2015, p. 691). As herbivores, nene are likely exposed by eating transport hosts such as insects or ingesting oocysts (reproductive phase of the parasite) in contaminated water, soil, or vegetation (Work *et al.* 2016, p. 255). For mortalities attributed to *T. gondii,* the cause of death is typically diagnosed as inflammation or lesions on multiple organs. The detection of *T. gondii* in over 30 percent of feral cats sampled (n=67) at 2 locations on Mauna Kea, Hawaii Island (Danner *et al.* 2007, p. 316) suggests that exposure to and infection by *T. gondii* is likely to continue and to play a role in mortality of nene. This parasite may also have non-lethal effects on nene, making them more susceptible to trauma caused by vehicle collisions, as a high prevalence of *T. gondii* was observed in road kills of other species (Work *et al.* 2016, p. 256). Widespread exposure to *T. gondii* was detected in wild birds from Kauai, Maui, and Molokai (21 to 48 percent of birds examined) (Work *et al.* 2016, p. 255). However, the parasite is implicated as the cause of death in a relatively low proportion (4 percent) in the number of nene mortalities submitted to the U.S. Geological Survey National Wildlife Health Center (USGS–NWHC) between 1992 and 2013 (Work *et al.* 2015, pp. 690–694). This suggests that although exposure to *T. gondii* is widespread and ongoing, the threat of disease caused by *T. gondii* is expected to be low in magnitude and is not likely to have significant population-level impacts on nene.

Omphalitis, a bacterial infection of the umbilical stump, has been found to cause mortality in both wild and captive nene goslings (USFWS 2004, p. 34). Work *et al.* (2015, supplemental material) recently diagnosed omphalitis at low levels (2 percent, 7 of 300) in a number of nene mortalities submitted to the USGS–NWHC.

Avian pox is caused by a virus that causes inflammation of the skin, and in severe cases may result in large scabs that block circulation and lead to the loss of digits or entire limbs or lead to blindness, the inability to eat, or death (USGS–NWHC 2017a, *in litt.*). Pox-like lesions have been reported in adult birds in captivity (Kear and Brown 1976, pp. 133–134; Kear and Berger 1980, pp. 42, 86, 138), and pox scars on many birds in the wild on Hawaii and Maui indicate that avian pox is common, but generally not fatal to nene (Banko *et al.* 1999, pp. 20–21). Avian pox was recently found in an emaciated bird, but was judged to be a secondary finding (Work *et al.* 2015, p. 693).

Avian malaria is caused by the microscopic parasitic protozoan, *Plasmodium relictum.* Avian malaria was diagnosed as the cause of death in only 1 out of 300 nene mortalities submitted to the USGS–NWHC for which the cause of death was identified (Work *et al.* 2015, supplemental material). Avian malaria has also been reported in at least one wild bird on Maui, but it does not appear that avian malaria is causing significant declines of nene populations (Banko *et al.* 1999, pp. 20–21). However, concern about the potential to transfer unique regional strains of avian malaria between islands has resulted in quarantine testing of any nene to be moved inter-island to ensure they are not infected; during the recent Nene Relocation Project, birds from Kauai in which *Plasmodium* was detected were kept on Kauai and not translocated to Maui or Hawaii Island (Kauai Lagoons 2015, *in litt.*).

Avian botulism is a paralytic disease caused by the ingestion of a natural toxin produced by the bacteria, *Clostridium botulinum.* Birds either ingest the toxin directly or may eat invertebrates (*e.g.,* non-biting midges, fly larvae) containing the toxin (USGS–NWHC 2017b, *in litt.*). Botulism outbreaks may occur year-round with distinct seasonal patterns based on location (Uyehara 2016b, *in litt.*).

Botulism has been found on Kauai, Oahu, Molokai, Maui, and Hawaii Island (USGS–NWHC 2017b, *in litt.*). Avian botulism was diagnosed as the cause of death in only 4 out of 300 nene mortalities submitted to the USGS–NWHC for which the cause of death was identified (Work *et al.* 2015, supplemental material). Also, between 2011 and 2015, only 1 percent of the 866 cases of botulism involved nene in the Kauai NWR Complex (Uyehara 2016b, *in litt.*). Avian botulism is thought to pose a minor threat to nene because they tend to forage on grasses rather than aquatic invertebrates (Work *et al.* 2015, p. 693).

The spread of avian influenza and West Nile Virus (WNV) in North America has serious implications if either arrives in Hawaii. West Nile Virus is transmitted by adults of various species of *Culex* mosquitoes, some of which are present in Hawaii (USGS–NWHC 2017c, *in litt.*). When an infected mosquito bites an animal, the virus enters the animal and infects the central nervous system. West Nile Virus causes mortality in domestic geese, with goslings more susceptible than adults (Austin *et al.* 2004, p. 117). In experimentally infected young domestic geese, the New York strain of WNV caused reduced activity, weight loss, abnormal neck and spine posture, and death with accompanying encephalitis

and myocarditis (Swayne *et al.* 2001, p. 753). Of the three known cases of nene infected with WNV on the U.S. mainland, all were adults and one died (Jarvi *et al.* 2008, p. 5,339).

Avian influenza has been reported to cause mortality in naturally infected Canada geese in Asia and Europe (Ellis *et al.* 2004, p. 496; Teifke *et al.* 2007, p. 138). Additional studies have shown that immunologically naïve, juvenile birds are particularly susceptible (Pasick *et al.* 2007, p. 1,827). Migratory birds have been implicated in the long-range spread of highly pathogenic avian influenza (HPAI), a virus (H5N1) from Asia to Europe and Africa. In 2006, the U.S. Departments of the Interior (DOI) and Agriculture (USDA) conducted surveillance for the presence of highly pathogenic avian influenza H5N1 in wild birds in the Pacific islands (American Samoa, Guam, Hawaii, Marshall Islands, Northern Mariana Islands, and Palau) (USGS–NWHC 2017d, *in litt.*). Over 4,000 specimens were collected from waterfowl, shorebirds, and other species from throughout the Pacific, and no highly pathogenic avian influenza was detected (Work and Eismueller 2007, p. 2).

The Hawaii Field Station of the USGS–NWHC continues to work with wildlife managers to monitor the impact of diseases and other mortality factors on nene and other wildlife populations. Cats are the sole known lifecycle host for the protozoan that causes toxoplasmosis. Reduction in the number of feral cats will reduce the likelihood of exposure of nene to the disease. Ongoing conservation measures in nene breeding areas, such as predator control and predator-proof fences that exclude cats, reduce, but do not eliminate, the risk of exposure to toxoplasmosis due to the abundance and range of feral cat populations.

Predation

Predation by introduced mammals continues to be a major factor limiting nene breeding success and survival. Predators known to take nene eggs, goslings, or adults include dogs (*Canis familiaris*), feral pigs (*Sus domesticus*), feral cats, small Indian mongooses (*Herpestes auropunctatus*), and black, Norway, and Pacific rats (*Rattus, R. norvegicus,* and *R. exulans,* respectively) (Hoshide *et al.* 1990, pp. 153–154; Baker and Baker 1995, p. 8; Banko *et al.* 1999, pp. 11–12; Hilton 2016, *in litt.*). In addition, cattle egrets (*Bubulcus ibis*) and barn owls (*Tyto alba*) are suspected to occasionally take goslings. When flightless and during molt, goslings and adults are extremely vulnerable to predation by any of these predators (USFWS 2004, p. 21). Yellow crazy ants (*Anoplolepis gracilipes*) and little fire ants (*Solenopsis papuana*) also have the potential to disturb incubating females and goslings (Plentovich 2017, *in litt.*).

The small Indian mongoose was introduced to the Hawaiian archipelago in 1883, and quickly became widespread on Oahu, Molokai, Maui, and Hawaii Island, from sea level to elevations as high as 7,000 ft (2,130 m) (Tomich 1986, pp. 93–94). Kauai remained mongoose-free when a planned introduction was aborted; however, there have been almost 350 reported sightings since 1968, and in 1976, a road-killed, lactating female was found on the island near Eleele (KISC 2016a, *in litt.;* Phillips and Lucey 2016). In 2012 and 2016, a total of three mongooses were captured in Lihue, Kauai, at air cargo and harbor facilities, as well as a resort adjacent to airport property (KISC 2016b, *in litt.*). The numerous sightings and four confirmed individuals have led to the perception that mongoose are now established on Kauai. While the recent arrivals of mongoose are troubling, there remains scant biological evidence that a breeding population of mongoose occurs on Kauai.

Mongooses are believed to be the most serious egg predator and are responsible for the most nene nest failures on Hawaii and Maui (Hoshide *et al.* 1990, p. 154; Banko 1992, pp. 101–102; Black and Banko 1994, p. 400; Baker and Baker 1995, p. 20). Mongoose also prey upon goslings and adults (Kear and Berger 1980, p. 57; Banko and Elder 1990, p. 122; K. Misajon 2016, pers. comm.). The success of the nene on Kauai demonstrates that mongooses may constitute the most significant predator elsewhere (Banko *et al.* 1999, p. 25). Despite relying on limited data, recent estimates of nest success on Kauai for private lands (75 percent) and the Kauai NWR Complex (82 percent) are far greater than estimates for both Haleakala National Park (62 percent) and Hawaii Volcanoes National Park (58 percent) (Hu, unpublished as cited in Banko *et al.* 1999; Bailey and Tamayose 2016, *in litt.;* Uyehara 2016a, *in litt.*).

Introduced European pigs hybridized with smaller, domesticated Polynesian pigs; became feral; and invaded forested areas, especially mesic and wet forests, from low to high elevations, and are present on all the main Hawaiian Islands except Lanai and Kahoolawe, where they have been eradicated (Tomich 1986, pp. 120–121; Munro 2007, p. 85). Pigs may roam over nearly the entire extent of the range of nene. Pigs are known to take eggs, goslings, and possibly adults (Kear and Berger 1980, p. 57; Banko and Elder 1990, p. 122; Baker and Baker 1995, p. 20; K. Misajon 2016, pers. comm.). The presence of pigs can also attract feral dogs that may then prey upon nene (NPS 2016, p. 2).

Three species of introduced rats occur in the Hawaiian Islands. Studies of Pacific rat DNA suggest they first appeared in the islands along with emigrants from the Marquesas Islands (French Polynesia) in about 400 A.D., with a second introduction around 1100 A.D. (Ziegler 2002, p. 315). The black rat and the Norway rat arrived in the islands more recently, as stowaways on ships sometime in the late 19th century (Atkinson and Atkinson 2000, p. 25). The Pacific rat and the black rat are primarily found in rural and remote areas of Hawaii, in dry to wet habitats, while the Norway rat is typically found in urban areas or agricultural fields (Tomich 1986, p. 41). The black rat is widely distributed throughout the main Hawaiian Islands and can be found in a range of ecosystems and as high as 9,000 ft (2,700 m), but it is most common at low- to mid-elevations (Tomich 1986, pp. 38–40). Sugihara (1997, p. 194) found both black and Pacific rats up to 7,000 ft (2,000 m) on Maui, but found the Norway rat only at lower elevations. Rats are known to prey upon nene eggs and goslings (Kear and Berger 1980, p. 57; Hoshide *et al.* 1990, p. 154; Baker and Baker 1995, p. 20).

Cats were introduced to Hawaii in the early 1800s, and are present on all the main Hawaiian Islands (Tomich 1986, p. 101). Although cats are more common at lower elevations, there are populations in areas completely isolated from human presence, including montane forests and alpine areas of Maui and Hawaii Island (Lindsey *et al.* 2009, p. 277; Scott *et al.* 1986, p. 363). Cats take nene goslings and adults, and have been observed moving eggs in nests, so they may also prey upon eggs (Kear and Berger 1980, p. 57; Banko and Elder 1990, p. 122; Baker and Baker 1995, p. 20; Zaun 2008, *in litt.*).

Dogs in Hawaii are products of animals brought by Polynesians and later introductions of mixed or selected breeds from all over the world (Tomich 1986, p. 52). Nene are particularly vulnerable to dogs because they have little instinctive fear of them. Along with mongooses, dogs are a significant predator of adult nene, and may also take goslings (Kear and Berger 1980, p. 57; Banko and Elder 1990, p. 122).

Cattle egrets and barn owls were both introduced into Hawaii in the late 1950s, in an attempt to address agricultural pests on farms and ranches.

In Hawaii, cattle egrets are now widespread on all the main islands, as well as on the islands and atolls of the Northwestern Hawaiian Islands. Barn owls occur on all of the main Hawaiian Islands in all habitat types, from sea level to upper elevation forests, and in recent years have been sighted with increasing frequency on offshore islets. Barn owls and cattle egrets may also take goslings occasionally (Banko *et al.* 1999, p. 11; S. Franklin 2016, pers. comm.).

The yellow crazy ant occurs in low- to mid-elevations (less than 2,000 ft (600 m)) in rocky areas of moderate rainfall (less than 100 in (250 cm) annually) (Reimer *et al.* 1990, p. 42). The tropical fire ant (*Solenopsis geminata*) is found in drier areas of all the main Hawaiian islands (Wong and Wong 1988, p. 175). Both species are nonnative and are known to cause significant injuries and developmental problems in adults and chicks of ground-nesting seabirds, and are expected to have similar effects on nene (S. Plentovich 2017, pers. comm.).

A variety of predator control programs have been initiated in areas where nene currently reside. Since 1994, Haleakala National Park has conducted intensive control of introduced predators using trapping and toxicants (Bailey and Tamayose 2016, *in litt.*). Ongoing efforts on the different islands include predator control programs aimed at mongooses, dogs, feral cats, rodents, and pigs. Some open-top pens previously used to rear captive nene on National Park Service lands are now often used to provide predator-free nesting and brooding habitat for free-flying pairs or as temporary holding pens for sick or injured birds (Hawaii Volcanoes National Park 2016, *in litt.*).

Nene population numbers at Hawaii Volcanoes National Park increased during a 10-year period (1989 to 1999), probably in part because of intensive predator control (Rave *et al.* 2005, p. 14). Since then, ongoing predator trapping focused in the primary breeding and brooding areas at Hawaii Volcanoes National Park during the breeding season has likely contributed to the overall increase in nene observed. The general increase in population at Haleakala National Park over the last 25 years is likely a response to increased habitat management—first, the removal of feral ungulates and control to ''near zero'' populations; later, the additional intensive control of introduced predators (Bailey and Tamayose 2016, *in litt.*). At Hawaii Volcanoes National Park, various fence designs have been used successfully to exclude mongooses, cats, dogs, and pigs. Predator control programs are currently conducted in most areas where nene nest, including Hanalei, Kilauea Point, and Hakalau Forest NWRs; Haleakala and Hawaii Volcanoes National Parks; and Piiholo Ranch, Haleakala Ranch (Waiopae), and Puu O Hoku Ranch on Molokai.

While the predator control programs have proven effective in localized areas, recovery of nene is dependent on more aggressive and widespread control of introduced predators. Despite documentation of the impact of mongooses, dogs, feral cats, rodents, and pigs on nene, there are relatively few predator control programs, and they are not being implemented over areas large enough to elicit a population response by native species (Scott *et al.* 2001, p. 11). Known control techniques should be applied at all habitats needed to recover nene (USFWS 2004, p. 41).

Summary of Factor C

Diseases such as toxoplasmosis, omphalitis, avian pox, avian malaria, and avian botulism cause low levels of mortality in nene populations. Avian influenza and WNV are not currently established in Hawaii, but could cause mortality of nene should they become established in the future. Measures to control feral cat populations will reduce the risk of exposure of nene to toxoplasmosis. Monitoring the occurrence of disease in nene populations, as well as early detection of avian botulism outbreaks or cases of avian influenza or WNV should minimize the impacts of these threats. Based on the above analysis, we conclude that disease will continue to affect nene now and in the foreseeable future, but it is not a significant threat because, at current and future levels, disease is not likely to cause population-level impacts.

Predation by introduced mammals is the most serious threat to nene. Predation by mongooses, dogs, cats, rats, and feral pigs continues to affect all life stages of nene (eggs, goslings, or adults), negatively impacting breeding success and survival. Predator control measures have improved survival and reproductive success and contributed to population increases in managed areas. However, these efforts are localized and overall predator populations are not being reduced; therefore, predators can readily recolonize an area. In addition, as nene populations expand into areas in their former historical range, such as lowland areas, they will likely encounter higher predator populations in and around human-occupied urban, suburban, and agricultural areas. Predation by cattle egrets and barn owls, and disturbance by ants, may result in injury or mortality of nene; however, this does not constitute a threat to nene, as such predation/disturbance occurs infrequently and is not known to have population-level impacts. Based on our analysis of the available information, we conclude that predation by introduced mammals is a threat to nene now and in the foreseeable future.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

The following section includes a discussion of Federal, State, and local laws, regulations, or treaties that apply to nene. It includes laws and regulations for Federal land management agencies and State and Federal regulatory authorities affecting land use or other relevant management.

Federal Laws and Regulations

National Wildlife Refuge System Improvement Act of 1997. The National Wildlife Refuge System Improvement Act of 1997 (Pub. L. 105–57, October 9, 1997) established the protection of biodiversity as the primary purpose of the National Wildlife Refuge (NWR) System. This has led to various management actions to benefit federally listed species, including development of comprehensive conservation plans (CCPs) on NWRs. The CCPs typically set goals and list needed actions to protect and enhance populations of key wildlife species on NWR lands. Where nene occur on NWR lands (Hanalei, Kilauea Point, Hakalau Forest, Kealia Pond, and James Campbell NWRs), their habitats in these areas are protected from large-scale loss or degradation due to the Service's mission ''to administer a national network of lands and waters for the conservation, management, and where appropriate, restoration of the fish, wildlife, and plant resources and their habitats within the United States for the benefit of present and future generations of Americans'' (16 U.S.C. 668dd(2)). National Wildlife Refuges must also conduct section 7 consultations under the Act (discussed below) for any refuge activity that may result in adverse effects to nene.

Hanalei NWR was established in 1972, to aid in the recovery of the four endangered Hawaiian waterbirds and nene (Endangered Species Conservation Act of 1969; 16 U.S.C. 668aa *et seq.*). Kilauea Point NWR, originally established in 1985 to enhance seabird nesting colonies, was later expanded to include adjacent lands to be managed for the protection and recovery of endangered waterbirds and nene (The Kilauea Point National Wildlife Refuge Expansion Act of 2004, Pub. L. 108–481, December 23, 2004; 16 U.S.C. 668dd

note). Approximately two-thirds of the Kauai nene population is supported by the Hanalei and Kilauea NWRs. The Kilauea Point CCP includes the following goals: (1) Protect, enhance, and manage the coastal ecosystem to meet the life-history needs of migratory seabirds and threatened and endangered species; (2) restore and/or enhance and manage populations of migratory seabirds and threatened and endangered species; and (3) gather scientific information (surveys, research, and assessments) to support adaptive management decisions (USFWS 2016, pp. 2:19–31). Both Hanalei and Kilauea Point NWRs conduct ongoing predator control and habitat improvement and enhancement actions.

At Hakalau Forest NWR, a new population was created with the reintroduction of 33 captive-bred nene between 1996 and 2003. Since then, Hakalau Forest NWR has supported approximately 20 to 25 percent of the nene population on Hawaii Island. The Hakalau Forest CCP includes the following goals: (1) Protect and maintain grassland habitat to support nene population recovery; and (2) collect scientific information (inventories, monitoring, research, assessments) necessary to support adaptive management decisions on both units of the Hakalau Forest NWR (USFWS 2010, pp. 2:30–37).

Kealia Pond NWR, on the south-central coast of Maui, was established in 1992, to conserve habitat for the endangered Hawaiian stilt (*Himantopus mexicanus knudseni*) and Hawaiian coot (*Fulica alai*). Nene are occasionally observed at Kealia Pond NWR (USFWS 2011b, p. 4:14).

James Campbell NWR on the northern shore of Oahu was created in 1976, also for the conservation of endangered Hawaiian waterbirds, and later expanded in 2005, to include conservation of additional threatened and endangered species, migratory birds, and their habitats (USFWS 2011c, p. 1:1). In 2014, a pair of nene arrived on Oahu, nested at James Campbell NWR, and produced three offspring. Both parents and one of the offspring have since died, leaving the two remaining offspring on NWR and adjacent lands.

Hawaii National Park Act of 1916. Congress established Hawaii National Park (later to become, separately, Hawaii Volcanoes National Park and Haleakala National Park) on August 1, 1916 (39 Stat. 432), ''for the benefit and enjoyment of the people of the United States'' and to provide for, ''the preservation from injury of all timber, birds, mineral deposits, and natural curiosities or wonders within said park, and their retention in their natural condition as nearly as possible'' (16 U.S.C. 394). Since that time, the enabling legislation of the park has been modified several times, both to establish the national parks on the islands of Hawaii and Maui as separate parks and to expand the boundary of Hawaii Volcanoes National Park. In 1960, Congress authorized the establishment of the Haleakala National Park (Pub. L. 86–744, September 13, 1960); the park was established the following year. Haleakala National Park, on the eastern side of Maui, encompasses 33,222 acres (ac) (13,444 hectares (ha)), of which 24,719 ac (10,003 ha) are designated wilderness (74 percent of the park). Hawaii Volcanoes National Park protects 330,086 ac (133,581 ha) of public land on Mauna Loa and Kilauea volcanoes on the southeastern side of Hawaii Island. Haleakala National Park and Hawaii Volcanoes National Park have supported nene recovery actions since the 1960s and 1970s, respectively. Past and ongoing actions include releases of captive-bred nene, habitat management (*e.g.,* predator control, feral ungulate control, nonnative plant species control), provision of supplemental food and water, monitoring, and outreach and education.

Migratory Bird Treaty Act (MBTA). Nene are a protected species under the MBTA (16 U.S.C. 703–712, 50 CFR 10.13), a domestic law that implements the U.S. commitment to four international conventions (with Canada, Japan, Mexico, and Russia) for the protection of shared migratory bird resources.

State Laws and Regulations

The Hawaii Endangered Species law (Hawaii Revised Statutes (HRS) 195D) prohibits take, possession, sale, transport, or commerce in designated species. This State law also recognizes as endangered or threatened those species determined to be endangered or threatened pursuant to the Federal Endangered Species Act. This Hawaii law states that a threatened species (under the Act) or an indigenous species may be determined to be an endangered species under State law. Protection of these species is under the authority of Hawaii's DLNR, and under administrative rule (Hawaii Administrative Rules (HAR) 13–124–11). Incidental take of threatened and endangered species may be authorized through the issuance of a temporary license as part of a safe harbor agreement (SHA) or habitat conservation plan (HCP) (HRS 195D–21, HCPs; 195D–22, SHAs). Although this State law can address threats such as habitat modification, collisions, and other human-caused mortality through HCPs that address the effects of individual projects or programs on nene, it does not address the pervasive threats to the nene posed by introduced mammalian predators. DLNR also maintains HAR 13–124–3, which protects indigenous and introduced wildlife.

The importation of nondomestic animals, including microorganisms, is regulated by a permit system (HAR 4–71) managed through the Hawaii Department of Agriculture (HDOA). The list of nondomestic animals (HAR 4–71) is defined by providing a list of those animals considered domestic: Dog, cat, horse, ass (burro or donkey), cattle and beefalo, sheep, goat, swine, pot-bellied pig, alpaca, llama, rabbit, chicken, turkey, pigeon, duck, geese, and their hybrids. The HDOA's Board of Agriculture maintains lists of nondomestic animals that are prohibited from entry, animals without entry restrictions, or those that require a permit for import and possession. The HDOA requires a permit to import animals, and conditionally approves entry for individual possession, businesses (*e.g.,* pets and resale trade, retail sales, and food consumption), or institutions.

Under statutory authorities provided by HRS title 12, subtitle 4, 183D Wildlife, the DLNR maintains HAR title 13, chapter 124 (2014), which defines, at section 13–124–2, ''injurious wildlife'' as ''any species or subspecies of animal except game birds and game mammals which is known to be harmful to agriculture, aquaculture, indigenous wildlife or plants, or constitute a nuisance or health hazard and is listed in the exhibit entitled Exhibit 5, Chapter 13–124, List of Species of Injurious Wildlife in Hawaii''. Under HAR section 13–124–3(c), ''no person shall, or attempt to: (1) Release injurious wildlife into the wild; (2) transport live injurious wildlife to islands or locations within the State where they are not already established and living in a wild state; or (3) export any such species, or the dead body or parts thereof, from the State.'' Permits for these actions may be considered on a case-by-case basis. The small Indian mongoose, a serious predator of nene, is included in Exhibit 5, chapter 13–124, List of Species of Injurious Wildlife in Hawaii. While this HAR may address intentional attempts to transport or release mongooses, there is evidence that inspection and biosecurity measures at inter-island ports may not adequately address their unintentional introduction (*e.g.,* as

stowaways in cargo) to islands such as Kauai and Lanai that are thought to be mongoose-free. Currently, there is no biosecurity at Honolulu ports focused on mongoose. At Nawiliwili Harbor (Kauai), low-level interdiction was conducted until about 2015, but has since been discontinued (B. Phillips 2017, pers. comm.). There are plans to reinitiate this in the coming months. Similarly, there is no interdiction being conducted on Lanai for mongoose.

Predation by mongooses is a serious threat to nene (see Factor C discussion, above). Currently, the nene population on Kauai represents approximately 43 percent of the total Statewide population. Establishment of a breeding population of mongoose on Kauai would significantly reduce the survival and reproduction of nene on Kauai, and as a result, significantly increase the risk of extinction of nene. Although based on limited data, nene nesting success estimates on unmanaged lands on Kauai (*i.e.,* no predator control) are higher than managed lands on Maui and Hawaii; this difference may indicate the additional impact of nest predation by mongoose, which are not found on Kauai (Amidon 2017).

Critical biosecurity gaps that reduce the effectiveness of animal introduction controls include inadequate staffing, facilities, and equipment for Federal and State inspectors devoted to invasive species interdiction (Hawaii Legislative Reference Bureau 2002; USDA–APHIS–PPQ 2010; Coordinating Group on Alien Pest Species (CGAPS) 2009). In recognition of these gaps, a State law has been passed that allows the HDOA to collect fees for quarantine inspection of freight entering Hawaii (Act 36 (2011) HRS 150A–5.3). Hawaii legislation enacted in 2011 (House Bill 1568) requires commercial harbors and airports to provide biosecurity and inspection facilities to facilitate the movement of cargo through ports. This bill is a significant step toward optimizing biosecurity capacity in the State, but only time will determine its effectiveness. The Hawaii Interagency Biosecurity Plan (2017) is a 10-year strategy that addresses Hawaii's most critical biosecurity gaps and provides a coordinated interagency path that includes policies and implementation tasks in four main areas: (1) Pre-border; (2) border; (3) post-border; and (4) education and awareness. Overall, there is an ongoing need for all civilian and military port and airport operations and construction to implement biosecurity measures in order to prevent the introduction or inter-island transportation of additional predators and diseases that could impact nene.

Feral pigs pose the threat of predation to nene (see Factor C discussion, above). The State provides opportunities to the public to hunt game mammals (ungulates, including feral pigs) on 91 State-designated public hunting areas (within 45 units) on all the main Hawaiian Islands except Kahoolawe and Niihau (HAR–DLNR 2010; see HAR title 13, chapter 123; DLNR 2009, pp. 28–29). The State's management objectives for game mammals range from maximizing public hunting opportunities (*i.e.,* ''sustained yield'') in some areas to removal by State staff or their designees from other areas (HAR–DLNR 2010; see HAR title 13, chapter 123; DLNR 2009, pp. 28–29). Nene populations exist in areas where habitat is used for game enhancement and game populations are maintained at levels for public hunting (HAR–DLNR 2010; see HAR title 13, chapter 123; see Nene Use Area Maps in USFWS 2017). Public hunting areas are defined, but not fenced, and game mammals have unrestricted access to most areas across the landscape, regardless of underlying land-use designation. While fences are sometimes built to protect certain areas from impacts of game mammals, the current number and locations of fences are not adequate to address the threat of habitat degradation and predation on the nene in unfenced areas throughout its range. There are no other State regulations than those described above that address protection of nene and their habitat from feral pigs.

Local Mechanisms

Local groups are working to implement actions urgently needed to address the importation of nonnative, invasive species. We discuss the primary groups below.

CGAPS, a partnership of managers from Federal, State, County, and private agencies and organizations involved in invasive species work in Hawaii, was formed in 1995, in an effort to coordinate policy and funding decisions, improve communication, increase collaboration, and promote public awareness (CGAPS 2009). This group facilitated the formation of the Hawaii Invasive Species Council (HISC), which was created by gubernatorial executive order in 2002, to coordinate local initiatives for the prevention of introduction and for control of invasive species by providing policy-level direction and planning for the State departments responsible for invasive species issues (CGAPS 2009). In 2003, the Governor signed into law Act 85, which conveys statutory authority to the HISC to continue to coordinate approaches among the various State and Federal agencies, and international and local initiatives, for the prevention and control of invasive species (DLNR 2003, p. 3–15; HISC 2009, *in litt.;* HRS 194–2). Reduced funding beginning in 2009 restricted State funding support of HISC, resulting in a serious setback of conservation efforts (HISC 2009, 2015, *in litt.*) and increasing the likelihood of new invasive plants and animals becoming established in nene habitat.

The Hawaii Association of Watershed Partnerships (HAWP) comprises 11 separate partnerships on 6 Hawaiian Islands. These partnerships are voluntary alliances of public and private landowners, ''committed to the common value of protecting forested watersheds for water recharge, conservation, and other ecosystem services through collaborative management'' (*http://hawp.org/partnerships*). Funding for the partnerships is provided through a variety of State and Federal sources, public and private grants, and in-kind services provided by the partners and volunteers. However, since 2009, decreases in available funding have limited the positive contributions of these groups to implementing the laws and rules that can protect and control threats to nene.

These three partnerships, CGAPS, HISC, and HAWP, are collaborative measures that attempt to address issues that are not resolved by individual State and Federal agencies. The capacity of State and Federal agencies and their nongovernmental partners in Hawaii to provide sufficient inspection services, enforce regulations, and mitigate or monitor the effects of nonnative species is limited due to the large number of taxa currently causing damage (CGAPS 2009). Many invasive, nonnative species established in Hawaii currently have limited but expanding ranges, and they cause considerable concern. Resources available to reduce the spread of these species and counter their negative effects are limited. Control efforts are focused on a few invasive species that cause significant economic or environmental damage to commercial crops and public and private lands. Comprehensive control of an array of nonnative species and management to reduce disturbance regimes that favor them remain limited in scope. If current levels of funding and regulatory support for control of nonnative species are maintained, the Service expects existing programs to continue to exclude, or, on a very limited basis, control these species only in the highest priority areas. Threats from established nonnative species to nene are ongoing and are expected to continue into the future.

Summary of Factor D

Based on our analysis of existing regulatory mechanisms, there is a diverse network of laws and regulations that provide some protections to the nene and its habitat. Nene habitat that occurs on NWRs is protected under the National Wildlife Refuge System Improvement Act of 1997 and section 7 of the Endangered Species Act. Nene habitat is similarly protected on lands owned by the National Park Service. Additionally, nene receive protection under State law in Hawaii.

As a conservation reliant species, nene are expected to require ongoing management to address the ongoing threat of predation by introduced mammals such as mongooses, dogs, cats, rats, and pigs (Factor C). Although State and Federal regulatory mechanisms have not prevented the introduction into Hawaii of nonnative predators or their spread between islands, with sustained management commitments, these mechanisms could be an important tool to ameliorate this threat.

On the basis of the information provided above, existing State and Federal regulatory mechanisms are not preventing the introduction of nonnative species and pathogens into Hawaii via interstate and international pathways, or via intrastate movement of nonnative species between islands and watersheds. These mechanisms also do not adequately address the current threats posed to the nene by established nonnative species. Therefore, we conclude State and Federal regulatory mechanisms do not adequately address the threats to nene and their habitats from potential new introductions of nonnative species or continued expansion of existing nonnative species populations on and between islands and watersheds. However, with sustained management commitment, these mechanisms could be tools to ameliorate these threats.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Low Genetic Variation

Studies have shown that nene went through a prehistoric population bottleneck and have very low genetic diversity (Paxinos *et al.* 2002, p. 1,827; Rave *et al.* 1999, p. 40; Veillet *et al.* 2008, pp. 1,158—1,160). Low levels of genetic diversity have been found in wild and captive nene populations, and there is some evidence that fertility and gosling survival have declined in captivity as inbreeding has increased (Rave *et al.* 1994, p. 747; Rave 1995, p. 87, Rave *et al.* 1999, p. 40). A condition known as ''hairy-down'' caused by a recessive gene, which creates a cottony appearance and impairs cold resistance in goslings, has been observed in captive and wild nene (USFWS 2004, pp. 33–34); such goslings observed in the wild at Hawaii Volcanoes National Park have not survived (K. Misajon 2017, pers. comm.).

Rave (1995, p. 87) found that nene on Kauai had a significantly higher genetic similarity coefficient distribution (*i.e.,* the lowest level of genetic variation) of all birds sampled from six wild populations on Hawaii, Maui, and Kauai. Despite low genetic diversity and high levels of inbreeding, nene numbers have increased dramatically on Kauai. Thus, low genetic variation may not be a factor limiting reproductive success of the nene on Kauai (Rave 1995, p. 88).

Wind Energy Facilities

A significant number of nene mortalities have been reported at wind energy facilities. Nene collide with the towers or collide with or are struck by blades of wind turbine generators (WTGs). The diameter of rotor blades (approximately 330 ft (100 m)) and combined height of WTGs (up to 428 ft (131 m)) create large obstacles for nene during flight. On Maui, 3 facilities with a total of 40 WTGs are in operation, Kaheawa Wind Power I (20 WTGs) and Kaheawa Wind Power II (12 WTGs) in western Maui, and Auwahi Wind (8 WTGs) in southeastern Maui. From 2006 to 2016, a total of 26 nene fatalities and an adjusted take of 50 nene have been reported at the three Maui wind energy facilities (DOFAW 2016, *in litt.*). Take is adjusted by adding estimates of take undetected by search efforts, indirect take (*e.g.,* eggs or goslings taken by parental deaths in the current year), and lost productivity in future years. All three Maui facilities have approved habitat conservation plans (HCPs) and have received Federal incidental take permits and State incidental take licenses authorizing the total combined take of 95 nene during the 20-year period of operation for each project. The HCPs include the following conservation measures to offset the amount of authorized take: (1) Establish an additional population of 75 nene at an off-site location (Haleakala Ranch), (2) conduct predator control and habitat enhancement at the additional population site, (3) conduct on-site habitat restoration, (4) conduct on-site monitoring of nene, and (5) fund nene conservation actions at Haleakala National Park (DOFAW 2016, *in litt.*).

On Hawaii Island, two facilities with a total of 30 WTGs are in operation in Hawi (16 WTGs) and South Point (14 WTGs); however, there are no reports of nene being killed at these facilities (D. Sether 2017, pers. comm.). Based on the proximity of these facilities to areas used by nene, there is the potential for collisions. On Oahu, a total of 42 WTGs are in operation at Kawailoa Wind Power (30 WTGs) and Kahuku Wind Power (12 WTGs), and an additional 9 to 10 WTGs are proposed at the Na Pua Makani project in the Kahuku area. Na Pua Makani has submitted a draft HCP and requested incidental take for nene due to the proximity of the proposed wind energy project to James Campbell NWR, where the nene have been frequently observed. Based on the recent occurrence of only two individuals, which failed to breed successfully in 2016, wind energy facilities on Oahu are not a current threat, but represent a potential future threat should a breeding population of nene become established. On Maui and Hawaii Island, we expect that collisions at wind energy facilities will continue to result in take of nene now and in the foreseeable future; however, conservation measures in approved and permitted HCPs are expected to offset any population-level impacts to the species.

Human Activities

Nene are attracted to feeding opportunities provided by mowed grass and human handouts, and can become tame and unafraid of human activity, making them vulnerable to the impacts of various human activities. These activities include direct harm, such as that caused by vehicles and golf ball strikes, as well as possible disturbance by hikers, hunters, and other outdoor recreationists (Banko *et al.* 1999, pp. 23–24; Rave *et al.* 2005, p. 12; USFWS 2011a, p. 11; Hawaii Volcanoes National Park 2015, *in litt.;* Mello 2017, *in litt.*). Nene may also be impacted by human activities through the application of pesticides and other contaminants, ingestion of plastics and lead, collisions with stationary or moving structures or objects, entanglement in artificial hazards (*e.g.,* fences, fishing nets, erosion control material), disturbance at nest and roost sites, and mortality or disruption of family groups through direct and indirect human activities (Banko *et al.* 1999, pp. 23–24; USFWS 2004, pp. 30–31; Work *et al.* 2015, pp. 692–693).

Vehicle Collisions

Vehicle collisions have been an ongoing cause of nene mortality (Hoshide *et al.* 1990, p. 153; Rave *et al.* 2005, p. 15; Work *et al.* 2015, pp. 692–693). In many areas, nene habitat is

bisected by roads, with nesting and roosting on one side, foraging on the other side. This poses a serious threat, particularly during the breeding season, when adults walk goslings across roads. The greatest number of vehicle collisions occurs between December and April, during the peak of the breeding and molting season. It is during this time of year that both adults and goslings are flightless for a period of time and are especially vulnerable. The problem is worse in some areas because birds are attracted to handouts by visitors and the young shoots of recently manicured or irrigated lawns of roadsides and golf courses. Nene are often seen foraging along the edges of highways and ditches as a result of regular mowing and runoff from the pavement creating especially desirable grass in these areas. The impact is further exacerbated when, after a nene is killed on a road, the remaining family members are often unwilling to leave the body, resulting in multiple birds being killed over a short period of time (DLNR 2016, *in litt.*) and potential loss of future reproductive output from breeding pairs.

In the past, a number of mortalities caused by vehicle collisions were reported in Hawaii Volcanoes National Park (41) and in Haleakala National Park (14) (USFWS 2004, pp. 30–31; Rave *et al.* 2005, p. 12). More recent data indicate this is an ongoing issue both inside and outside park boundaries on Maui and Hawaii Island; the average annual number of nene killed by cars at Haleakala National Park was 1.2 ± 1.2 (from 1988 to 2011), and occurred at an average annual rate of 3 ± 2.39 at Hawaii Volcanoes National Park and an adjacent State highway (from 2009 to 2016) (Bailey and Tamayose 2016, *in litt.;* Misajon 2017, *in litt.*). Mortality of nene due to vehicle collisions has also been a continual problem on Kauai (Uyehara 2016c, *in litt.*). Over 50 nene were struck and killed by cars across the roadways of Kauai in 2 years (Kauai DOFAW 2016, *in litt.*). On Kauai, typically the majority of vehicle strikes occur in Hanalei and Kilauea, where the largest proportion of the Kauai population occurs; however, the most recent strikes are occurring on the western side of the island.

The National Park Service (NPS) is actively implementing aggressive traffic-calming measures (Haleakala National Park 2014, *in litt.;* USFWS 2016, *in litt.*). A press release is sent out at the beginning of the nesting season, asking park visitors to drive carefully. Posters are displayed at car rental agencies asking visitors to drive carefully when visiting the park. ''Nene Crossing'' postcards with ''Slow Down'' messages in different languages are handed out to vehicles entering the park. Cones, signs, and a radar trailer are placed along roadsides where nene are frequently seen. Permanent ''Nene Crossing'' signs alert drivers to the potential for birds in the primary area(s) of concern, and temporary crossing signs are deployed when birds are observed frequenting specific road side sites. The NPS conducts regular outreach and education to raise visitor awareness of nene near roads. The Kauai DOFAW conducts educational outreach and has signs placed to encourage driving at reduced speeds. The conservation measures reduce but do not eliminate the threat of vehicle collisions. Based on the available information, we conclude vehicle collisions are an ongoing cause of nene injury and mortality on Kauai, Maui, and Hawaii.

Natural and Artificial Hazards

Nene can become entangled or trapped in artificial hazards (*e.g.,* old grass-covered fence wire; fishing line, predator traps; spilled tar) and some natural hazards (lava tube openings or deep depressions in ash deposits) (Banko *et al.* 1999, p. 24). Goslings occasionally drown in stock ponds, water troughs, and other water sources where exit to land is difficult (Banko *et al.* 1999, p. 24). Predator traps outfitted with protective guards have been effective at reducing the incidence of injury to goslings (NRCS 2007, p. 6).

The use of certain fencing and erosion control materials has resulted in entanglement of nene with the potential to cause impaired movement, injury, and in some cases mortality. Over 2 years, a total of 44 nene (27 adults and 17 hatch-year birds) in the Poipu/Koloa population on Kauai have been observed with woven threads from erosion control slope matting wrapped around their legs at a single construction site (Kauai DOFAW 2016, *in litt.*). Once the material is wrapped around their legs, nene have an increased risk of becoming entangled with other objects, experiencing skin lacerations, and having the circulation cut from their legs leading to infection and the death of the limb (Kauai DOFAW 2015, *in litt.*). Not all instances of entanglement result in harm to nene, as birds may free themselves from threads. Nine of the 44 entangled nene have been observed with constriction or swelling on their legs; 3 have received rehabilitation and been released; and 1 was euthanized due to injuries sustained from the material. Kauai DOFAW is working with the landowners to minimize impacts and has recommended that the use of this type of erosion control matting be discontinued.

Summary of Factor E

As nene populations continue to recover and increase in number and range, they will be subject to increased human interactions in and around urban, suburban, agricultural, and recreational areas. Vehicle collisions are an ongoing cause of nene injury and mortality; however, we do not have evidence that this factor is limiting population sizes. We acknowledge that increasing nene population sizes could result in increased mortality rates in the future, especially for those populations near areas with human presence. While vehicle collisions could potentially impact certain populations, they do not constitute a threat to the entire species now, and we do not expect them to be a threat in the foreseeable future. Artificial hazards that result in entanglement or drowning occur at low frequency and thus are not expected to result in population-level impacts. Collisions at wind energy facilities will result in take of nene now and in the foreseeable future; however, conservation measures in approved and permitted HCPs are expected to offset any population-level impacts to the species. While nene exhibit low levels of genetic variation, this does not appear to be a factor limiting reproductive success. Thus, low genetic variation is not a threat to nene now or in the foreseeable future.

Overall Summary of Factors Affecting Nene

The current Statewide nene population estimate is 2,855 (NRAG 2017). The population on Kauai, estimated at 1,107 birds, is stable and increasing, sustained by ongoing predator control and habitat management (NRAG 2017). Nene on Kauai exhibit successful breeding, likely due to abundant food in managed grasslands and the absence of mongooses, which are a significant nest predator on other islands. Between 2011 and 2016, 640 nene were relocated from Kauai to Maui and Hawaii Island. The Kauai population is expected to continue to exhibit an increasing trend. On Maui, the current population estimate is 616, with approximately half of the population in Haleakala National Park, and the remainder is distributed across areas of western Maui, southern Maui, and the northwestern slopes of Haleakala. The population at Haleakala National Park shows a general increasing trend with numbers consistently above 200 birds since

intensive habitat management (feral ungulate and predator control) measures were initiated in the 1990s. On Hawaii Island, the current population estimate is 1,095, which includes 592 birds relocated from Kauai (NRAG 2017). Prior to the addition of nene from Kauai, population estimates on Hawaii Island ranged between 331 and 611, and in general show an increasing trend during the previous 10-year period since the last major release of 53 birds in 2001. For many years, the largest population of nene on Hawaii Island has occurred in Hawaii Volcanoes National Park. Over the last 10 years, population estimates at Hawaii Volcanoes National Park have remained relatively constant (ranging between 200 and 250 birds), sustained by ongoing predator control and habitat management. On Molokai, the current population estimate of 35 (NRAG 2017), down from an estimate of 78 in 2015, is likely due to predation (Franklin 2017, *in litt.*). While nene on Molokai have bred successfully, periodically low fledging success has been reported due to the high mortality of nestlings, possibly due to overcrowding at the release site. Estimates of the population on Molokai have fluctuated widely since the reintroduction of 74 birds was completed in 2004. Nene are considered a conservation-reliant species, especially on Maui and Hawaii Island, where populations are spread across a large area and exposed to ongoing threats of predation, habitat loss (development, feral ungulates, nonnative plants), and disease (Reed *et al.* 2012, p. 888). At a minimum, current management levels must be continued to sustain current population trends.

Threats to nene from habitat destruction or modification (Factor A) remain and will likely continue into the foreseeable future in the form of urbanization, agricultural activities, habitat alteration by feral ungulates and nonnative plants, and drought. These factors contribute to a lack of suitable breeding and flocking habitat and, in combination with predation (Factor C) and human activities (Factor E), continue to threaten nene and limit expansion of nene populations. Some habitats are expected to be affected by habitat changes resulting from the effects of climate change (Factor A). Overutilization (Factor B) is not a threat. Diseases (Factor C) such as toxoplasmosis, avian malaria, omphalitis, and avian botulism are not currently known to contribute significantly to mortality in nene. Thus, we do not consider disease to be a threat. Predation (Factor C) by introduced mammals, including mongooses, dogs, cats, rats, and pigs, is a significant limiting factor for nene populations now and into the foreseeable future. Therefore, we consider predation to be a threat. Existing regulatory mechanisms, including those to prevent predation will be an important component of ongoing management of nene as a conservation reliant species, but do not currently adequately ameliorate threats and will require continuing commitment to implementation (Factor D). Human activities such as vehicle collisions, artificial hazards, and other human interactions (Factor E) continue to result in injury and mortality; while the individual impacts of these hazards do not constitute threats with population-level impacts to nene, they collectively and in combination with other factors (Factors A, C, and D) constitute an ongoing threat.

Proposed Determination of Species Status

Introduction

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for determining whether a species is an endangered species or threatened species and should be included on the Federal Lists of Endangered and Threatened Wildlife and Plants (listed). The Act defines an endangered species as any species that is ''in danger of extinction throughout all or a significant portion of its range'' and a threatened species as any species ''that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future.'' On July 1, 2014, we published a final policy interpreting the phrase ''significant portion of its range'' (SPR) (79 FR 37578). In our policy, we interpret the phrase ''significant portion of its range'' in the Act's definitions of ''endangered species'' and ''threatened species'' to provide an independent basis for listing a species in its entirety; thus there are two situations (or factual bases) under which a species would qualify for listing: A species may be in danger of extinction or likely to become so in the foreseeable future throughout all of its range; or a species may be in danger of extinction or likely to become so throughout a significant portion of its range. If a species is in danger of extinction throughout an SPR, the species, is an ''endangered species.'' The same analysis applies to ''threatened species.''

The SPR policy is applied to all status determinations, including analyses for the purposes of making listing, delisting, and reclassification determinations. Under section 4(a)(1) of the Act, we determine whether a species is an endangered species or threatened species because of any one or a combination of the following: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. These five factors apply whether we are analyzing the species' status throughout all of its range or throughout a significant portion of its range.

Determination of Status Throughout All of Its Range

As required by the Act, we considered the five factors in assessing whether nene is endangered or threatened throughout all of its range. We carefully examined the best scientific and commercial information available regarding the past, present, and future threats faced by nene. We reviewed the information available in our files and other available published and unpublished information, and we consulted with recognized experts and State agencies. The current statewide nene population estimate is 2,855 individuals, with the wild populations on the islands of Hawaii, Maui, Molokai, Kauai, and Oahu estimated to have 1,095, 616, 35, 1,107, and 2 individuals, respectively. Populations on Kauai, Maui, and Hawaii are exhibiting a stable or increasing trend, while the nene population on Molokai is experiencing a fluctuation in population numbers. Continuation of current population trends into the future is dependent on, at a minimum, maintaining current levels of management (*e.g.,* predator control and habitat enhancement). Nene are still affected by predation (Factor C), loss and degradation of habitat (Factor A), and effects of human activities (Factor E); and some subpopulations may potentially be affected in the future by habitat changes resulting from the effects of climate change such as increases in drought, hurricanes, or sea level rise (Factor A). Regulatory mechanisms do not adequately address these threats. While threat intensity and management needs vary somewhat across the range of the species (for example, the current lack of an established mongoose population on Kauai influences predator control strategies there), nene populations on

islands throughout the range of the species continue to be reliant on active conservation management and require adequate implementation of regulatory mechanisms, and all remain vulnerable to threats that could cause substantial population declines in the foreseeable future. Despite the existing regulatory mechanisms and conservation efforts (Factor D), the factors identified above continue to affect the nene such that it is likely to become in danger of extinction within the foreseeable future throughout all of its range. Thus, after assessing the best available information, we conclude that the nene is not currently in danger of extinction, but is likely to become in danger of extinction within the foreseeable future throughout all of its range.

Determination of Status Throughout a Significant Portion of Its Range

Because we have determined that the nene is likely to become in danger of extinction in the foreseeable future throughout all of its range, per the Service's Final Policy on Interpretation of the Phrase ''Significant Portion of Its Range'' in the Endangered Species Act's Definitions of ''Endangered Species'' and ''Threatened Species'' (79 FR 37578, July 1, 2014) (SPR Policy), no portion of the species' range can be ''significant'' for the purposes of the definitions of endangered and threatened species. Therefore, we do not need to conduct an analysis of whether there is any significant portion of its range because the species is likely to become in danger of extinction in the foreseeable future.

Proposed Determination of Status

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the nene. Based on the analysis above and given increases in population numbers due to recovery efforts, we conclude the nene does not currently meet the Act's definition of an endangered species in that it is not in danger of extinction throughout all of its range. Although population numbers have increased, our analysis indicates that because of significant remaining threats, the species remains likely to become in danger of extinction in the foreseeable future throughout all of its range. Because the species is likely to become in danger of extinction in the foreseeable future throughout all of its range, the species meets the definition of a threatened species. Therefore, we propose to reclassify the nene from an endangered species to a threatened species.

This proposal, if made final, would revise 50 CFR 17.11(h) to reclassify nene from endangered to threatened. Reclassification of nene from endangered to threatened is due to the substantial efforts made by Federal, State, and local government agencies and private landowners to recover the species. Adoption of this proposed rule would formally recognize that this species is no longer in danger of extinction throughout all or a significant portion of its range and, therefore, does not meet the definition of endangered, but is still impacted by predation, habitat loss and degradation, and inadequacy of regulatory mechanisms to the extent that the species meets the definition of a threatened species under the Act.

Proposed 4(d) Rule

Whenever a species is listed as threatened, the Act allows promulgation of a rule under section 4(d). Section 4(d) of the Act states that ''the Secretary shall issue such regulations as he deems necessary and advisable to provide for the conservation'' of species listed as threatened species. Conservation is defined in the Act to mean ''to use and the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to [the Act] are no longer necessary.'' The purposes of the Act are to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, to provide a program for the conservation of endangered species and threatened species, and to take such steps as may be appropriate to achieve the purposes of the treaties and conventions set forth in the Act. For any threatened fish and wildlife species, the Secretary has the discretion to prohibit by regulation any action prohibited under section 9(a)(1) of the Act. Exercising this discretion, the Service has by regulation (50 CFR 17.31) applied the prohibitions in section 9(a)(1) to all threatened wildlife species except for those for which a rule has been promulgated under section 4(d) of the Act. A 4(d) rule may include some or all of the prohibitions under section 9(a)(1), as set out at 50 CFR 17.21, but also may be less or more restrictive than those general provisions.

Section 9 of the Act prohibits the taking of any federally listed endangered species, including nene. Section 3(19) defines ''take'' to mean ''to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct.'' Service regulations (50 CFR 17.3) define ''harm'' to include significant habitat modification or degradation which actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering. Harass is defined at 50 CFR 17.3 as an intentional or negligent act or omission which creates the likelihood of injury to wildlife by annoying it to such an extent as to significantly disrupt normal behavioral patterns which include, but are not limited to, breeding, feeding, or sheltering. Section 9 also prohibits import, export, and sale of endangered species in interstate or foreign commerce. The Act provides for civil and criminal penalties for the unlawful taking of listed species or other violations of section 9.

Under 50 CFR 17.32, permits may be issued for certain actions affecting threatened fish and wildlife species that would otherwise be prohibited under the Act. The processes and criteria for such permit issuance are governed by 50 CFR 17.32, unless otherwise provided in a 4(d) rule. If an activity that may affect the nene is not covered in this proposed 4(d) rule and the activity would result in an act that would be otherwise prohibited, authorization under 50 CFR 17.32 would be required. In addition, nothing in this 4(d) rule affects in any way other provisions of the Act, such as the designation of critical habitat under section 4, recovery planning provisions of section 4(f), and consultation requirements under section 7.

For the nene, the Service has determined that a 4(d) rule is appropriate. We propose to issue a rule for this species under section 4(d) of the Act as a means to provide continued protection from take and to facilitate conservation of nene and expansion of their range by increasing flexibility in management activities. This proposed 4(d) rule would apply only if and when the Service finalizes the reclassification of the nene as threatened. We propose a 4(d) rule for nene, as described below.

Anyone taking, attempting to take, or otherwise possessing a nene, or parts thereof, in violation of section 9 of the Act would still be subject to a penalty under section 11 of the Act, except for the actions that would be covered under the proposed 4(d) rule. Under section 7 of the Act, Federal agencies must ensure that any actions they authorize, fund, or carry out are not likely to jeopardize the continued existence of nene.

Under the proposed 4(d) rule, take will generally continue to be prohibited, but the following forms of take would be allowed under the Act:

- Take by landowners or their agents conducting intentional harassment in

the form of hazing or other deterrent measures not likely to cause direct injury or mortality;

- Take that is incidental to conducting lawful control of introduced predators or habitat management activities for nene; and
- Take by authorized law enforcement officers for the purposes of aiding or euthanizing sick, injured, or orphaned nene; disposing of dead specimens; and salvaging a dead specimen that may be used for scientific study.

The proposed 4(d) rule targets activities to facilitate conservation and management of nene where they currently occur and may occur in the future through increased flexibility by eliminating the Federal take prohibition under certain conditions. These activities are intended to encourage support for the occurrence of nene in areas with land use practices compatible with the conservation of nene, and to redirect nene use away from areas that do not support the conservation of nene (see *Justification,* below).

As nene increase in number and range, they are facing increased interaction and potential conflict with the human environment. In addition, the nene recently translocated from Kauai to Maui and Hawaii Island have expanded into new areas on these islands, often in close proximity to human populations. Nene are known to use and interact with human-modified environments (such as wind farms, airports, resorts, golf courses, agricultural operations, residential areas, parks, public recreation areas, and transportation routes) during feeding, breeding, molting, and sheltering activities, as well as during seasonal intra-island movements. In these environments, nene may be subject to injury or mortality as a result of activities such as vehicle collisions, collisions with wind turbines, golf ball strikes, predation or attack by unrestrained pets, entanglement with foreign materials, and ingestion of herbicides and pesticides associated with construction, maintenance, or normal business activities in these areas. The proposed 4(d) rule would not change the prohibition on any take of nene associated with these activities, although hazing to move nene away from these activities would be allowed under the 4(d) rule. For these types of activities on non-Federal lands or those without a Federal nexus where section 7 would provide incidental take exemption, landowners or project proponents may develop an HCP and apply for an incidental take permit to address any potential take of the nene to avoid violating the prohibition on take.

Intentional Harassment Not Likely To Cause Mortality or Direct Injury

Hazing and other persistent deterrence actions are management strategies that may be used to address wildlife conflict issues. As nene populations increase, particularly in heavily human-populated lowland areas, they may often come into conflict with human activities. For example, nene are known to use a variety of human-modified areas including wind farms, airports, resorts, golf courses, agricultural operations, residential areas, parks, public recreation areas, and transportation routes. Nene using these areas may present a conflict with normal business activities or cause crop depredation or safety hazards to humans. Humans may also inadvertently harm nene by feeding them, which could result in nene showing aggressive behaviors towards humans, being injured or killed by vehicles or humans, or being placed at increased risk from predators. Methods such as hazing are necessary to prevent and address these potential human-nene conflicts, allowing nene to coexist with areas of established human activity and providing for continued public support of nene recovery actions.

Any deterrence activity that does not create a likelihood of injury by significantly disrupting normal nene behavioral patterns such as breeding, feeding, or sheltering is not take and is not prohibited under the Act.

If an activity creates the likelihood of injury to wildlife by annoying it to such an extent as to significantly disrupt normal behavioral patterns such as breeding, feeding, and sheltering, then the activity has the potential to cause take in the form of harassment. Hazing of nene is considered intentional harassment, which creates the likelihood of injury and has been prohibited under section 9 of the Act. Under this proposed 4(d) rule, hazing and other deterrence activities that may cause indirect injury to nene by disrupting normal behavioral patterns, but are not likely to be lethal or cause direct injury (including the need for veterinary care or rehabilitation), would be classified as intentional harassment not likely to cause direct injury or mortality, and would be allowed under Federal law. Such activities may include the use of predator effigies (including raptor kites, predator replicas, etc.), commercial chemical repellents, ultrasonic repellers, audio deterrents (noisemakers, pyrotechnics, etc.), herding or harassing with trained or tethered dogs, or access control (including netting, fencing, etc.). This proposed 4(d) rule would not apply to scenarios involving lethal or directly injurious take. For example, laser irradiation used for hazing may cause ocular damage resulting in temporary or permanent loss of visual acuity or blindness (Oregon State University 2017, *in litt.*), impairing the ability of nene to feed or avoid predators or other hazards (*e.g.,* vehicle collisions). Feral dogs or unrestrained pets are known to take nene adults and goslings, and nene are particularly vulnerable to dogs because they have little instinctive fear of them (NRCS 2007, p. 6). Therefore, the proposed rule would not cover hazing methods such as lasers or untrained and untethered dogs.

Intentional harassment activities not likely to cause direct injury or mortality that are addressed in this proposed 4(d) rule are recommended to be implemented prior to the nene breeding season (September through April) wherever feasible. If, during the breeding season, a landowner desires to conduct an action that would intentionally harass nene to address nene loafing or foraging in a given area, a qualified biologist familiar with the nesting behavior of nene must survey in and around the area to determine whether a nest or goslings are present. If a nest or families with goslings is discovered, a qualified biologist must be notified and the following measures implemented to avoid disturbance of nests and broods: (1) No disruptive activities may occur within a 100-foot (30-meter) buffer around all active nests and broods until the goslings have fledged; and (2) brooding adults (*i.e.,* adults with an active nest or goslings) or adults in molt may not be subject to intentional harassment at any time. In general, any observation of nene nest(s) or gosling(s) should be reported to the Service and authorized State wildlife officials within 72 hours. Additionally, follow-up surveys of the property by qualified biologists should be arranged by the landowner to assess the status of birds present.

Predator Control and Habitat Management

Control of introduced predators and habitat management are identified as two primary recovery actions for nene (USFWS 2004, p. 52). Control of predators (*e.g.,* mongooses, dogs, feral pigs, cats, rats, cattle egrets, and barn owls) may be conducted to eliminate or reduce predation on nene during all life stages. These predators are managed using a variety of methods, including fencing, trapping, shooting, and

toxicants. All methods must be used in compliance with State and Federal regulations. In addition to the application of the above tools, predator control as defined here includes activities related to predator control, such as performing efficacy surveys, trap checks, and maintenance duties. Predator control may occur year-round or during prescribed periods. During approved predator control activities, incidental take of nene may occur in the following manner: (1) Injury or death to goslings, juveniles, or adults from accidental trapping; (2) injury or death due to fence strikes caused from introduction of equipment or materials in a managed area; and (3) injury or death due to ingestion of chemicals approved for use in predator control. Under this proposed 4(d) rule, take resulting from actions implementing predator control activities to benefit nene would not be prohibited as long as reasonable care is practiced to minimize the effects of such taking. Reasonable care may include but is not limited to: (1) Procuring and implementing technical assistance from a qualified biologist(s) on predator control methods and protocols prior to application of methods; (2) compliance with all applicable regulations and following principles of integrated pest management; and (3) judicious use of methods and tool adaptations to reduce the likelihood that nene would ingest bait, interact with mechanical devices, or be injured or die from an interaction with mechanical devices.

Nene productivity and survival are currently limited by insufficient nutritional resources due to habitat degradation and the limited availability of suitable habitat due to habitat loss and fragmentation, especially in lowland areas (USFWS 2004, pp. 29–30). Active habitat management is necessary for populations of nene to be sustained or expanded without the continued release of captive-bred birds. Active habitat management in protected nesting and brooding areas should improve productivity and survival, as well as attract birds to areas that can be protected during sensitive life stages. Habitat management actions may include: (1) Mowing, weeding, fertilizing, herbicide application, and irrigating existing pasture areas for conservation purposes; (2) planting native food resources; (3) providing watering areas, such as water units or ponds or catchments, designed to be safe for goslings and flightless/molting adults; (4) providing temporary supplemental feeding and watering stations when appropriate, such as under poor quality forage or extreme conditions (*e.g.,* drought or fire); (5) if mechanical mowing of pastures is not feasible, alternative methods of keeping grass short, such as grazing; or (6) large-scale restoration of native habitat (*e.g.,* feral ungulate control, fencing).

In the course of habitat management activities, incidental take of nene may occur in the following manner: (1) Accidental crushing of non-flighted juveniles, goslings, or nests with eggs; (2) injury or death due to collisions with vehicles and equipment; (3) injury or death due to ingestion of plants sprayed with herbicides or ingestion of fertilizers; (4) injury or death due to entanglement with landscaping materials or choking on foreign materials; and (5) injury or death of goslings if goslings are separated from parents because of disturbance by restoration activities (*e.g.,* use of heavy equipment or mechanized tools). Under this proposed 4(d) rule, take resulting from habitat management activities would not be prohibited as long as reasonable care is practiced to minimize the effects of such taking. Reasonable care may include but is not limited to: (1) Procuring and implementing technical assistance from a qualified biologist on habitat management activities prior to implementation; and (2) best efforts to minimize nene exposure to hazards (*e.g.,* predation, habituation to feeding, entanglement, vehicle collisions, golf ball strikes).

Additional Authorizations for Law Enforcement Officers

The increased interaction of nene with the human environment also increases the likelihood of encounters with injured, sick, or dead nene. This proposed 4(d) rule would exempt take of nene by law enforcement officers in consultation with State wildlife biologists to provide aid to injured or sick nene, or disposal or salvage of a dead nene. Law enforcement officers would be allowed take of nene for the following purposes: Aiding or euthanizing sick, injured, or orphaned nene; disposing of a dead specimen; and salvaging a dead specimen that may be used for scientific study.

Justification

As the nene population increases in number and range, nene are facing increased interaction and potential conflict with the human environment. If finalized, the reclassification of the nene to threatened status would allow employees of State conservation agencies operating a conservation program pursuant to the terms of a cooperative agreement with the Service in accordance with section 6(c) of the Act, and who are designated by their agencies for such purposes, and who are acting in the course of their official duties, to take nene in the course of carrying out conservation programs (see 50 CFR 17.31(b)). However, there are many activities carried out or managed by landowners or their agents that help reduce conflict or benefit the recovery of nene, and thereby facilitate the expansion of nene populations, but would not be exempted from take prohibitions without a 4(d) rule. These activities include intentional harassment not likely to result in mortality or direct injury, predator control, and habitat management. We anticipate that reclassification and implementation of a 4(d) rule would facilitate the expansion of nene into additional areas with land use practices compatible with the conservation of nene, and reduce the occurrence of nene in areas that do not support the conservation of nene across the landscape. The proposed 4(d) rule would provide incentives to landowners to support the occurrence of nene on their properties, as well as neighboring properties, by alleviating concerns about unauthorized take of nene.

Except as outlined in the proposed 4(d) rule, prohibitions on take of nene would remain in effect. Harm or harassment that is likely to cause mortality or injury would continue to be prohibited because allowing these forms of take would be incompatible with restoring robust populations of nene and restoring and maintaining their habitat.

This rule does not alter the requirements of the Act's section 7 or the interagency regulations implementing section 7 found at 50 CFR part 402. Federal actions covered by this rule would still be subject to section 7. The effect of this rule would be to exclude certain specific actions from the prohibitions on take so that such actions may not require an exemption through section 7(o) of the Act. However, under 50 CFR 402.14 the Federal agency would still need to consult with the Service if the proposed action may affect nene, unless the agency determines with written concurrence from the Service that the proposed action is not likely to adversely affect the nene.

One of the limiting factors in the recovery of nene has been the concern of landowners regarding nene on their property due to the potential damage to agricultural crops and potential conflicts with normal business, recreational, and residential activities. Landowners express concern over their inability to prevent or address the

damage or conflicts caused by nene because of the threat of penalties under the Act. Furthermore, State and Federal wildlife agencies expend resources addressing landowner complaints regarding potential nene damage to agricultural crops and conflicts during normal business, recreational, and residential activities. By providing more flexibility to the landowners regarding management of nene, we envision enhanced support for the conservation of the species, by providing a tool to reduce potential human-wildlife conflicts in areas incompatible with the conservation of nene, as well as promote expansion of the species' range into additional areas compatible with conservation of nene across the State.

The proposed 4(d) rule would address intentional harassment of nene by landowners and their agents that is not likely to result in mortality or direct injury, and predator control and habitat management. Exempting targeted activities that may normally result in take under the prohibitions of the Act would increase the incentive for all landowners to support nene recovery and provide enhanced options for wildlife managers with respect to nene management, thereby encouraging their participation in recovery actions for nene.

We believe the actions and activities that would be allowed under the proposed 4(d) rule, while they may cause some minimal level of harm or disturbance to individual nene, would not be expected to cause mortality or direct injury, would not adversely affect efforts to conserve and recover nene, and in fact should facilitate these efforts because they would make it easier to implement recovery actions and redirect nene activity toward lands that are managed for conservation.

This proposed 4(d) rule would not be made final until we have reviewed and fully considered comments from the public and peer reviewers.

Provisions of the 4(d) Rule

The increased interaction of nene with the human environment increases the potential for nene to cause conflicts for business, agricultural, residential, and recreational activities, as well as the potential for nene to become habituated to hazardous areas (*e.g.,* golf courses, roadways, parks, farms). Therefore, this proposed 4(d) rule would increase the flexibility of nene management for landowners and their agents by allowing take of nene resulting from intentional harassment of nene that is not likely to result in mortality or direct injury, control of introduced predators of nene, and nene habitat management activities.

The proposed 4(d) rule only addresses Federal Endangered Species Act requirements, and would not change State law. It is our understanding that current State of Hawaii (HRS section 195D–4) law does not include the authority to issue regulations, equivalent to those under section 4(d) of the Act, to exempt take prohibitions for endangered and threatened species. Instead, State law requires the issuance of a temporary license for the take of endangered and threatened animal species, if the activity otherwise prohibited is: (1) For scientific purposes or to enhance the propagation or survival of the affected species (HRS 195D–4(f)); or (2) incidental to an otherwise lawful activity (HRS 195D–4(g)). Incidental take licenses require the development of an HCP (section 195D–21) or a safe harbor agreement (section 195D–22), and consultation with the State's Endangered Species Recovery Committee. Therefore, persons may need to obtain a State permit for some of the actions described in the proposed 4(d) rule. In addition, it is our understanding that current State regulations for endangered and threatened wildlife (HAR section 13–124, subchapter 3) do not allow permits for the intentional harassment or hazing of endangered or threatened species, thus changes to these State regulations may be necessary to allow the State to issue such permits.

As explained above, the provisions included in this proposed 4(d) rule are necessary and advisable to provide for the conservation of the nene. Nothing in this proposed 4(d) rule would change in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or the ability of the Service to enter into partnerships for the management and protection of the nene. However, the consultation process may be further streamlined through planned programmatic consultations between Federal agencies and the Service for these activities. We ask the public, particularly State agencies and other interested stakeholders that may be affected by the proposed 4(d) rule, to provide comments and suggestions regarding additional guidance and methods that the Service could provide or use, respectively, to streamline the implementation of this 4(d) rule (see Information Requested, above).

Required Determinations

Clarity of This Proposed Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act

We have determined that an environmental assessment or an environmental impact statement, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations such as this. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of all references cited in this proposed rule is available at *http://www.regulations.gov* at Docket No. FWS–R1–ES–2017–0050, or upon request from the Pacific Islands Fish and Wildlife Office (see **ADDRESSES**).

Authors

The primary authors of this document are staff members of the Pacific Islands Fish and Wildlife Office in Honolulu, Hawaii (see **FOR FURTHER INFORMATION CONTACT**).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we hereby propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h) by revising the entry for ''Goose, Hawaiian'' under BIRDS in the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
Birds				
*	*	*	*	*
Goose, Hawaiian (Nene) ..	*Branta sandvicensis*	Wherever found	T	32 FR 4001, 3/11/1967; [Insert **Federal Register** citation when published as a final rule]; 50 CFR 17.41(d) [4d].
*	*	*	*	*

■ 3. Amend § 17.41 by adding a paragraph (d) to read as follows:

§ 17.41 Special rules—birds.

* * * * *

(d) Hawaiian goose (*Branta sandvicensis*) (nene).

(1) *General requirements.* Except as expressly provided in paragraphs (d)(3) and (4) of this section, all provisions of § 17.21, except § 17.21(c)(5), and all provisions of § 17.31(b) apply to the nene.

(2) *Definitions.* For the purposes of this paragraph:

(i) *Nene* means the Hawaiian goose (*Branta sandvicensis*);

(ii) *Intentional harassment* means an intentional act which creates the likelihood of injury to wildlife by annoying it to such an extent as to significantly disrupt normal behavior patterns which include, but are not limited to, breeding, feeding, or sheltering (Intentional harassment may include prior purposeful actions to attract, track, wait for, or search out nene, or purposeful actions to deter nene); and

(iii) *Person* means a person as defined by section 3(13) of the Act.

(3) *Allowable forms of take of nene.* Any person may take nene as a result of the following legally conducted activities in accordance with this paragraph.

(i) *Intentional harassment of nene that is not likely to cause direct injury or mortality.* A person may harass nene on lands they own, rent, or lease, if the action is not likely to cause direct injury or mortality of nene. Techniques for such harassment may include the use of predator effigies (including raptor kites, predator replicas, etc.), commercial chemical repellents, ultrasonic repellers, audio deterrents (noisemakers, pyrotechnics, etc.), herding or harassing with trained or tethered dogs, or access control (including netting, fencing, etc.). Such harassment techniques must avoid causing direct injury or mortality to nene. Before implementation of any intentional harassment activities during the nene breeding season (September through April), a qualified biologist knowledgeable about the nesting behavior of nene must survey in and around the area to determine whether a nest or goslings are present. If a nest is discovered, the Service and authorized State wildlife officials must be notified within 72 hours (see paragraph (d)(5) of this section for contact information) and the following measures implemented to avoid disturbance of nests and broods:

(A) No disruptive activities may occur within a 100-foot (30-meter) buffer around all active nests and broods until the goslings have fledged; and

(B) Brooding adults (*i.e.,* adults with an active nest or goslings) or adults in molt may not be subject to intentional harassment at any time.

(ii) *Nonnative predator control or habitat management activities.* A person may incidentally take nene in the course of carrying out nonnative predator control or habitat management activities for conservation purposes if reasonable care is practiced to minimize effects to the nene.

(A) Predator control activities include use of fencing, trapping, shooting, and toxicants to control predators, and related activities such as performing efficacy surveys, trap checks, and maintenance duties. Reasonable care for predator control activities may include, but is not limited to, procuring and implementing technical assistance from a qualified biologist on predator control methods and protocols prior to application of methods; compliance with all State and Federal regulations and guidelines for application of predator control methods; and judicious use of methods and tool adaptations to reduce the likelihood of nene ingesting bait, interacting with mechanical devices, or being injured or dying from interaction with mechanical devices.

(B) Habitat management activities include mowing, weeding, fertilizing, herbicide application, and irrigating existing pasture areas for conservation purposes; planting native food resources; providing watering areas, such as water units or ponds or catchments, designed to be safe for goslings and flightless/molting adults; providing temporary supplemental feeding and watering stations when appropriate, such as under poor quality forage or extreme conditions (*e.g.,* drought or fire); if mechanical mowing of pastures is not feasible, alternate methods of keeping grass short, such as grazing; and large-scale restoration of native habitat (*e.g.,* feral ungulate control, fencing). Reasonable care for habitat management may include, but is not limited to, procuring and implementing technical assistance from a qualified biologist on habitat management activities, and best efforts to minimize nene exposure to hazards (*e.g.,* predation, habituation to feeding, entanglement, vehicle collisions, golf ball strikes).

(4) *Additional authorizations for law enforcement officers.* When acting in the course of their official duties, State and local government law enforcement officers, working in conjunction with authorized wildlife biologists and wildlife rehabilitators in the State of Hawaii, may take nene for the following purposes:

(i) Aiding or euthanizing sick, injured, or orphaned nene;

(ii) Disposing of a dead specimen; or

(iii) Salvaging a dead specimen that may be used for scientific study.

(5) *Reporting and disposal requirements.* Any injury or mortality of nene associated with the actions

authorized under paragraphs (d)(3) and (4) of this section must be reported to the Service and authorized State wildlife officials within 72 hours, and specimens may be disposed of only in accordance with directions from the Service. Reports should be made to the Service's Law Enforcement Office at (808) 861–8525, or the Service's Pacific Islands Fish and Wildlife Office at (808) 792–9400. The State of Hawaii Department of Land and Natural Resources, Division of Forestry and Wildlife may be contacted at (808) 587–0166. The Service may allow additional reasonable time for reporting if access to these offices is limited due to closure.

(6) *Take authorized by permits.* Any person with a valid permit issued by the Service under § 17.22 or § 17.32 may take nene, subject to all take limitations and other special terms and conditions of the permit.

(7) Federal actions remain subject to section 7 of the Act. Nothing in this section relieves Federal agencies from compliance with the provisions of 16 U.S.C. 1536 or 50 CFR part 402.

(8) Nothing in this section provides authorization for take of nene under the Migratory Bird Treaty Act (16 U.S.C. 703–712).

* * * * *

Dated: February 7, 2018.

James W. Kurth,

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

[FR Doc. 2018–06571 Filed 3–30–18; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 83, No. 63
Monday, April 2, 2018

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

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Intent To Renew Information Collection

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice and request for comment.

SUMMARY: The U.S. Department of Agriculture (USDA) seeks comments on the intent of the USNA to renew an information collection that expires August 31, 2018. The information collection serves as a means to collect for certain use of the facilities, grounds, programs and services. This includes fees for educational programs and workshops and for use of the grounds and facilities, as well as for commercial photography and cinematography. Fees generated will be used to defray USNA expenses or to promote the missions of the USNA.

DATES: Comments on this notice must be received by June 1, 2018 to be assured of consideration.

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

- *Email: richard.olsen@ars.usda.gov.*
- *Fax:* 202–245–4514.
- *Mail:* Director, U.S. National Arboretum, Northeast Area, Agricultural Research Service, 3501 New York Avenue NE, Washington, DC 20002.
- *Hand Delivery/Courier:* Director, U.S. National Arboretum, Northeast Area, Agricultural Research Service, 3501 New York Avenue NE, Washington, DC 20002.

SUPPLEMENTARY INFORMATION:

Title: Use of the Grounds and Facilities as well as Commercial Photography and Cinematography.

OMB Number: 0518–0032.

Expiration Date: 3 years from date of approval.

Type of Request: Renewal of approved information collection.

Abstract: The mission of the U.S. National Arboretum (USNA) is to serve the public need for scientific research, education, and gardens that conserve and showcase plants to enhance the environment. The USNA is a 446-acre facility, open to the general public for purposes of education and passive recreation. The USNA is a national center for public education that welcomes visitors in a stimulating and aesthetically pleasing environment. The USNA receives approximately 610,000 visitors on the grounds each year. Many garden clubs and societies utilize the USNA grounds to showcase their activities.

Section 890(b) of the Federal Agriculture Improvement and Reform Act of 1996, Public Law 104–127 (1996 Act), expanded the authorities of the Secretary of Agriculture to charge reasonable fees for the use of USNA facilities and grounds. These authorities include the ability to charge fees for temporary use by individuals or groups of USNA facilities and grounds in furtherance of the mission of the USNA. Also, authority was provided to charge fees for tram tours and for the use of the USNA for commercial photography and cinematography. All rules and regulations noted in 7 CFR 500, subpart 2A, conducted on the USNA property will apply to individuals or groups granted approval to use the facilities and grounds. In order to administer the use of the USNA facilities and to determine if the requested use is consistent with the mission of the USNA, it is necessary for the USNA to obtain information from the requestor. Each request will require the completion of an application and submission of an application fee. The application is simple and requires only information readily available to the requestor. The requestor is asked to indicate by whom and for what the purpose the USNA facilities are to be used. Applications are available in hard copy format as well as electronic format (PDF fillable) on the USNA website *www.usna.usda.gov.* Completed permit requests are received in person, by mail, by facsimile or electronically.

Paperwork Reduction Act: In accordance with the Office of Management and Budget (OMB) regulations (5 CFR part 1320) implementing the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the information collection and recordkeeping requirements that will be imposed will be submitted to OMB for approval. These requirements will not become effective prior to OMB approval.

Estimate of Burden: 145 hours.

Estimated Number of Responses: The USNA estimates 250 requests for the use of facilities, 40 for photography and cinematography, and 1,800 educational programs and workshops registrations on an annual basis.

Estimate of Total Annual Burden on Respondents: The total cost for responding is $5,206.95 for 145 hours of time at $35.91 per hour.

Obtaining Permit Requests: In addition to the current process of obtaining the permit requests in person, by mail, by facsimile, and electronically (and receiving them back in a like manner), the application for photography and cinematography is available on the USNA website and can be submitted electronically: *http://www.usna.usda.gov/about/photography/photography-and-cinematography.*

The PDF fillable application for the use of facilities is available on the website and can be submitted electronically to USNA. Completed hard copies of permit requests can be submitted to the Administrative Office, USDA, ARS, U.S. National Arboretum, 3501 New York Avenue NE, Washington, DC 20002.

Comments: Comments are invited on whether the proposed collection is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; 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; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of collection on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technology.

Dated: March 14, 2018.

Chavonda Jacobs-Young,

Administrator, ARS.

[FR Doc. 2018–06616 Filed 3–30–18; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Farm Service Agency

Information Collection Request; Assignment of Payment and Joint Payment Authorization

AGENCY: Commodity Credit Corporation and Farm Service Agency, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Commodity Credit Corporation (CCC) and Farm Service Agency (FSA) are requesting comments from all interested individuals and organizations on an extension with a revision of a currently approved information collection. The information collection is associated with assignment of payment, joint payment authorization, and request for a paper check (new). Certain services for FSA and the National Resources Conservation Service (NRCS) are being merged to consolidate services. The information on the forms is used by FSA and NRCS employees in order to record the payment or contract being assigned, the amount of the assignment, the date of the assignment, and the name and address of the assignee and the assignor. This will enable FSA and NRCS employees to pay the proper party when payment becomes due. A new waiver request form to receive a paper check for program payments in lieu of electronic fund transfer is being added in the information collection request. In general, NRCS programs are exempt from the Paperwork Reduction Act.

DATES: We will consider comments that we receive by June 1, 2018.

ADDRESSES: We invite you to submit comments on this notice. In your comments, include the date, volume, and page number of this issue of the **Federal Register**, the OMB control number and the title of the information collection. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail, hand delivery, or courier:* Yanira Sanabria, Financial Specialist, USDA/FSA/FMD, STOP 0581, Patriot Plaza III, 355 E. Street SW, Washington, DC 20024–0581.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Copies of the information collection may be requested by contacting Yanira Sanabria at the above address.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, Yanira Sanabria, (202) 772–6032. Persons with disabilities who require alternative mean for communication (Braille, large print, audio tape, etc.) should contact the USDA's TARGET Center at (202)720–2600 (Voice).

SUPPLEMENTARY INFORMATION:

Title: Assignment and Joint Payment Elections.

Forms: CCC–36, ''Assignment of Payment;'' CCC–37, ''Joint Payment Authorization;'' CCC–251, ''Notice of Assignment;'' CCC–252, ''Instrument of Assignment;'' and CCC–40, ''Request for FSA and NRCS Payments of Federal Benefits by Check (Request for Waiver).''

OMB Control Number: 0560–0183.

Expiration Date of Approval: July 31, 2018.

Type of Request: Revision and extension of a currently approved information collection request.

Abstract: FSA and CCC are requesting an extension with a revision of the currently approved information collection, which as revised will include forms CCC–36, ''Assignment of Payment;'' CCC–37, ''Joint Payment Authorization;'' CCC–40, ''Request for FSA and NRCS Payments of Federal Benefits by Check (Request for Waiver);'' CCC–251, ''Notice of Assignment;'' and CCC–252, ''Instrument of Assignment.''

Section 8(g) of the Soil Conservation and Domestic Allotment Act (16 U.S.C. 590h(g)) authorizes producers to assign FSA conservation program payments in accordance with regulations issued by the Secretary. The Assignment of Payment regulation in 7 CFR part 1404 requires that any such assignment be signed by both the assignor and the assignee. The Agricultural Act of 1949, as amended, extends that authority to CCC programs, including rice, feed grains, cotton, and wheat. There are no regulations governing joint payments, but this service is offered as a result of public requests for the type of payment option.

The Department of the Treasury (Treasury) amended its regulation to require recipients of Federal nontax payments to receive payment by electronic funds transfer (EFT), effective May 1, 2011. The Treasury regulation allows an automatic waiver for customers who were born before May 1, 1921. The Treasury regulation is focused on requiring payments to be received by EFT, therefore customers who want a payment by paper check need to submit a waiver request, even for the automatic waiver category. The Treasury regulation also provides 2 hardship waiver categories related to a mental impairment or living in a remote geographic location.

For FSA and NRCS payments, USDA collects the customer information and submits it to Treasury, including any account information for those customers requesting payment by paper check instead of EFT. To collect the waiver request information, FSA and NRCS will use the new CCC–40 form. FSA used the Treasury form FS Form 1201W (March 2014) (approved under OMB #1530–0019) as the model for CCC–40. The differences in the forms are that FSA and NRCS use a tax identification number instead of a social security number and the CCC–40 form will be submitted by FSA or NRCS customers to FSA or NRCS, respectively, instead of to Treasury. Once approved by FSA or NRCS, such request will be forwarded by FSA or NRCS to Treasury as part of the payment information.

The overall burden hours increased because FSA added a new form of CCC–40, ''Request for FSA and NRCS Payments of Federal Benefits by Check (Request for Waiver)'' (paper form), and FSA increased the number of respondents who are currently participating in the FSA, CCC, and NRCS programs.

For the following estimated total annual burden on respondents, the formula used to calculate the total burden hours is the estimated average time per response multiplied by the estimated total annual responses.

Estimate of Respondent Burden: Public reporting burden for collecting information under this notice is estimated to average 0.166 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collections of information.

Type of Respondents: Producers participating in FSA, CCC, and NRCS programs.

Estimated Number of Respondents: 126,542.

Estimated Average Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 126,542.

Estimated Average Time per Response: 0.16663.

Estimated Total Annual Burden on Respondents: 21,083 hours.

We are requesting comments on all aspects of this information collection to help FSA.

(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 burden of the collection of information including the validity of the methodology and assumptions used;

(3) Evaluate the quality, ability and clarity of the information technology; and

(4) Minimize the burden of the information collection on those who respond through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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

Steven J. Peterson,

Acting Administrator, Farm Service Agency, and Executive Vice President, Commodity Credit Corporation.

[FR Doc. 2018–06597 Filed 3–30–18; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Emergency Food Assistance Program; Availability of Foods for Fiscal Year 2018

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the surplus and purchased foods that the Department expects to make available for donation to States for use in providing nutrition assistance to the needy under The Emergency Food Assistance Program (TEFAP) in Fiscal Year (FY) 2018. The foods made available under this notice must, at the discretion of the State, be distributed to eligible recipient agencies (ERAs) for use in preparing meals and/or for distribution to households for home consumption.

DATES: Implementation date October 1, 2017.

FOR FURTHER INFORMATION CONTACT: Polly Fairfield, Policy Branch, Food Distribution Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, Virginia 22302–1594 or telephone (703) 305–2662.

SUPPLEMENTARY INFORMATION: In accordance with the provisions set forth in the Emergency Food Assistance Act of 1983 (EFAA), 7 U.S.C. 7501, *et seq.,* and the Food and Nutrition Act of 2008, 7 U.S.C. 2036, the Department makes foods available to States for use in providing nutrition assistance to those in need through TEFAP. In accordance with section 214 of the EFAA, 7 U.S.C. 7515, 60 percent of each State's share of TEFAP foods is based on the number of people with incomes below the poverty level within the State and 40 percent on the number of unemployed persons within the State. State officials are responsible for establishing the network through which the foods will be used by ERAs in providing nutrition assistance to those in need and for allocating foods among those ERAs. States have full discretion in determining the amount of foods that will be made available to ERAs for use in preparing meals and/or for distribution to households for home consumption.

The types of foods the Department expects to make available to States for distribution through TEFAP in FY 2018 are listed in the table below.

Surplus Foods

Surplus foods donated for distribution under TEFAP are Commodity Credit Corporation (CCC) foods purchased under the authority of section 416 of the Agricultural Act of 1949, 7 U.S.C. 1431 (section 416) and foods purchased under the surplus removal authority of section 32 of the Act of August 24, 1935, 7 U.S.C. 612c (section 32). The types of foods typically purchased under section 416 include dairy, grains, oils, and peanut products. The types of foods purchased under section 32 include meat, poultry, fish, vegetables, dry beans, juices, and fruits.

Approximately $184.4 million in surplus foods acquired in FY 2017 are being delivered to States in FY 2018. These foods include Alaska pollock, apples, applesauce, apple slices, beans, blueberries, cranberries, cranberry sauce, eggs, figs, grape juice, peaches, pears, plums, raisins, and turkey. Other surplus foods may be made available to TEFAP throughout the year. The Department would like to point out that food acquisitions are based on changing agricultural market conditions; therefore, the availability of foods is subject to change.

Purchased Foods

In accordance with section 27 of the Food and Nutrition Act of 2008, 7 U.S.C. 2036, the Secretary is directed to purchase an estimated $288.8 million worth of foods in FY 2018 for distribution through TEFAP. These foods are made available to States in addition to those surplus foods which otherwise might be provided to States for distribution under TEFAP.

For FY 2018, the Department anticipates purchasing the foods listed in the following table for distribution through TEFAP. The amounts of each item purchased will depend on the prices the Department must pay, as well as the quantity of each item requested by the States. Changes in agricultural market conditions may result in the availability of additional types of foods or the non-availability of one or more types listed in the table.

FY 2018 USDA Foods Available List for The Emergency Food Assistance Program (TEFAP)

Fruits:
Apples, Braeburn, Fresh
Apples, Empire, Fresh
Apples, Fuji, Fresh
Apples, Gala, Fresh
Apples, Granny Smith, Fresh
Apples, Red Delicious, Fresh
Apples, Fresh
Apple Juice, 100%, Unsweetened
Apple Slices, Unsweetened, Frozen (IQF)
Applesauce, Unsweetened, Canned
Applesauce, Unsweetened, Cups, Shelf-Stable
Apricots, Halves, Extra Light Syrup, Canned
Cherry Apple Juice, 100%, Unsweetened
Cranberry Apple Juice, 100%, Unsweetened
Grape Juice, Concord, 100%, Unsweetened
Grapefruit Juice, 100%, Unsweetened
Fruit and Nut Mix, Dried
Mixed Fruit, Extra Light Syrup, Canned
Orange Juice, 100%, Unsweetened
Peaches, Sliced, Extra Light Syrup, Canned
Pears, Bartlett, Fresh
Pears, Bosc, Fresh
Pears, D'Anjou, Fresh
Pears, Fresh
Pears, Extra Light Syrup, Canned
Plums, Pitted, Dried
Raisins, Unsweetened, Individual Portion
Raisins, Unsweetened
Protein Foods:
Alaska Pollock Fish, Whole Grain, Oven Ready Sticks
Beef, Coarse Ground, Canned/Pouch
Beef, Fine Ground, 85% Lean/15% Fat, Frozen
Beef, Fine Ground, 85% Lean/15% Fat, Frozen
Beef Stew, Canned/Pouch
Catfish, Fillets, Frozen
Chicken, Canned
Chicken, Split Breast, Frozen
Chicken, Whole, Frozen
Eggs, Fresh
Egg Mix, Dried
Peanut Butter, Smooth
Peanut Butter, Smooth (K)
Peanut Butter, Individual Portion
Peanuts, Roasted, Unsalted
Pork, Coarse Ground, Canned/Pouch
Pork, Ham, Frozen
Salmon, Pink, Canned
Salmon, Pink, Canned (K)

FY 2018 USDA FOODS AVAILABLE LIST FOR THE EMERGENCY FOOD ASSISTANCE PROGRAM (TEFAP)—Continued

Tuna, Chunk Light, Canned (K)
Vegetables:
Beans, Green, Low-sodium, Canned
Carrots, Diced, No Salt Added, Frozen
Carrots, Sliced, Low-sodium, Canned
Corn, Whole Kernel, No Salt Added, Canned
Corn, Cream, Low sodium, Canned
Mixed Vegetables, 7-Way Blend, Low-sodium, Canned
Peas, Green, Low-sodium, Canned
Peas, Green, No Salt Added, Frozen
Potatoes, Dehydrated Flakes
Potatoes, Round, Fresh
Potatoes, Russet, Fresh
Potatoes, Sliced, Low-sodium, Canned
Pumpkin, No Salt Added, Canned
Spaghetti Sauce, Low-sodium, Canned
Spinach, Low-sodium, Canned
Sweet Potatoes, Light Syrup, No Salt Added, Canned
Tomato Juice, 100%, Low-sodium
Tomato Sauce, Low-sodium, Canned
Tomato Sauce, Low-sodium, Canned (K) (H)
Tomato Soup, Condensed, Low-sodium, Canned
Tomatoes, Diced, No Salt Added, Canned
Vegetable Soup, Condensed, Low-Sodium, Canned
Legumes:
Beans, Black, Low-sodium, Canned
Beans, Black-eyed Pea, Low-sodium, Canned
Beans, Black-eyed Pea, Dry
Beans, Garbanzo, Dry
Beans, Great Northern, Dry
Beans, Kidney, Light Red, Low-sodium, Canned
Beans, Kidney, Light Red, Dry
Beans, Lima, Baby, Dry
Beans, Pinto, Low-sodium, Canned
Beans, Pinto, Dry
Beans, Refried, Low-sodium, Canned
Beans, Vegetarian, Low-sodium, Canned
Lentils, Dry
Dairy:
Cheese, American, Reduced Fat, Loaves, Refrigerated
Milk, 1%, Shelf-Stable UHT
Milk, 1%, Individual Portion, Shelf-Stable UHT
Oils:
Oil, Vegetable
Other:
Soup, Cream of Chicken, Reduced Sodium
Soup, Cream of Mushroom, Reduced Sodium
Key:
Grains:
Bakery Mix, Lowfat
Cereal, Corn Flakes
Cereal, Corn/Rice Biscuits
Cereal, Corn Squares
Cereal, Oat Circles
Cereal, Rice Crisp
Cereal, Wheat Bran Flakes
Cereal, Wheat Farina
Cereal, Wheat, Shredded
Crackers, Unsalted
Flour, All Purpose, Enriched, Bleached
Flour, White Whole Wheat
Grits, Corn, White
Grits, Corn, Yellow
Oats, Rolled
Pasta, Egg Noodles
Pasta, Macaroni, Enriched
Pasta, Macaroni, Whole Grain
Pasta, Macaroni and Cheese
Pasta, Rotini, Whole Grain
Pasta, Spaghetti, Enriched
Pasta, Spaghetti, Whole Grain
Rice, Brown, Long-Grain, Parboiled
Rice, Brown, Long-Grain, Parboiled
Rice, Medium Grain
Rice, Medium Grain
Rice, Long Grain
Rice, Long Grain
Tortillas, Whole Grain, Frozen

H—Halal Certification Required.
K—Kosher Certification Required.
IQF—Individually Quick Frozen.
UHT—Ultra-High Temperature Pasteurization.

Dated: March 12, 2018.

Brandon Lipps,

Administrator, Food and Nutrition Service.

[FR Doc. 2018–06177 Filed 3–30–18; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–882, C–570–078, C–580–898, C–489–834]

Large Diameter Welded Pipe From India, the People's Republic of China, the Republic of Korea, and the Republic of Turkey: Postponement of Preliminary Determinations in the Countervailing Duty Investigations

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

DATES: Applicable April 2, 2018.

FOR FURTHER INFORMATION CONTACT: Jerry Huang at (202) 482–4047 (the People's Republic of China (China)), Robert Palmer at (202) 482–9068 (India), George Ayache at (202) 482–2623 (the Republic of Korea (Korea)), and Ajay Menon at (202) 482–1993 (the Republic of Turkey (Turkey)), AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On February 9, 2018, the Department of Commerce (Commerce) initiated countervailing duty (CVD) investigations on large diameter welded pipe from China, India, Korea, and Turkey.[1] Currently, the preliminary determinations are due no later than April 16, 2018.

Postponement of Preliminary Determinations

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a CVD investigation within 65 days after the date on which Commerce initiated the investigation. However, if the petitioner makes a timely request for a postponement, section 703(c)(1)(A) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation. Under 19 CFR 351.205(e), a petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reason for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On March 20, 2018, the petitioners[2] submitted timely requests to postpone the preliminary CVD determinations. The petitioners stated that the purpose of their requests was to provide Commerce with additional time to receive questionnaire responses from the respondents and to allow Commerce and interested parties sufficient time to analyze the respondents' questionnaire responses and request clarification and additional information, as necessary.[3] In accordance with 19 CFR 351.205(e), the petitioners stated the reasons for requesting a postponement of the preliminary determinations, and Commerce finds no compelling reason to deny the requests. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determinations to no later than 130 days after the date on which the investigations were initiated. Accordingly, Commerce will issue the preliminary determinations no later than June 19, 2018. In accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determinations of these investigations will continue to be 75 days after the date of the preliminary determinations, unless postponed at a later date.

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

[1] *See Large Diameter Welded Pipe from India, the People's Republic of China, the Republic of Korea, and the Republic of Turkey: Initiation of Countervailing Duty Investigations,* 83 FR 7148 (February 20, 2018) (*Initiation Notice*).

[2] The petitioners are American Cast Iron Pipe Company, Berg Steel Pipe Corp., Berg Spiral Pipe Corp., Dura-Bond Industries, Stupp Corporation, Skyline Steel, Greens Bayou Pipe Mill, LP, JSW Steel (USA) Inc., and Trinity Products LLC.

[3] *See* the petitioners' letters, ''Large Diameter Welded Pipe from India: Petitioners' Request for Postponement of the Preliminary Determination;'' ''Large Diameter Welded Pipe from the People's Republic of China: Petitioners' Request for Postponement of the Preliminary Determination;'' ''Large Diameter Welded Pipe from the Republic of Korea: Petitioners' Request for Postponement of the Preliminary Determination;'' and ''Large Diameter Welded Pipe from the Republic of Turkey: Petitioners' Request for Postponement of the Preliminary Determination,'' all dated March 20, 2018.

Dated: March 27, 2018.

Gary Taverman,

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

[FR Doc. 2018–06596 Filed 3–30–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

President's Advisory Council on Doing Business In Africa (PAC–DBIA)

AGENCY: U.S. Department of Commerce, International Trade Administration

ACTION: Notice of an Open Meeting of the President's Advisory Council on Doing Business in Africa

SUMMARY: The President's Advisory Council on Doing Business in Africa (Council) will meet to deliberate and adopt a report containing recommendations to the President on actions the United States Government could take to mitigate obstacles U.S. companies face in doing business in Kenya, Côte d'Ivoire, Ethiopia, and Ghana, countries the Council has identified as holding particular promise of business opportunities for U.S. companies. The report of recommendations will be a follow-up to the Council's report of analysis adopted on November 29, 2017, which identified the top issues U.S. companies face in approaching African markets for the first time, competing for business opportunities on the continent, and executing business operations. The final agenda for the meeting will be posted at least one week in advance of the meeting on the Council's website at *http://trade.gov/pac-dbia.*

DATES: April 18, 2018, 3:00 p.m. (EDT).

ADDRESSES: The President's Advisory Council on Doing Business in Africa meeting will be broadcast via live webcast on the internet at *http://whitehouse.gov/live.*

FOR FURTHER INFORMATION CONTACT: Giancarlo Cavallo or Ashley Bubna, Designated Federal Officers, President's Advisory Council on Doing Business in Africa, Department of Commerce, 1401 Constitution Ave. NW, Room 22004, Washington, DC, 20230, telephone: 202–482–2091, email: *dbia@trade.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Council was established on November 4, 2014, to advise the President, through the Secretary of Commerce, on strengthening commercial engagement between the United States and Africa. The Council's charter was renewed most recently in September 2017 for a two-year term. The Council was established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App.

Public Submissions: The public is invited to submit written statements to the Council. Statements must be received by 5:00 p.m. EDT April 11, 2018 by either of the following methods:

a. *Electronic Submissions:* Submit statements electronically to Giancarlo Cavallo and Ashley Bubna, Designated Federal Officers, President's Advisory Council on Doing Business in Africa, via email: *dbia@trade.gov.*

b. *Paper Submissions:* Send paper statements to Giancarlo Cavallo and Ashley Bubna, Designated Federal Officers, President's Advisory Council on Doing Business in Africa, Department of Commerce, 1401 Constitution Ave. NW, Room 22004, Washington, DC 20230.

Statements will be provided to the members in advance of the meeting for consideration and also will be posted on the Council website (*http://trade.gov/pac-dbia*). Any business proprietary information should be clearly designated as such. All statements received, including attachments and other supporting materials, are part of the public record and subject to public disclosure.

Meeting minutes: Copies of the Council's meeting minutes will be available within ninety (90) days of the meeting on the Council's website at *http://trade.gov/pac-dbia.*

Dated: March 27, 2018.

Fred Stewart,

Director, Office of Africa.

[FR Doc. 2018–06477 Filed 3–30–18; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–924]

Polyethylene Terephthalate Film, Sheet, and Strip From the People's Republic of China: Rescission of Antidumping Duty Administrative Review; 2016–2017

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

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the antidumping duty (AD) order on polyethylene terephthalate film, sheet, and strip (pet film) from the People's Republic of China (China) for the period of review (POR) November 1, 2016, through October 31, 2017.

DATES: Applicable April 2, 2018.

FOR FURTHER INFORMATION CONTACT: Jonathan Hill, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3518.

SUPPLEMENTARY INFORMATION:

Background

On November 1, 2017, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the AD order on pet film from China for the period November 1, 2016, through October 31, 2017.[1] On November 30, 2017, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b), Mitsubishi Polyester Film, Inc. and SKC, Inc. (collectively, the petitioners), requested a review of the AD order with respect to the following four companies: (1) Fuwei Films (Shandong) Co., Ltd.; (2) Shaoxing Xiangyu Green Packing Co., Ltd.; (3) Sichuan Dongfang Insulating Material Co., Ltd.; and (4) Tianjin Wanhua Co., Ltd.[2] On January 11, 2018, in accordance with section 751(a) of the Act and 19 CFR 351.221(c)(1)(i), Commerce initiated an administrative review of the AD order on pet film from China with respect to these companies.[3]

Commerce exercised its discretion to toll all deadlines affected by the closure of the Federal Government from January 20 through 22, 2018. If the new deadline falls on a non-business day, in accordance with Commerce's practice, the deadline will become the next business day.[4] On February 28, 2018, the petitioners timely withdrew their request for an administrative review of all companies named in the petitioners'

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 82 FR 50620 (November 1, 2017).

[2] *See* the petitioners' request for administrative review, ''*Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China:* Request for Antidumping Duty Administrative Review,'' dated November 30, 2017 (Review Request).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 1329 (January 11, 2018).

[4] *See* Memorandum, ''Deadlines Affected by the Shutdown of the Federal Government,'' (Tolling Memorandum), dated January 23, 2018. All deadlines in this segment of the proceeding have been extended by 3 days.

Review Request.[5] No other party requested a review.

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the publication date of the notice of initiation of the requested review. The petitioners withdrew their request for review within the 90-day deadline. Because Commerce received no other requests for review of the above-referenced companies, and no other requests were made for a review of the AD order on pet film from China with respect to other companies, we are rescinding the administrative review covering the period November 1, 2016, through October 31, 2017, in full, in accordance with 19 CFR 351.213(d)(1).

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of pet film from China during the POR at rates equal to the cash deposit rate for estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as the only reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: March 28, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–06636 Filed 3–30–18; 8:45 am]

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[5] *See* the petitioners' withdrawal of administrative review request, ''*Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China:* Withdrawal of Request for Antidumping Duty Administrative Review,'' dated February 28, 2018.

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 a review 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 May 2018

Pursuant to section 751(c) of the Act, the following Sunset Review is scheduled for initiation in May 2018 and will appear in that month's *Notice of Initiation of Five-Year Sunset Review* (Sunset Review).

	Department contact
Antidumping duty proceedings	
Solid Agricultural Grade Ammonium Nitrate from Ukraine (A–823–810) (3rd Review)	James Terpstra, (202) 482–3965.
Countervailing duty proceedings	
No Sunset Review of countervailing duty orders is scheduled for initiation in May 2018.	
Suspended investigations	
No Sunset Review of suspended investigations is scheduled for initiation in May 2018.	

Commerce's procedures for the conduct of Sunset Reviews are set forth in 19 CFR 351.218. The *Notice of Initiation of Five-Year (Sunset) Review* provides further information regarding what is required of all parties to participate in Sunset Review.

Pursuant to 19 CFR 351.103(c), Commerce will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact Commerce in writing within 10 days of the publication of the Notice of Initiation.

Please note that if Commerce receives a Notice of Intent to Participate from a member of the domestic industry within 15 days of the date of initiation, the review will continue.

Thereafter, any interested party wishing to participate in the Sunset Review must provide substantive comments in response to the notice of initiation no later than 30 days after the date of initiation.

This notice is not required by statute but is published as a service to the international trading community.

Dated: March 12, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–06610 Filed 3–30–18; 8:45 am]

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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.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

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. In order to provide parties additional certainty with respect to when Commerce will exercise its discretion to extend this 90-day deadline, interested parties are advised that, with regard to reviews requested on the basis of anniversary months on or after April 2018, Commerce does not intend to extend the 90-day deadline unless the requestor demonstrates that an extraordinary circumstance prevented it from submitting a timely withdrawal request. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Commerce is providing this notice on its website, as well as in its ''Opportunity to Request Administrative Review'' notices, so that interested parties will be aware of the manner in which Commerce intends to exercise its discretion in the future.

Opportunity To Request a Review: Not later than the last day of April 2018,[1] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in April for the following periods:

	Period of review
Antidumping Duty Proceedings	
Republic of Korea: Phosphor Copper, A–580–885	10/14/16–3/31/18
The People's Republic of China:	
1,1,1,2-Tetrafluoroethane (R–134A), A–570–044	10/7/16–3/31/18

[1] Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when Commerce is closed.

	Period of review
Activated Carbon, A–570–904	4/1/17–3/31/18
Drawn Stainless Steel Sinks, A–570–983	4/1/17–3/31/18
Magnesium Metal, A–570–896	4/1/17–3/31/18
Non-Malleable Cast Iron Pipe Fittings, A–570–875	4/1/17–3/31/18
Stainless Steel Sheet and Strip, A–570–042	9/19/16–3/31/18
Steel Threaded Rod, A–570–932	4/1/17–3/31/18
Countervailing Duty Proceedings	
The People's Republic of China:	
Drawn Stainless Steel Sinks, C–570–984	1/1/17–12/31/17
Stainless Steel Sheet and Strip, C–570–043	7/18/16–12/31/17

Suspension Agreements

None.

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 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 final 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.[2]

Commerce no longer considers the non-market economy (NME) entity as an exporter conditionally subject to an antidumping duty administrative reviews.[3] Accordingly, the NME entity will not be under review unless Commerce specifically receives a request for, or self-initiates, a review of the NME entity.[4] 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 Enforcement and Compliance's ACCESS website at *http://access.trade.gov.*[5] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request.

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 April 2018. If Commerce does not receive, by the last day of April 2018, 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.

[2] *See also* the Enforcement and Compliance website at *http://trade.gov/enforcement/.*

[3] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[4] 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.

[5] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

Dated: March 22, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–06609 Filed 3–30–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Docket No.: 180320298–8298–01]

RIN 0625–XC038

Swiss-U.S. Privacy Shield; Invitation for Applications for Inclusion on the Supplemental List of Arbitrators

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice; Invitation for applications.

SUMMARY: Under the Swiss-U.S. Privacy Shield Framework, the U.S. Department of Commerce (DOC) and the Swiss Administration have committed to implement an arbitration mechanism as set forth in Annex I, to provide Swiss individuals with the ability to invoke binding arbitration to determine, for residual claims, whether an organization has violated its obligations under the Privacy Shield Framework. The DOC and the Swiss Administration will work together to implement the arbitration mechanism, including by jointly developing a list of up to five arbitrators with European or Swiss expertise to supplement the list of arbitrators developed under the EU-U.S. Privacy Shield Framework. Parties to a binding arbitration under this Swiss-U.S. Privacy Shield mechanism may only select arbitrators from the list developed under the EU-U.S. Privacy Shield Framework to be supplemented by this list. This notice announces the opportunity to apply for inclusion on the Swiss-U.S. Privacy Shield Supplemental List of Arbitrators developed by the DOC and the Swiss Administration.

DATES: Applications should be received by Friday April 30th, 2018.

ADDRESSES: Please submit applications to David Ritchie at the U.S. Department of Commerce, either by email at *david.ritchie@trade.gov,* or by fax at: 202–482–5522. More information on the arbitration mechanism may be found at *https://www.trade.gov/td/services/odsi/swiss-us-privacyshield-framework.pdf.*

FOR FURTHER INFORMATION CONTACT: David Ritchie, International Trade Administration, 202–482–4936 or *david.ritchie@trade.gov.*

SUPPLEMENTARY INFORMATION: The Swiss-U.S. Privacy Shield Framework was designed by the U.S. Department of Commerce (DOC) and the Swiss Administration (Swiss) to provide companies in both Switzerland and the United States with a mechanism to comply with data protection requirements when transferring personal data from Switzerland to the United States in support of transatlantic commerce. On January 12, 2017, the Swiss deemed the Swiss-U.S. Privacy Shield Framework (Swiss Privacy Shield) adequate to enable data transfers under Swiss law, and on April 12, 2017, the DOC began accepting self-certifications from U.S. companies to join the program (82 FR 16375; April 12, 2017). For more information on the Privacy Shield, visit *www.privacyshield.gov.*

As described in Annex I of the Swiss Privacy Shield, the DOC and the Swiss have committed to implement an arbitration mechanism to provide Swiss individuals with the ability to invoke binding arbitration to determine, for residual claims, whether an organization has violated its obligations under the Privacy Shield. Organizations voluntarily self-certify to the Swiss Privacy Shield and, upon certification, the commitments the organization has made to comply with the Swiss Privacy Shield become legally enforceable under U.S. law. Organizations that self-certify to the Swiss Privacy Shield commit to binding arbitration of residual claims if the individual chooses to exercise that option. Under the arbitration option, a Privacy Shield Panel [1] (consisting of one or three arbitrators, as agreed by the parties) has the authority to impose individual-specific, non-monetary equitable relief (such as access, correction, deletion, or return of the individual's data in question) necessary to remedy the violation of the Swiss Privacy Shield only with respect to the individual. The parties will select the arbitrators from the list of arbitrators described below.

The DOC and the Swiss Administration seek to develop a list of up to five arbitrators to supplement the list of arbitrators developed under the EU-U.S. Privacy Shield Framework. To be eligible for inclusion on the supplemental list, applicants must be admitted to practice law in the United States and have expertise in both U.S. privacy law and European or Swiss data protection law. Applicants shall not be subject to any instructions from, or be affiliated with, any Privacy Shield organization, or the U.S., Switzerland, EU, or any EU Member State or any other governmental authority, public authority or enforcement authority.

Eligible individuals will be evaluated on the basis of independence, integrity, and expertise:

Independence:

- Freedom from bias and prejudice.

Integrity:

- Held in the highest regard by peers for integrity, fairness and good judgment.
- Demonstrates high ethical standards and commitment necessary to be an arbitrator.

Expertise:

Required:

- Admission to practice law in the United States.
- Level of demonstrated expertise in U.S. privacy law and European or Swiss data protection law.

Other expertise that may be considered includes any of the following:

- Relevant educational degrees and professional licenses.
- Relevant professional or academic experience or legal practice.
- Relevant training or experience in arbitration or other forms of dispute resolution.

Evaluation of applications for inclusion on the list of arbitrators will be undertaken by the DOC and the Swiss Administration. Selected applicants will remain on the list for a period of 3 years, absent exceptional circumstances, change in eligibility, or for cause, renewable for one additional period of 3 years.

The DOC selected the International Centre for Dispute Resolution-American Arbitration Association (ICDR–AAA) as administrator for Privacy Shield arbitrations brought under either the Swiss-U.S. or EU-U.S. Privacy Shield Frameworks.[2] Among other things, the ICDR–AAA will facilitate arbitrator fee arrangements, including the collection and timely payment of arbitrator fees and other expenses. Arbitrators are expected to commit their time and effort when included on the supplemental Swiss-U.S. Privacy Shield List of Arbitrators and to take reasonable steps

[1] The Privacy Shield Panel would govern arbitration proceedings brought under either the Swiss-U.S. or EU-U.S. Privacy Shield Frameworks.

[2] For more information about the selection process and the role of the administrator, see *https://www.privacyshield.gov/Arbitration-Fact-Sheet.*

to minimize the costs or fees of the arbitration.

Arbitrators will be subject to a code of conduct consistent with Annex I of the Swiss-U.S. Privacy Shield Framework and generally accepted ethical standards for arbitrators. The DOC and the Swiss Administration agreed to adopt the arbitral procedures adopted under the EU-U.S. Privacy Shield Framework to govern the arbitral proceedings, subject to considerations identified in Annex I of the Swiss-U.S. Privacy Shield Framework, including that materials submitted to arbitrators will be treated confidentially and will only be used in connection with the arbitration. For more information, please visit *https://www.privacyshield.gov/article?id=G-Arbitration-Procedures* where you can find information on the arbitration procedures. *(Please note that the Arbitration procedures apply to both the EU-U.S. Privacy Shield Framework and the Swiss-U.S. Privacy Shield Framework.)*

Applications

Eligible individuals who wish to be considered for inclusion on the Swiss-U.S. Privacy Shield Supplemental List of Arbitrators are invited to submit applications. Applications must be typewritten and should be headed ''Application for Inclusion on the Swiss-U.S. Privacy Shield Supplemental List of Arbitrators.'' Applications should include the following information, and each section of the application should be numbered as indicated:

—Name of applicant.

— Address, telephone number, and email address.

1. Independence

—Description of the applicant's affiliations with any organization that has self-certified under either the Swiss-U.S. or EU–U.S. Privacy Shield Frameworks, or the U.S., Switzerland, any EU Member State or any other governmental authority, public authority, or enforcement authority.

2. Integrity

— On a separate page, the names, addresses, telephone, and fax numbers of three individuals willing to provide information concerning the applicant's qualifications for service, including the applicant's character, reputation, reliability, and judgment.

—Description of the applicant's willingness and ability to make time commitments necessary to be an arbitrator.

3. Expertise

—Demonstration of admittance to practice law in the United States.

—Relevant academic degrees and professional training and licensing.

—Current employment, including title, description of responsibility, name and address of employer, and name and telephone number of supervisor or other reference.

—Employment history, including the dates and addresses of each prior position and a summary of responsibilities.

—Description of expertise in U.S. privacy law and European or Swiss data protection law.

—Description of training or experience in arbitration or other forms of dispute resolution, if applicable.

—A list of publications, testimony, and speeches, if any, concerning U.S. privacy law and European or Swiss data protection law, with copies appended.

Paperwork Reduction Act

OMB has reviewed and approved this information collection on an emergency basis as of March 26, 2018 under Control Number 0625–0278. The emergency approval is only valid for 180 days. ITA will submit a request for a 3-year approval through OMB's general PRA clearance process. Notwithstanding any other provision of 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, unless that collection of information displays a currently valid OMB control number.

Written comments regarding the burden estimate for this data collection requirement, or any other aspect of this data collection, to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for the International Trade Administration via email at *oira_submission@omb.eop.gov* or via fax at (202) 395–5806 (this is not a toll-free number).

Public Disclosure

Applications will be covered by the Department of Commerce's Privacy Act System of Records Notice 23. Submission of your application will be considered written consent to share your information with the Swiss Administration to enable joint development of the list of arbitrators.

Dated: March 27, 2018.

James M. Sullivan,

Deputy Assistant Secretary for Services, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2018–06737 Filed 3–29–18; 4:15 pm]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–045, C–570–046, A–588–873, A–570–028, A–570–914, C–570–915]

1-Hydroxyethylidene-1, 1-Diphosphonic Acid From the People's Republic of China; Cold-Rolled Steel Flat Products From Japan; Hydrofluorocarbon Blends From the People's Republic of China; Light-Walled Rectangular Pipe and Tube From the People's Republic of China: Opening of Scope Segments and Opportunity To Comment

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

SUMMARY: The Department of Commerce (Commerce) received information from U.S. Customs and Border Protection (CBP) relating to the antidumping duty (AD) and countervailing duty (CVD) orders on 1-Hydroxyethylidene-1, 1-Diphosphonic Acid (HEDP) from the People's Republic of China (China); the AD order on cold-rolled steel from Japan; the AD order on hydrofluorocarbon blends (HFCs) from China; and the AD and CVD orders on light-walled rectangular pipe and tube from China. Commerce is providing notice that it is opening scope segments in each proceeding in order to place this information on the record of the respective cases, and provide an opportunity for interested parties to comment.

DATES: Applicable April 2, 2018.

FOR FURTHER INFORMATION CONTACT: Omar Qureshi at (202) 482–5307 (HEDP), Trisha Tran at (202) 482–4852 (cold-rolled steel), Andrew Medley at (202) 482–4987 (HFCs), or Celeste Chen at (202) 482–0890 (light-walled rectangular pipe and tube), AD/CVD Operations, Enforcement & Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

AD and CVD orders on HEDP from China: Commerce received information from CBP regarding an entry into the

United States of powdered HEDP. Commerce opened a segment entitled ''Powdered HEDP,'' in order to place this information on the record.

AD order on certain cold-rolled steel from Japan: Commerce received information from CBP regarding entries into the United States of certain products that closely resemble merchandise subject to this order that have a manganese content of greater than 2.5 percent. Commerce opened a segment entitled ''Manganese Content,'' in order to place this information on the record.

AD order on HFCs from China: Commerce received information from CBP regarding entries into the United States of certain products that closely resemble merchandise subject this order. Commerce opened a segment entitled ''Certain R–32/R–125 Blends,'' in order to place this information on the record.

AD and CVD orders on light-walled rectangular pipe and tube from China: Commerce received information from CBP regarding entries into the United States of certain products that closely resemble merchandise subject to these orders that have a vanadium content greater than 0.15 percent. Commerce opened a segment entitled ''Vanadium Content'' in order to place this information on the record.

Notification to Interested Parties

Commerce is hereby notifying interested parties that it has received the information discussed above and intends to provide interested parties with the opportunity to submit comments, and, if appropriate, new factual information. Parties are invited to submit factual information and/or comment on these materials no later than April 20, 2018.

Parties are also hereby notified that this is the only notice that Commerce intends to publish in the **Federal Register** concerning this request for comments. Therefore, interested parties that wish to submit factual information and/or comments must submit their letters of appearance as discussed below. Further, any party desiring access to business proprietary information (BPI) must file an application on the respective proceeding segment for access to BPI under Administrative Protective Order (APO), as discussed below.

Scope of the Orders

The scope of the relevant AD and CVD orders may be found in the Appendices to this document as follows:

Appendix I: Scope of the AD and CVD Orders on HEDP from China (A–570–045 and C–570–046)

Appendix II: Scope of the AD Order on Cold-Rolled Steel Flat Products from Japan (A–588–873)

Appendix III: Scope of the AD Order on HFCs from China (A–570–028)

Appendix IV: Scope of the AD and CVD Orders on Light-Walled Rectangular Pipe and Tube from China (A–570–914 and C–570–915).

Filing Requirements

All submissions to Commerce must be filed electronically using Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS).[1] An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, and stamped with the date of receipt by the applicable deadlines.

Letters of Appearance and Administrative Protective Order

Interested parties that wish to participate in the respective segments of the proceedings and be added to the public service list for that segment must file a letter of appearance in accordance with 19 CFR 351.103(d)(1) on the record of the appropriate segment.

Commerce placed APOs on the respective records as follows: On January 10, 2018, for the segments involving light-walled rectangular pipe and tube from China[2] and cold-rolled steel flat products from Japan;[3] on January 30, 2018, for the segment involving HFCs from China;[4] and on February 22, 2018, for the segment involving HEDP from China.[5] Commerce intends to place the business proprietary versions of the documents on the record of the appropriate proceeding in ACCESS within five days of publication of this notice.

Interested parties must submit applications for disclosure under the APO in accordance with the procedures outlined in Commerce's regulations at 19 CFR 351.305. Those procedures apply to the respective segments of each proceeding addressed in this notice.

Dated: March 23, 2018.

Gary Taverman,

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

Appendix I—Scope of the AD and CVD Orders on 1-Hydroxyethylidene-1, 1-Diphosphonic Acid From China (A–570–045 and C–570–046)

The merchandise covered by these orders includes all grades of aqueous acidic (non-neutralized) concentrations of HEDP, also referred to as hydroxyethylidenendiphosphonic acid, hydroxyethanediphosphonic acid, acetodiphosphonic acid, and etidronic acid. The Chemical Abstract Service (CAS) registry number for HEDP is 2809–21–4.

The merchandise subject to these orders is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheading 2931.90.9043. It may also enter under HTSUS subheadings 281.19.6090 and 2931.90.9041. While HTSUS subheadings and the CAS registry number are provided for convenience and customs purposes only, the written description of the scopes of these orders is dispositive.

Appendix II—Scope of the AD Order on Cold-Rolled Steel Flat Products From Japan (A–588–873)

The products covered by this order are certain cold-rolled (cold-reduced), flat-rolled steel products, whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement (width) of 12.7 mm or greater, regardless of form of coil (*e.g.,* in successively superimposed layers, spirally oscillating, *etc.*). The products covered also

[1] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011), as amended in *Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filing%20Procedures.pdf.*

[2] *See* the Administrative Protective Order ''In the Matter of the Antidumping Duty Order on Cold-Rolled Steel Flat Products from Japan (A–588–873)'' (Manganese Content), dated January 10, 2018.

[3] *See* the Administrative Protective Order ''In the Matter of the Antidumping Duty Order on Light-Walled Rectangular Pipe and Tube from the People's Republic of China (A–570–914 and C–570–915)'' (Vanadium Content), dated January 10, 2018.

[4] *See* the Administrative Protective Order ''In the Matter of the Antidumping Duty Order on Hydrofluorocarbon Blends from the People's Republic of China (A–570–028)'' (Certain R–32 R–125 Blends), dated January 30, 2018.

[5] *See* the Administrative Protective Order ''In the Matter of the Antidumping Duty Order on HEDP from the People's Republic of China (A–570–045/C–570–046)'' (Powdered HEDP), dated February 22, 2018.

include products not in coils (*e.g.,* in straight lengths) of a thickness less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of 4.75 mm or more and a width exceeding 150 mm and measuring at least twice the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process, *i.e.,* products which have been ''worked after rolling'' (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above, and

(2) where the width and thickness vary for a specific product (*e.g.,* the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, *etc.*), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this order are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten (also called wolfram), or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium (also called columbium), or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. Motor lamination steels contain micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Subject merchandise includes cold-rolled steel that has been further processed in a third country, including but not limited to annealing, tempering, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the order if performed in the country of manufacture of the cold-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this order unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of this order:

- Ball bearing steels; [6]
- Tool steels; [7]
- Silico-manganese steel; [8]
- Grain-oriented electrical steel (GOES) as defined in the final determination of the U.S. Department of Commerce in Grain-Oriented Electrical Steel from Germany, Japan, and Poland.[9]
- Non-Oriented Electrical Steels (NOES), as defined in the antidumping orders issued by the U.S. Department of Commerce in Non-Oriented Electrical Steel from the People's Republic of China, Germany, Japan, the Republic of Korea, Sweden, and Taiwan.[10]

Also excluded from the scope of this order is ultra-tempered automotive steel, which is hardened, tempered, surface polished, and meets the following specifications:

- Thickness: less than or equal to 1.0 mm;
- Width: less than or equal to 330 mm;
- Chemical composition:

Element	C	Si	Mn	P	S
Weight %	0.90–1.05	0.15–0.35	0.30–0.50	Less than or equal to 0.03	Less than or equal to 0.006.

- Physical properties:

Width less than or equal to 150 mm.	Flatness of less than 0.2% of nominal strip width.
Width of 150 to 330 mm.	Flatness of less than 5 mm of nominal strip width.

- Microstructure: Completely free from decarburization. Carbides are spheroidal and fine within 1% to 4% (area percentage) and are undissolved in the uniform tempered martensite;
- Surface roughness: less than or equal to 0.80 to µm Rz;
- Non-metallic inclusion:

[6] Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.37 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

[7] Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and not less than 5.5 percent tungsten.

[8] Silico-manganese steel is defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

[9] *See Grain-Oriented Electrical Steel from Germany, Japan, and Poland: Final Determinations of Sales at Less Than Fair Value and Certain Final Affirmative Determination of Critical Circumstances,* 79 FR 42501, 42503 (July 22, 2014) (*Grain-Oriented Electrical Steel from Germany, Japan, and Poland*). This determination defines grain-oriented electrical steel as ''a flat-rolled alloy steel product containing by weight at least 0.6 percent but not more than 6 percent of silicon, not more than 0.08 percent of carbon, not more than 1.0 percent of aluminum, and no other element in an amount that would give the steel the characteristics of another alloy steel, in coils or in straight lengths.''

[10] *See Non-Oriented Electrical Steel from the People's Republic of China, Germany, Japan, the Republic of Korea, Sweden, and Taiwan: Antidumping Duty Orders,* 79 FR 71741, 71741–71742 (December 3, 2014) (*Non-Oriented Electrical Steel from the People's Republic of China, Germany, Japan, the Republic of Korea, Sweden, and Taiwan*). The orders define NOES as ''cold-rolled, flat-rolled, alloy steel products, whether or not in coils, regardless of width, having an actual thickness of 0.20 mm or more, in which the core loss is substantially equal in any direction of magnetization in the plane of the material. The term 'substantially equal' means that the cross grain direction of core loss is no more than 1.5 times the straight grain direction (*i.e.,* the rolling direction) of core loss. NOES has a magnetic permeability that does not exceed 1.65 Tesla when tested at a field of 800 A/m (equivalent to 10 Oersteds) along (*i.e.,* parallel to) the rolling direction of the sheet (*i.e.,* B800 value). NOES contains by weight more than 1.00 percent of silicon but less than 3.5 percent of silicon, not more than 0.08 percent of carbon, and not more than 1.5 percent of aluminum. NOES has a surface oxide coating, to which an insulation coating may be applied.''

○ Sulfide inclusion less than or equal to 0.04% (area percentage);

○ Oxide inclusion less than or equal to 0.05% (area percentage); and

• The mill test certificate must demonstrate that the steel is proprietary grade ''PK'' and specify the following:

○ The exact tensile strength, which must be greater than or equal to 1600 N/mm2;

• The exact hardness, which must be greater than or equal to 465 Vickers hardness number;

• The exact elongation, which must be between 2.5% and 9.5%; and

• Certified as having residual compressive stress within a range of 100 to 400 N/mm2.

Also excluded from the scope of this order is certain cold-rolled flat-rolled steel meeting the requirements of ASTM A424 Type 1 and having each of the following characteristics:

• Continuous annealed cold-reduced steel in coils with a thickness of between 0.30 mm and 0.36 mm that is in widths either from 875 mm to 940 mm or from 1,168 to 1,232 mm;

• a chemical composition, by weight, of:

○ Not more than 0.004% carbon;

○ not more than 0.010% aluminum;

○ 0.006%–0.010% nitrogen;

○ 0.012%–0.030% boron;

○ 0.010%–0.025% oxygen;

○ less than 0.002% of titanium;

○ less than 0.002% by weight of vanadium;

○ less than 0.002% by weight of niobium;

○ less than 0.002% by weight of antimony;

• a yield strength of from 179.3 MPa to 344.7 MPa;

• a tensile strength of from 303.7 MPa to 413.7 MPa;

• a percent of elongation of from 28% to 46% on a standard ASTM sample with a 5.08 mm gauge length;

• a product shape of flat after annealing, with flat defined as less than or equal to 1 I unit with no coil set as set forth in ASTM A568, Appendix X5 (alternate methods for expressing flatness).

The products subject to this order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7209.15.0000, 7209.16.0030, 7209.16.0060, 7209.16.0070, 7209.16.0091, 7209.17.0030, 7209.17.0060, 7209.17.0070, 7209.17.0091, 7209.18.1530, 7209.18.1560, 7209.18.2510, 7209.18.2520, 7209.18.2580, 7209.18.6020, 7209.18.6090, 7209.25.0000, 7209.26.0000, 7209.27.0000, 7209.28.0000, 7209.90.0000, 7210.70.3000, 7211.23.1500, 7211.23.2000, 7211.23.3000, 7211.23.4500, 7211.23.6030, 7211.23.6060, 7211.23.6090, 7211.29.2030, 7211.29.2090, 7211.29.4500, 7211.29.6030, 7211.29.6080, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7225.50.6000, 7225.50.8080, 7225.99.0090, 7226.92.5000, 7226.92.7050, and 7226.92.8050. The products subject to the order may also enter under the following HTSUS numbers: 7210.90.9000, 7212.50.0000, 7215.10.0010, 7215.10.0080, 7215.50.0016, 7215.50.0018, 7215.50.0020, 7215.50.0061, 7215.50.0063, 7215.50.0065, 7215.50.0090, 7215.90.5000, 7217.10.1000, 7217.10.2000, 7217.10.3000, 7217.10.7000, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.19.0000, 7226.19.1000, 7226.19.9000, 7226.99.0180, 7228.50.5015, 7228.50.5040, 7228.50.5070, 7228.60.8000, and 7229.90.1000. The HTSUS subheadings above are provided for convenience and U.S. Customs and Border Protection purposes only. The written description of the scope of the order is dispositive.

Appendix III—Scope of the AD Order on HFCs From China (A–570–028)

The products subject to this order are HFC blends. HFC blends covered by the scope are R–404A, a zeotropic mixture consisting of 52 percent 1,1,1 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-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.[11]

Any blend that includes an HFC component other than R–32, R–125, R–143a, or R–134a is excluded from the scope of this order.

Excluded from this order are blends of refrigerant chemicals that include products other than HFCs, such as blends including chlorofluorocarbons (CFCs), hydrochlorofluorocarbons (HCFCs), hydrocarbons (HCs), or hydrofluoroolefins (HFOs).

Also excluded from this order are patented HFC blends, including, but not limited to, ISCEON® blends, including MO99TM (R–438A), MO79 (R–422A), MO59 (R–417A), MO49PlusTM (R–437A) and MO29TM (R–4 22D), Genetron® PerformaxTM LT (R–407F), Choice® R– 421A, and Choice® R–421B.

HFC blends covered by the scope of this 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 convenience and customs purposes, the written description of the scope is dispositive.

[11] R–404A is sold under various trade names, including Forane® 404A, Genetron® 404A, Solkane® 404A, Klea® 404A, and Suva®404A. R–407A is sold under various trade names, including Forane® 407A, Solkane® 407A, Klea®407A, and Suva®407A. R–407C is sold under various trade names, including Forane® 407C, Genetron® 407C, Solkane® 407C, Klea® 407C and Suva® 407C. R–410A is sold under various trade names, including EcoFluor R410, Forane® 410A, Genetron® R410A and AZ–20, Solkane® 410A, Klea® 410A, Suva® 410A, and Puron®. R–507A is sold under various trade names, including Forane® 507, Solkane® 507, Klea®507, Genetron®AZ–50, and Suva®507. R–32 is sold under various trade names, including Solkane®32, Forane®32, and Klea®32. R–125 is sold under various trade names, including Solkane®125, Klea®125, Genetron®125, and Forane®125. R–143a is sold under various trade names, including Solkane®143a, Genetron®143a, and Forane®125.

Appendix IV—Scope of the AD and CVD Orders on Light-Walled Rectangular Pipe and Tube From China (A–570–914 and C–570–915)

The merchandise subject to these orders is certain welded carbon quality light-walled steel pipe and tube, of rectangular (including square) cross section, having a wall thickness of less than 4 mm. The term carbon-quality steel includes both carbon steel and alloy steel which contains only small amounts of alloying elements. Specifically, the term carbon-quality includes products in which none of the elements listed below exceeds the quantity by weight respectively indicated: 1.80 percent of manganese, or 2.25 percent of silicon, or 1.00 percent of copper, or 0.50 percent of aluminum, or 1.25 percent of chromium, or 0.30 percent of cobalt, or 0.40 percent of lead, or 1.25 percent of nickel, or 0.30 percent of tungsten, or 0.10 percent of molybdenum, or 0.10 percent of niobium, or 0.15 percent vanadium, or 0.15 percent of zirconium. The description of carbon-quality is intended to identify carbon-quality products within the scope. The welded carbon-quality rectangular pipe and tube subject to these orders is currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7306.61.50.00 and 7306.61.70.60. While HTSUS subheadings are provided for convenience and Customs purposes, our written description of the scope of these orders is dispositive.

[FR Doc. 2018–06607 Filed 3–30–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG041

Programmatic Environmental Impact Statement (PEIS) for the Marine Mammal Health and Stranding Response Program

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

ACTION: Notice of intent to prepare a PEIS; request for comments.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA) and the Council on Environmental Quality Regulations (CEQ), the National Marine Fisheries Service (NMFS) announces its intention to prepare a Programmatic Environmental Impact Statement (PEIS) to evaluate potential environmental effects associated with continued implementation of the Marine Mammal Health and Stranding Response Program

(MMHSRP). In addition, this PEIS will address changes to increase efficiencies made in the program since the initial MMHSRP PEIS was published in 2009. These updates include changes to the Best Practices for Marine Mammal Stranding Response, Rehabilitation and Release (Policies and Practices), as well as other aspects of the program including large whale entanglement response, health surveillance, research, morbidity and mortality investigations, and assessments.

DATES: Comments must be received by June 1, 2018. Scoping meetings are scheduled as follows:

1. May 1, 2018, 3 p.m. EDT—Webinar (Registration Required)
2. May 15, 2018, 3:30 p.m. EDT—Webinar (Registration Required)
3. May 18, 2018, 3 p.m. EDT—(valid ID compliant with the REAL ID Act required)—NOAA Science Center, 1301 East-West Highway, Silver Spring, MD
4. May 21, 2018, 10:30 a.m. EDT—Webinar (Registration Required)

ADDRESSES: Those wishing to attend either the webinars or in-person meeting must register at *https://mmhsrp-peis.eventbrite.com.* Valid ID that is compliant with the REAL ID Act is required to attend the in-person scoping meeting on May 18, 2018. Further information on types of ID that comply with this Act can be found at *https://www.dhs.gov/real-id-public-faqs.* Foreign nationals wishing to attend the in-person meeting must contact Stephen Manley 30 days in advance.

NMFS invites comments from all interested parties regarding the scope and content of a PEIS for changes and updates to the MMHSRP. For additional background and reference, the previous MMHSRP PEIS published in 2009 is available in electronic form via the internet at *https://repository.library.noaa.gov/view/noaa/4939.* Comments may be submitted using either of the following methods:

Federal e-Rulemaking Portal: Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0036,* click the ''Comment Now!'' icon, complete the required fields and enter or attach your comments.

Mail: Send comments to: Chief, Marine Mammal and Sea Turtle Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3226, Attn: MMHSRP PEIS.

Instructions: NMFS may not consider comments if they are sent by any other method, to any other address or individual, or received after the comment period ends. All comments received are a part of the public record and will generally be posted to *http://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 is publicly accessible. NMFS will also accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Stephen Manley, NMFS, Office of Protected Resources, 301–427–8402, *Stephen.Manley@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Title IV of the Marine Mammal Protection Act (MMPA; 16 U.S.C. 1421), NMFS implements the MMHSRP. The mandated goals and purposes of the MMHSRP are to: (1) Facilitate the collection and dissemination of reference data on the health of marine mammals and health trends of marine mammal populations in the wild; (2) correlate the health of marine mammals and marine mammal populations in the wild, with available data on physical, chemical, and biological environmental parameters; and (3) coordinate effective responses to unusual mortality events in accordance with section 404 of the MMPA.

To meet the goals of the MMPA, the MMHSRP carries out several important activities, including: Coordinating the National Marine Mammal Stranding Network, the John H. Prescott Marine Mammal Rescue Assistance Grant Program, the National Marine Mammal Entanglement Response Program, the Marine Mammal Unusual Mortality Event and Emergency Response Programs, the Marine Mammal Biomonitoring Program, the Marine Mammal Tissue Bank, the Marine Mammal Analytical Quality Assurance Program, the MMHSRP Information Management Program, and the facilitation of several regional health assessment programs on wild marine mammals.

Individuals, groups and organizations throughout the country have been responding to stranded marine mammals for decades. After the passage of Title IV of the MMPA in 1992, NMFS began the process of codifying the roles, responsibilities, and activities of participant organizations in the National Marine Mammal Stranding Network through a Stranding Agreement (SA), issued under MMPA section 112(c) (16 U.S.C. 1382) and through the 109(h) authority for Federal, state, and local government employees (16 U.S.C. 1379). By issuing SAs under section 112(c), NMFS allows stranding network response organizations, acting as agents of the government, an exemption to the prohibition on takes of marine mammals established under the MMPA. A standardized national template for SAs was developed, including sections that may be customized by each region in order to maintain flexibility. NMFS also developed a list of minimum criteria for organizations wishing to obtain a SA and participate in the stranding network. NMFS proposes to modify both the template and the list of minimum criteria to become a member of the stranding network. Additionally, NMFS has national protocols to help standardize the stranding network across the country while maintaining regional flexibility where appropriate. These protocols, as well as the SAs and minimum criteria, were analyzed in the initial PEIS and were issued in 2009 as one consolidated manual, titled ''*Policies and Best Practices for Marine Mammal Stranding Response, Rehabilitation and Release*'' (Policies and Practices). The MMHSRP will update these documents to reflect the information gained from and the developments in marine mammal emergency response that have occurred over the past decade, and would like to identify the scope of issues that should be addressed.

Stranded marine mammals undergoing rehabilitation and the facilities conducting rehabilitation activities are not subject to inspection or review by the Animal and Plant Health Inspection Service (APHIS) under the United States Department of Agriculture, if they are not also a public display facility (separate from their rehabilitation activities) or a research facility. These facilities are therefore not subject to APHIS minimum requirements for facilities, husbandry, or veterinary standards. Previously, NMFS developed minimum standards for marine mammal rehabilitation facilities that are required of all facilities operating under a SA with NMFS. Additionally, section 402(a) (16 U.S.C. 1421a) of the MMPA charges NMFS with providing guidance for determining at what point a rehabilitated marine mammal is releasable to the wild. Standards for release of rehabilitated marine mammals were developed by NMFS and are part of the Policies and Practices document. NMFS proposes to review the rehabilitation guidelines, as well as the criteria for release of rehabilitated

marine mammals into the wild and update these documents, as necessary.

In addition, the MMHSRP maintains a permit from the NMFS Office of Protected Resources Permits and Conservation, issued under the MMPA (16 U.S.C. 1361 *et seq.*) and the ESA (16 U.S.C. 1531 *et seq.*). The permit authorizes the MMHSRP to carry out stranding and entanglement response, rescue, rehabilitation, and release of threatened and endangered marine mammals and conduct health-related scientific research studies on marine mammals and marine mammal parts. The current permit issued to the MMHSRP will expire on June 30, 2020. For additional information about the MMHSRP, the national stranding network, and other related information, please visit our website at *https://www.fisheries.noaa.gov/national/marine-life-in-distress/marine-mammal-health-and-stranding-response-program*.

NEPA, CEQ Regulations (40 CFR 1500.4(i), 1502.4 and 1502.20) and NOAA Administrative Order (NAO) 216–6A require all proposals for major actions to be reviewed with respect to environmental consequences on the human environment and encourage the use of programmatic NEPA documents and tiering to streamline decision making in a process that progresses from programmatic analyses to site-specific reviews. NMFS determined a programmatic approach is appropriate because multiple activities are conducted in support of the MMHSRP and activities occur nationally, over large geographical areas. Therefore, the analysis in the PEIS will support NMFS planning-level decisions associated with oversight and implementation of the MMHRSP and establish the framework and parameters for subsequent analyses based on the programmatic review. In addition, NMFS will rely on this PEIS for permitted activities as well as the basis for tiering in site-specific NEPA review.

Purpose and Scope of the Action

NMFS is proposing to continue coordinating and implementing the MMHSRP. Using a programmatic approach, NMFS will identify and prepare a qualitative analysis of environmental impacts covering a range of activities conducted in support of the MMHSRP program, including the issuance of revised Policies and Best Practices, revised protocols and procedures, and a new MMPA/ESA permit for this program. Resource areas to be addressed in this analysis include, but are not limited to, biological resources (notably marine mammals, threatened and endangered species, fish and other wildlife species and their habitat), sediments and water quality, historic and cultural resources, socioeconomics and tourism, and public health and safety. This PEIS will supersede the initial PEIS published in 2009 and will assess the potential environmental effects of marine mammal health and stranding response under a range of alternatives characterized by different methods, mitigation measures, and level of response. For all potentially significant impacts, the proposed PEIS will identify avoidance, minimization and mitigation measures to reduce these impacts, where feasible, to a level below significance.

The scoping process will be used to identify public concerns along with national and local issues to be addressed in the PEIS. Federal agencies, state agencies, local agencies, Native American Indian Tribes and Nations, the public, and interested persons are encouraged to identify specific issues or topics of environmental concern that NMFS should consider. Public participation is invited by providing written comments to NMFS and/or attending the scoping meetings and webinars.

Special Accommodations

The in-person meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Stephen Manley (see **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: March 28, 2018.

Elaine T. Saiz,

Acting Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–06611 Filed 3–30–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Office of National Marine Sanctuaries Visitor Centers Survey

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before June 1, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at *pracomments@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Dr. Danielle Schwarzmann 240–533–0706 or *danielle.schwarzmann@noaa.gov*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for a new collection of information. NOAA's Office of National Marine Sanctuaries (ONMS) is conducting research to measure the public's opinions about sanctuary visitor centers, exhibits, and kiosks. Exhibits and kiosks covered under the survey can be permanent or traveling/temporary. The survey will be administered annually both within an ONMS visitor center as well as at partner venues that host an exhibit or kiosk on a national marine sanctuary or marine national monument. The survey will cover visitor centers, exhibits, and kiosks system-wide across all the national marine sanctuaries and marine national monuments managed or co-managed by NOAA's ONMS.

The visitor survey will be conducted to obtain an objective analysis of visitor experiences within a sanctuary visitor center or at a partner venue that includes an exhibit or kiosk with information on a national marine sanctuary or marine national monument. Information will be obtained on visitor satisfaction with the overall exhibits or kiosks, graphics, multi-media products, interactives, along with the overall feelings about the facilities and services offered at the centers/venues. The survey will acquire data on the effectiveness of sanctuary/monument messaging, awareness about and use of sanctuary/monument resources, as well as additional recreational and/or educational opportunities available to the public. Lastly, the survey will include questions about visitor demographics.

The information will aid NOAA's Office of National Marine Sanctuaries budget allocation and prioritization, strategic planning, and management

review process to better interpret the sanctuary/monument system and engage with constituents and the larger community on resource protection and conservation topics. Survey results will be used by sanctuary/monument site superintendents to improve visitor services where the survey is administered and will also aide sanctuary/monument headquarters communication and education staff to more effectively communicate key messages. In addition, the survey data will contribute to NOAA and DOC performance reports and year end summaries.

II. Method of Collection

The surveys will be conducted in person or through web applications at kiosks.

III. Data

OMB Control Number: 0648–xxxx.

Form Number: None.

Type of Review: Regular submission (new information collection).

Affected Public: Individuals or households.

Estimated Number of Respondents: 2,000.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 166.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: March 28, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–06605 Filed 3–30–18; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Weather Modification Activities Reports.

OMB Control Number: 0648–0025.

Form Number(s): NOAA Forms 17–4 and 17–4a.

Type of Request: Regular (reinstatement, without changes, of a current information collection).

Number of Respondents: 30.

Average Hours per Response: 1 hour per report (2 reports per respondent).

Burden Hours: 60.

Needs and Uses: This request is for reinstatement, without changes, of a current information collection.

Section 6(b) of Public Law 92–205 requires that persons who engage in weather modification activities (*e.g.,* cloud seeding) provide reports prior to and after the activity. They are also required to maintain certain records. The requirements are detailed in 15 CFR part 908. NOAA uses the data for scientific research, historical statistics, international reports and other purposes.

Affected Public: Business or other non-profit organizations; not-for-profit institutions; state, local or tribal government; federal government; individuals or households.

Frequency: Annually and on occasion.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: March 28, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–06603 Filed 3–30–18; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Economic Value of Wildlife Viewing Passengers in Stellwagen Bank National Marine Sanctuary.

OMB Control Number: 0648-xxxx.

Form Number(s): None.

Type of Request: Regular (request for a new information collection).

Number of Respondents: 2,000.

Average Hours per Response: Screening survey, 2 minutes; full survey, 30 minutes.

Burden Hours: 568.

Needs and Uses: Stellwagen Bank National Marine Sanctuary is currently in the process of updating the 2010 Management Plan, and has identified a lack of baseline socioeconomic information on ocean recreation businesses. The information is not available to assess the possible economic benefits of marine wildlife protection to the local economy, or the potential impact on ocean recreation businesses. The type of data targeted for this collection; that is, user demographic profiles, importance/satisfaction of wildlife viewing trips and expenditures of trips that involve wildlife viewing has never been collected in this region. Thus, current information on the importance/satisfaction of marine wildlife viewing and the expenditures generated from these activities is needed. The primary focus for the survey will be to gather data on the non-consumptive, importance/satisfaction and expenditures of marine wildlife viewing passengers. Specifically, researchers will collect data to help determine the contribution of marine wildlife watching passengers to the economy in the Stellwagen Bank region. Expenditures will be used in IMPLAN to estimate the economic contributions of the activity (jobs, income, GDP and value-added).

Affected Public: Individuals or households.

Frequency: Once or twice during a three-year period.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at *reginfo.gov.* Follow

the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: March 28, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–06604 Filed 3–30–18; 8:45 am]

BILLING CODE 3510–NK–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2018–0013]

Request for Information Regarding Bureau Guidance and Implementation Support

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for information.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau) is seeking comments and information from interested parties to assist the Bureau in assessing the overall effectiveness and accessibility of its guidance materials and activities (including implementation support) to members of the general public, including regulated entities. The Bureau is also considering whether it would be appropriate to make changes, consistent with law, to the formats, processes, and delivery methods for providing such guidance.

DATES: Comments must be received by July 2, 2018.

ADDRESSES: You may submit responsive information and other comments, identified by Docket No. CFPB–2018–0013, by any of the following methods:

- *Electronic:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: FederalRegisterComments@cfpb.gov.* Include Docket No. CFPB–2018–0013 in the subject line of the message.
- *Mail:* Comment Intake, Consumer Financial Protection Bureau, 1700 G Street NW, Washington, DC 20552.
- *Hand Delivery/Courier:* Comment Intake, Consumer Financial Protection Bureau, 1700 G Street NW, Washington, DC 20552.

Instructions: The Bureau encourages the early submission of comments. All submissions must include the document title and docket number. Please note the number of the topic on which you are commenting at the top of each response (you do not need to address all topics). Because paper mail in the Washington DC area and at the Bureau is subject to delay, commenters are encouraged to submit comments electronically. In general, all comments received will be posted without change to *http://www.regulations.gov.* In addition, comments will be available for public inspection and copying at 1700 G Street NW, Washington, DC 20552, on official business days between the hours of 10:00 a.m. and 5:00 p.m. eastern time. You can make an appointment to inspect the documents by telephoning 202–435–7275.

All submissions in response to this request for information, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Proprietary information or sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Kristin Switzer, Regulatory Implementation Program Manager; Angela Fox and Eliott C. Ponte, Attorneys (Regulatory Guidance and Implementation); and Brian Shearer, Counsel, at 202–435–7700. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION: The Dodd-Frank Act transferred to the Bureau rulemaking authority that previously had been exercised by seven other Federal agencies. Those agencies used a variety of methods for providing guidance to industry on interpretive questions arising under the statutes and regulations they administered. Such guidance is ''widely understood to be an essential instrument of [F]ederal administration'' [1] and facilitates compliance with Federal law. In particular, it allows agencies to articulate their positions in a ''relatively low cost and flexible'' [2] way and facilitates stakeholders' knowledge of agency positions and intentions ahead of enforcement or similar actions.[3]

For example, the Board of Governors of the Federal Reserve System (''Board'') primarily relied upon what it denominated as ''Official Staff Interpretations,'' which were published in the Code of Federal Regulations (CFR) as an appendix to the Board's rules, typically following a notice-and-comment process.[4] Board staff also provided informal guidance orally in response to individual inquiries. Other agencies, such as the Department of Housing and Urban Development and the Federal Trade Commission, used various other forms of written guidance (such as standalone interpretive rules, letters or advisory opinions, and frequently asked questions), while also providing some informal oral guidance in response to individual inquiries.

As described further below, the Bureau, since its inception, has provided guidance through a variety of means, and its guidance and implementation support functions are continuing to evolve in response to feedback from industry and other stakeholders. This Request for Information (RFI) seeks input on a number of aspects of the Bureau's guidance activities to date and suggestions for future improvements.

Legal Background

Unless specified otherwise by statute, agency rulemaking activities and many guidance activities are governed by the Administrative Procedure Act (APA). 5 U.S.C. 551 *et seq.* The APA distinguishes among several types of agency issuances, including rules.[5] The

[1] Nicholas R. Parrillo, ''Federal Agency Guidance: An Institutional Perspective,'' at 28 (Oct. 12, 2017) (Yale L. Sch.), *available at https://www.acus.gov/report/agency-guidance-final-report* (report on guidance submitted to the Admin. Conf. of the U.S.) [hereinafter ACUS Guidance Report].

[2] John F. Manning, ''Nonlegislative Rules,'' 72 Geo. Wash. L. Rev. 893, at 914–15 (2004).

[3] *See, e.g., Hoctor* v. *USDA,* 82 F.3d 165, 167 (7th Cir. 1996) (''It would be no favor to the public to discourage the announcement of agencies' interpretations by burdening the interpretive process with cumbersome formalities.''); C*mty. Nutrition Inst.* v. *Young,* 818 F.2d 943, 949 (D.C. Cir. 1987) (''We recognize that such guidelines have the not inconsiderable benefits of apprising the regulated community of the agency's intentions as well as informing the exercise of discretion by agents and officers in the field.'').

[4] The Board's practice has evolved over time. For example, before the Truth in Lending Simplification and Reform Act of 1980, the Board generally issued three different kinds of guidance under the Truth in Lending Act and its implementing rules, known as Regulation Z: Official Board Interpretations; Official Staff Interpretations; and Public Information Letters. Official Board Interpretations had the most weight of these guidance documents; Official Staff Interpretations had less weight but did provide a safe harbor from private liability under Regulation Z; and Public Information Letters were unofficial staff interpretations and therefore did not provide a safe harbor from private liability. In doing so, the Board noted that the volume of the varying interpretations and letters published by the Board (over 1,500, of which only 60 were Official Board Interpretations) complicated rather than facilitated compliance. See Truth in Lending; Proposed Official Staff Commentary, 46 FR 28560 (May 27, 1981).

[5] 5 U.S.C. 551(4) (defining ''rule'' in relevant part as ''the whole or part of an agency statement of

Continued

most authoritative type of rulemaking that the Bureau and most other agencies engage in creates what are known as ''substantive'' or ''legislative'' rules under the APA.[6] When adopted as authorized by law, legislative rules have the ''force and effect of law'' in that, among other things, they can affect individual rights and obligations, such as those of consumers and financial services providers.[7] Legislative rules also bind ''members of the public, the agency, and even the courts, in the sense that courts must affirm a legislative rule as long as it represents a valid exercise of agency authority.'' [8] Such rules are promulgated, amended, and repealed through notice-and-comment procedures, unless an exception applies, and published in the **Federal Register**.[9]

The APA also designates ''interpretive rules,'' which advise the public of an agency's construction of the statutes and rules which it administers, and ''general statements of policy,'' which articulate the agency's prospective plans to exercise discretionary authorities.[10] Interpretive rules can be binding in some respects; for example, agencies may be subject to a duty to provide appropriate notice prior to changing an interpretation in certain circumstances.[11] However, neither an interpretive rule nor a general statement of policy can create new rights and obligations for regulated entities.[12] The level of deference that interpretive rules and general statements of policy receive from the courts is more variable,[13] and interpretive rules and general statements of policy can be issued and changed through less formal procedures than legislative rules.[14] They are to be published in the **Federal Register** but do not need to go through notice-and-comment procedures, although the Bureau and other agencies sometimes seek comment to gather input before issuance or revision to refine their thinking about certain factual and policy issues.[15]

Interpretive rules and general statements of policy are frequently referred to as ''guidance.'' [16] However, the Bureau also uses the term guidance more broadly to refer to compliance guides and other materials and activities that it does not believe are rules within the meaning under the APA (hereinafter ''non-rule guidance''). These non-rule guidance materials and activities generally reiterate requirements, positions, or priorities that previously have been announced in a regulation or elsewhere, and include such documents as rule summaries, compliance guides, checklists, institutional and transactional coverage charts, webinars, and other compliance aids directed to regulated entities, the general public, or agency staff (*e.g.,* staff manuals). Such materials do not go through notice-and-comment procedures, are typically not published in the **Federal Register**, do not have the force and effect of law, and are not binding under the APA.[17]

The type of guidance issued also can have legal and practical significance under certain Federal consumer financial laws that provide industry a safe harbor for good faith reliance on legislative rules and certain interpretations issued by the Bureau or duly authorized staff. *See e.g.,* 15 U.S.C. 1640(f); 12 CFR part 1026, Supp. I, Part 1 (''Good faith compliance with this commentary affords protection from liability under section 130(f) of the Truth in Lending Act.'').

Consistent with the practice of many Federal agencies, including its predecessor agencies, the Bureau has released an array of guidance. These documents and activities have included interpretive rules,[18] general statements of policy or ''policy guidance,'' [19] and non-rule guidance, such as implementation support materials and activities.[20] However, each Bureau

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'').

[6] *See* 5 U.S.C. 552(a)(1)(D) (referring to ''substantive rules of general applicability''); *Perez* v. *Mortgage Bankers Ass'n,* 135 S. Ct. 1199, 1203 (2015) (noting that ''rules issued through the notice-and-comment process are often referred to as 'legislative rules' '').

[7] U.S. Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act, at 30 n.3 (1947) (hereinafter ''Attorney General Manual'') (describing substantive rules as ''rules, other than organizational or procedural, issued by an agency pursuant to statutory authority and which implement the statute'' and noting that ''[s]uch rules have the force and effect of law''); *see Chrysler Corp* v. *Brown,* 441 U.S. 281, 302 (1979) (advising that legislative rules that carry the force of law ''affect individual rights and obligations'') (quoting *Morton* v. *Ruiz,* 415 U.S. 199, 232 (1974)).

[8] Richard J. Pierce, Administrative Law Treatise, at § 6.4 (5th ed. 2017).

[9] *See* 5 U.S.C. 551(5) (defining rulemaking as ''agency process for formulating, amending, or repealing a rule''); 5 U.S.C. 552(a)(1)(D) (requiring legislative rules ''adopted as authorized by law'' to be published in the **Federal Register**); 5 U.S.C. 553(b)(B) (requiring notices of proposed rulemaking to be published in the **Federal Register**).

[10] *See* 5 U.S.C. 553(b)(A) (referring to ''interpretative rules'' and ''general statements of policy''); *see also* Attorney General Manual, *supra* note 7, at 30 n.3.

[11] *See generally FCC* v. *Fox TV Stations, Inc.,* 567 U.S. 239, 253–54 (2012) (*Fox II*) (describing need for ''fair notice'' of change from previous agency interpretation). In contrast, general statements of policy do not bind the public or the agency. *See, e.g., Syncor Int'l* v. *Shalala,* 127 F.3d 90 (D.C. Cir. 1997) (''The agency retains the discretion and the authority to change its position—even abruptly—in any specific case because a change in its policy does not affect the legal norm.'').

[12] *See Perez* v. *Mortgage Bankers Ass'n,* 135 S. Ct. 1199, 1208 (2015) (noting the ''longstanding recognition that interpretive rules do not have the force and effect of law''); *see also Chrysler Corp.* v. *Brown,* 441 U.S. 281, 302 n.31 (1979) (citing Attorney General Manual, at 30 n.3); *Skidmore* v. *Swift & Co.,* 323 U.S. 134, 140 (1944).

[13] *See Metro. Stevedore Co.* v. *Rambo,* 521 U.S. 121, 136 (1997) (stating that reasonable agency interpretations carry ''at least some added persuasive force''); *Reno* v. *Koray,* 515 U.S. 50, 61 (1995) (according ''some deference'' to an interpretive rule that ''do[es] not require notice and comment''); *Martin* v. *Occupational Safety and Health Review Comm'n,* 499 U.S. 144, 157 (1991) (indicating that ''some weight'' is due to informal interpretations though not ''the same deference as norms that derive from the exercise of . . . delegated lawmaking powers''). Courts give ''substantial deference'' to agency interpretations of ambiguous agency regulations, including interpretations issued without notice and comment. *See Halo* v. *Yale Health Plan, Dir. of Benefits & Records Yale U.,* 819 F.3d 42, 53 (2d Cir. 2016) (citing *Auer* v. *Robbins,* 519 U.S. 452 (1997)); *see also Shalala* v. *Guernsey Meml. Hosp.,* 514 U.S. 87, 94–95 (1995) (deferring to ''a reasonable regulatory interpretation'' contained in an interpretive rule).

[14] *See* 5 U.S.C. 553(b), (d) (exempting interpretive rules and general statements of policy from notice-and-comment procedures).

[15] 5 U.S.C. 552(a)(1)(D) (providing that, among other things, ''statements of general policy or interpretations of general applicability'' formulated and adopted by an agency must be published in the **Federal Register**).

[16] *See, e.g.,* ACUS Guidance Report, *supra* note 1, at 4 (defining ''guidance'' as ''general statements of policy'' and ''interpretive rules'').

[17] For example, some courts have held that such documents are not ''general statements of policy'' or ''rules'' under the APA because these documents do not ''implement, interpret, or prescribe law or policy.'' *See Indep. Equip. Dealers Ass'n* v. *EPA,* 372 F.3d 420, 428 (D.C. Cir. 2004) (Roberts, J.) (finding that EPA letter declining to concur in entity-requested interpretation was not a rule, because the letter merely restated EPA longstanding interpretation; because it tread no new ground, it did not ''implement, interpret, or prescribe law or policy''); *see also Golden and Zimmerman, LLC* v. *Domenech,* 599 F.3d 426, 431–32 (4th Cir. 2010) (finding that ATF Reference Guide restating statutes and regulations and providing FAQs reiterating interpretations was not a rule).

[18] *See, e.g.,* Application of Regulation Z's Ability-To-Repay Rule to Certain Situations Involving Successors-in-Interest, 79 FR 41631 (July 17, 2014); Safe Harbors From Liability Under the Fair Debt Collection Practices Act for Certain Actions Taken in Compliance With Mortgage Servicing Rules Under the Real Estate Settlement Procedures Act (Regulation X) and the Truth in Lending Act (Regulation Z), 81 FR 71977 (Oct. 19, 2016).

[19] The Bureau's policy guidance has included forward-looking, first-time announcements of Bureau positions or priorities regarding the Bureau's discretionary supervisory, enforcement, or other powers, as well as statements reminding entities of its legal obligations in these areas, identifying potential risk areas, and providing general compliance management suggestions. *See, e.g.,* Policy Guidance on Supervisory and Enforcement Priorities Regarding Early Compliance With the 2016 Amendments to the 2013 Mortgage Rules Under the Real Estate Settlement Procedures Act (Regulation X) and the Truth in Lending Act (Regulation Z), 82 FR 29713 (June 30, 2017); Compliance Bulletin and Policy Guidance; 2016–02, Service Providers, 81 FR 74410 (Oct. 26, 2016).

[20] This category includes implementation support provided in response to individual inquiries

guidance material and activity has not or may not necessarily fit neatly within a single category, as some may include elements from multiple categories.[21]

Like other agencies, the Bureau faces tradeoffs that it must consider when issuing guidance. Where the Bureau does not use notice-and-comment procedures, it can act more quickly to issue or update guidance materials to address industry interpretive questions and respond to developments in the marketplace. However, the more expedited the process is in developing guidance, the more likely that an agency may find a need over time to revise or adjust its initial guidance statements and address related legal, factual, and policy issues, even though revisiting such materials can impose additional costs on both the agency and regulated entities. Materials issued through less formal processes also may, depending on the circumstances, receive less deference from courts in litigation.[22] Also, diversifying the number of channels through which the Bureau provides guidance can create more flexibility for the Bureau to respond to different circumstances and stakeholder needs, but also can make it more challenging for stakeholders to identify all relevant forms of information. On the other hand, legislative rules and Official Interpretations (otherwise known as commentary and discussed further below) collected in appendices to particular rules in the CFR after notice and comment provide the greatest amount of certainty, reliability, and ease of access, but take a considerable amount of time and agency resources to promulgate.

Overview of This Request for Information

The Bureau is using this request for information (RFI) to seek public input regarding the overall effectiveness and accessibility of the Bureau's guidance as well as changes that it may make, consistent with applicable law, to the formats, processes, and delivery methods for providing such guidance. Additionally, the Bureau is seeking comment on potential new forms of guidance that could support regulatory implementation and compliance, as well as on the disclaimers used for its non-rule guidance.

In this RFI, the Bureau is not seeking comments on the following topics, as these have been addressed or will be addressed in other Bureau RFIs: (1) Educational materials on its regulations developed for consumers or in response to consumer inquiries; (2) the substance of any particular proposed or final rule (for both rules the Bureau adopted and those it inherited), including a proposed or final rule's Official Interpretations that are published with the regulations; or (3) the guidance provided in the Bureau's Supervision and Examination Manuals or Supervisory Highlights.[23]

The Bureau encourages comments from all interested members of the public. The Bureau anticipates that the responding public may include entities subject to Bureau rules, trade associations and professional services organizations that represent these entities, individual consumers, consumer advocates, regulators, and researchers or members of academia.

Suggested Topics for Commenters

To allow the Bureau to evaluate suggestions more effectively, the Bureau requests that, where possible, comments include:

- Specific discussions of the positive and negative aspects of the Bureau's guidance materials and activities (including implementation support).
- Specific suggestions regarding any potential updates or modifications to the Bureau's approach to providing guidance (including implementation support), and including, in as much detail as possible, supporting data or other information on impacts and costs, or information concerning alignment with the processes of other agencies.
- Specific identification of any aspects of the Bureau's approach to guidance (including implementation support) provided by the Bureau that should not be modified, and including, in as much detail as possible, supporting data or other information on impacts and costs, or information concerning alignment with the processes of other agencies.

The following sections list areas of interest on which commenters may want to focus input. This non-exhaustive list is meant to assist in the formulation of comments and is not intended to restrict what may be addressed by the public. Commenters may comment on matters that are related to the Bureau's guidance (including implementation support), but do not appear in the list below. The Bureau requests that, in addressing these questions, commenters identify with specificity the Bureau guidance material or activity, format, process, or delivery platform at issue, providing specific examples where appropriate. In discussing Bureau guidance provided to date, the Bureau also requests that commenters provide examples and supporting information where possible, as well as relevant information about the frequency with which particular types of guidance have been used within an institution, by which parties, and in what ways. Commenters should feel free to comment on some or all of the questions below, but are encouraged to indicate in which area their comments are focused.

From all of the suggestions, the Bureau requests that commenters offer their highest priorities, where possible, along with an explanation of how or why certain suggestions have been prioritized. Commenters are asked to single out their top priority where possible. Suggestions will be most helpful if they focus on revisions that the Bureau could implement without changes in the law, consistent with the Bureau's authorities and in light of tradeoffs under the APA framework described above.

Regulatory Inquiries Function

The Bureau's Regulatory Inquiries Function assists individual inquirers

through the Bureau's Regulatory Inquiries Function. Additional examples include: Bureau of Consumer Fin. Prot., ''Home Mortgage Disclosure (Regulation C) Small Entity Compliance Guide,'' (Oct. 2017), *available at https://www.consumerfinance.gov/documents/5692/cfpb_hmda_small-entity-compliance-guide.pdf;* Bureau of Consumer Fin. Prot., ''Preparing the Short Form Disclosure for Prepaid Accounts,'' (Apr. 20, 2017), *available at https://www.consumerfinance.gov/documents/4528/201704_cfpb_Prepaid_preparingtheshortformdisclosure_v2.pdf.* The Bureau has also issued other types of non-rule guidance relating principally to the Bureau's supervisory processes (rather than support of regulatory implementation), including the Bureau's Supervision and Examination Manuals. Such other non-rule guidance is outside the scope of this RFI.

[21] For example, some contemporaneous guidance documents, such as preambles of rules, may, among other things, contain both interpretive rules and general statements of policy. *See* Admin. Conf. of the U.S., ''Administrative Conference Recommendation 2014–3: Guidance in the Rulemaking Process,'' (June 6, 2014), *available at https://www.acus.gov/recommendation/guidance-rulemaking-process* (describing ''guidance that agencies provide about the meaning and purpose of their rules at the time those rules are issued'').

[22] *See U.S.* v. *Mead Corp.,* 533 U.S. 218, 229–31 (2001) (recognizing ''a very good indicator of delegation meriting [deference] in express congressional authorizations to engage in the process of rulemaking or adjudication that produces regulations or rulings,'' but also noting that ''we have sometimes found reasons for [deference] even when no such administrative formality was required and none was afforded'').

[23] For commenters interested in addressing guidance provided in the Official Interpretations of Bureau-issued rules, see the RFI on that topic, Docket No. CFPB–2018–0011, 83 FR 12286 (Mar. 21, 2018). For commenters interested in addressing guidance provided in the Official Interpretations of rules the Bureau inherited, see the RFI on that topic, Docket No. CFPB–2018–0012, 83 FR 12881 (Mar. 26, 2018). For commenters interested in addressing the Bureau's Supervision and Examination Manual or Supervisory Highlights publications, see the RFI on the Bureau's Supervision Program, Docket No. CFPB–2018–0004, 83 FR 7168 (Feb. 20, 2018).

who have specific questions about the Bureau's statutes and regulations. At times, the Bureau has received several thousand inquiries per year, largely focused on implementation by industry of new or revised regulations. The Regulatory Inquiries Function is an example of an implementation support activity that falls within the category of non-rule guidance. Similar to the regulatory inquiries functions of many of its predecessor agencies, the Bureau's function is designed to provide inquirers with relatively quick, informal assistance concerning the statutes and regulations that the Bureau administers. However, in part because of the APA constraints discussed above, the function is limited in scope. Responses are not intended to be interpretations of the regulations or general statements of policy, as described earlier, but rather to assist in the application and implementation by industry of the Bureau's regulations and Official Interpretations. For example, the Bureau emphasizes on its website that the informal assistance provided through this function does not constitute an official interpretation of the Bureau and is not a substitute for formal legal counsel or other compliance advice. The Bureau also does not moderate disputes between parties, provide guidance on matters that are under examination or investigation by the Bureau or another State or Federal agency, or answer questions about specific business plans.

Although the assistance provided through the Regulatory Inquiries Function is limited and individualized, the Bureau believes that the assistance is valuable to those receiving it. In addition, the inquiries received through this channel provide an important information source, which helps the Bureau prioritize provision of the various other types of guidance described in this RFI by providing a window (supplementing the Bureau's general market monitoring and outreach activities) into the implementation and compliance challenges faced by regulated entities. Thus, when the Bureau receives multiple individual inquiries about the same topic, as described below, the Bureau often prioritizes that topic for webinars and various forms of written guidance, potentially culminating in revisions to the Official Interpretations to the particular rule after a notice-and-comment process.

Generally, individual inquiries are submitted to the Bureau through a phone message or a form accessed on the Bureau's website. However, inquiries related specifically to the Home Mortgage Disclosure Act (HMDA) and its implementing Regulation C are also submitted through a separate channel—the Bureau's HMDA Help function—via phone, email, or a form accessed on a specific Bureau website dedicated to HMDA operational support.

Historically, responses to regulatory inquiries have been provided orally via phone conversations with Bureau staff. However, the Bureau has been providing an increasing number of responses to regulatory inquiries through emails, most extensively with the responses provided through its HMDA Help function.

The Bureau is seeking feedback on all aspects of its Regulatory Inquiries Function, including the following areas of interest:

1. The preferred vehicle(s) for submitting inquiries *(i.e.,* phone message, email, web form, or other specific vehicle).

2. Preferences regarding the responses to regulatory inquiries; the format and delivery method for the responses provided (*i.e.,* oral response, email, or other format or delivery method); and the desired timing of the responses provided.

3. The relative value of responses to regulatory inquiries. In particular, the Bureau is interested in the tradeoffs between providing quick guidance orally to individuals through the Regulatory Inquiries Function and providing written guidance, which is generic and takes more time, but generally is more broadly accessible.

4. Whether the Bureau should, as a matter of practice, publish written responses to regulatory inquiries and, if so, consistent with law, the appropriate vehicle or platform for such publications, the desired frequency for publishing such responses, and the appropriate disclaimers to accompany such publications.

5. Additional ways that the Bureau can improve the Regulatory Inquiries Function, including improvements to the process for submitting inquiries, the process for receiving responses, the substance of responses, or the timing of responses.

Regulatory Implementation and Compliance Aids

The Bureau creates and releases on its website several categories of regulatory implementation and compliance aids, including: (1) Compliance guides; (2) rule summaries and other quick reference materials; and (3) webinars. These regulatory implementation and compliance aids are examples of implementation support materials categorized as non-rule guidance. These materials provide relatively brief, informal summaries of Federal consumer financial laws and regulations, generally focusing on summarizing statutes and interpretations and positions previously announced in Bureau legislative or non-legislative rules using language and formats that may be particularly useful to compliance professionals. As noted above, both the content and format of regulatory implementation and compliance aids are informed by what the Bureau learns as it administers its Regulatory Inquiries Function and general market monitoring and outreach activities.

Compliance guides are plain language summaries of a Bureau rule and, like other examples of non-rule guidance in this section, are not intended to be interpretations of that rule or general statements of policy. Compliance guides include Small Entity Compliance Guides as well as instructional guides for disclosure forms. The Bureau is statutorily required to provide Small Entity Compliance Guides for rules it issues that meet certain criteria, although it also provides them for certain rules for which they are not required.[24]

Quick reference materials are additional plain language summaries of a rule or portions of a rule, but are shorter than compliance guides. These include, but are not limited to, executive summaries, summaries of changes, factsheets, flow charts, decision trees, and summary tables. Executive summaries are posted at the same time that the underlying rule is released, and other quick reference materials are posted as they are completed.[25]

Webinars are recorded presentations in which the Bureau (either

[24] Section 212(a) of the Small Business Administration Regulatory Enforcement Act (SBREFA) requires, among other things, that with respect to certain rules, an agency ''publish[es] 1 or more guides to assist small entities in complying with the rule and shall entitle such publications 'small entity compliance guides.' '' The Bureau's Small Entity Compliance Guides fulfill the Bureau's requirements under Section 212(a), although the Bureau occasionally provides these guides even when not required under the SBREFA statute, as in the case of the Prepaid Rule Small Entity Compliance Guide. The Bureau also understands that these guides are used by all entity types, not just those defined as ''small entities'' under the SBREFA statute. Compliance guides are provided in PDF format on the Bureau's Regulatory Implementation and Guidance web page. *See* Bureau of Consumer Fin. Prot., ''Implementation and Guidance,'' *https://www.consumerfinance.gov/policy-compliance/guidance/implementation-guidance/* (last visited Mar. 16, 2018).

[25] Quick reference materials are also provided in PDF format on the Bureau's Regulatory Implementation and Guidance web page. *Id.*

independently or in collaboration with other Federal agencies or trade associations) provides information to facilitate further understanding of a rule, either in a question-and-answer or topic-based explanation format. The Bureau has created webinars for production on trade association websites, other regulatory agency websites, and most recently its own public YouTube™ channel. Each webinar is accompanied by the presentation slides used for the discussion, and some have hyperlinked video section breaks, either in a separate document or in the video description.

The Bureau is seeking feedback on all aspects of its regulatory implementation and compliance aids, including the following areas of interest: [26]

6. The utility of the Bureau's compliance guides and quick reference materials as well as potential areas for improvement, including:

a. The scope of topics addressed and the format in which they are presented;

b. The ease of navigation to materials on the Bureau's website and to sections within the compliance guides or quick reference materials;

c. The effectiveness of the Bureau's use of the plain language writing style in the Small Entity Compliance Guides and quick reference materials to help make the rules more easily understandable; and

d. The usefulness of the Bureau providing Small Entity Compliance Guides and quick reference materials when not legally required to do so (particularly for entities that do not meet the Small Business Administration's definition of ''small business.'').[27]

7. The utility of the Bureau's webinars as well as potential areas for improvement, including issues related to the website utilized for viewing; the format of the webinar guidance (*i.e.,* question and answer format, explanatory format, or other formats); the supplemental materials (*e.g.,* hyperlinked navigation tools, presentation slides, or other materials); and the ease with which topics of interest may be located within webinar materials.

8. For the identified types of regulatory implementation and compliance aids in questions six and seven, feedback on the delivery methods (*e.g.,* provision on the Bureau's website and email notifications to the appropriate email listserv), and the delivery method and timing for notifying stakeholders of the availability of new or amended materials.

Official Interpretations and Standalone Interpretive Rules

Many regulations issued under the Bureau's rulemaking authority contain Official Interpretations within the supplement or appendix to the regulatory text in the CFR. The Bureau, as a matter of practice, has published Official Interpretations in the **Federal Register** after notice and comment. Among other purposes, the Bureau uses Official Interpretations to clarify regulatory text and provide examples of practices that comply with regulatory provisions. The Bureau also uses Official Interpretations to memorialize the Bureau's responses to recurring questions on particular legislative rules over time. For example, after issuing a new regulation, during the implementation period for that rule, the Bureau frequently has amended the Official Interpretations (and sometimes the regulatory text) in response to questions posed during the implementation process.[28] As discussed earlier, under certain enumerated consumer financial laws, such as the Truth in Lending Act,[29] Official Interpretations also provide financial services providers protection from civil liability for acts committed in good faith reliance on those interpretations.

Although the Bureau has generally used Official Interpretations as a cumulative repository of the Bureau's interpretations issued over time, the Bureau also occasionally has issued standalone interpretive rules without notice and comment when rapid issuance of interpretive clarification will assist industry with regulatory implementation or compliance.[30] The Bureau identifies regulatory areas that would benefit from these types of clarifications from a variety of sources, including inquiries received through the Regulatory Inquiries Function and feedback obtained through industry outreach or market monitoring activities. The Bureau generally expects that it will periodically amend the relevant Official Interpretations in the CFR to reflect the positions taken in these materials, after notice and comment to assess whether further refinement is warranted.[31]

Consistent with applicable law, the Bureau is seeking feedback on all aspects of the process by which it issues interpretive rules and Official Interpretations, including the following areas of interest:

9. The efficiency and effectiveness of providing guidance through the Bureau's Official Interpretations.

10. Which types of standalone interpretive rules are most efficient and effective and, if any, with what frequency and through what processes the Bureau should amend the Official Interpretations to incorporate standalone interpretive guidance into the CFR.

11. Whether there are circumstances in which the Bureau should use the notice-and-comment process (even though not legally required) for standalone interpretive rules.

SEFL Guidance Materials

The Bureau's Division of Supervision, Enforcement, and Fair Lending (SEFL) issues a number of documents meant to provide industry and the public with insight into the Bureau's enforcement and supervision priorities, perspectives regarding compliance with Federal consumer financial law, and supervisory expectations. For example, SEFL guidance materials have helped to identify compliance risks, made recommendations to strengthen compliance management systems, and provided options for reducing compliance risks. Those materials include, for example, compliance bulletins, policy statements, and statements on supervisory practices. They generally are examples of policy

[26] The Bureau understands that industry has expressed concerns regarding its use of disclaimers for non-rule guidance such as regulatory implementation and compliance aids. See below for a discussion and questions on the Bureau's use of disclaimers.

[27] *See* 13 CFR 121.201; U.S. Small Bus. Admin., ''Small Business Compliance Guide Size and Affiliation,'' (Mar. 2014), *available at https://www.sba.gov/sites/default/files/articles/affiliation_ver_03.pdf.*

[28] By including this implementation guidance in the Official Interpretations on routine basis during the implementation period, the Bureau has expanded on the practice of the Federal Reserve Board described above of incorporating guidance into the Official Interpretations in an effort to make such guidance more readily accessible and to clarify its legal effect.

[29] *See* 15 U.S.C. 1640(f).

[30] *See* 79 FR 41631 (July 17, 2014) and 81 FR 71977 (Oct. 19, 2016*), supra* note 18. In the past, the Bureau has used labels for interpretive guidance that are different than what is used in this RFI. For example, interpretive guidance may have been issued in other documents, such as bulletins. *See, e.g.,* CFPB Bulletin 2013–12, Implementation Guidance for Certain Mortgage Servicing Rules (Oct. 15, 2013).

[31] For example, the Bureau addressed in the Official Interpretations some of the guidance previously provided in CFPB Bulletin 2013–12, *supra* note 30. *See* Amendments to the 2013 Mortgage Rules Under the Real Estate Settlement Procedures Act (Regulation X) and the Truth in Lending Act (Regulation Z), 81 FR 72160, 72236–38 (Oct. 19, 2016). In some cases, for example, there is no existing implementing regulation for some or all of the statute and, thus, no Official Interpretations that may be used to incorporate guidance about that portion of the statute. *See, e.g.,* Fair Debt Collection Practices Act, 15 U.S.C. 1692–1692p.

guidance as described above, and, for example, do not have the force and effect of law.[32] Examples include the Bureau's policy guidance on supervisory and enforcement priorities regarding early compliance with the 2016 amendments to the 2013 Mortgage Rules under the Real Estate Settlement Procedures Act (Regulation X) and the Truth in Lending Act (Regulation Z),[33] and the Bureau's compliance bulletin on detecting and preventing consumer harm from production incentives.[34]

The Bureau is seeking feedback on all aspects of these SEFL guidance materials, including but not limited to:

12. The timing, frequency, scope, and delivery method of SEFL guidance materials.

13. The benefits or drawbacks associated with the Bureau's use of each particular type of SEFL guidance vehicle.

14. Other feedback or suggestions related to SEFL guidance materials.

Recommendations for New Forms of Written Guidance

The Bureau has received feedback from industry and other external stakeholders encouraging the use of forms of written guidance that have been used frequently by some other agencies, such as Frequently Asked Questions (FAQs) and advisory opinions. In response to this feedback, the Bureau has begun to explore new and enhanced methods for delivering direct, easy-to-understand written guidance that can be delivered via a public-facing platform on a shorter timeline than might be required for interpretive rules.[35]

For example, the Bureau recently published on its website FAQs on bankruptcy issues related to mortgage servicing,[36] and issued FAQs on HMDA operational and regulatory requirements.[37] These FAQs have historically been non-rule guidance—written responses to questions received from regulated entities and other stakeholders that do not constitute an interpretive rule under the APA, consistent with the kinds of information that the Bureau has provided orally or by email through the Regulatory Inquiries Function described above. However, the Bureau could choose to change its approach in the future to issue interpretive rules in the form of FAQs.

The Bureau has also begun exploring the use of advisory opinions and similar types of focused guidance to assist industry in better understanding its legal and regulatory obligations.[38] The Bureau understands that Federal agencies have described different types of guidance as advisory opinions. In the most formal cases, advisory opinions are interpretive rules—written opinions providing interpretations of a statute or regulation, often applying that interpretation to a particular situation. In other cases, advisory opinions are policy or non-rule guidance. The Bureau also understands that advisory opinions typically are focused on reducing uncertainty by providing a written response to a specific inquiry regarding the conformance of a specific transaction or activity with a particular statute or regulation subject to the agency's jurisdiction.

The Bureau is seeking feedback on potential new methods or channels for providing guidance, including but not limited to:

15. The utility of FAQs. Specifically, comment is sought on the types of questions that are appropriately dealt with through FAQs rather than another instrument, and the mechanisms that the Bureau should use to identify and prioritize issues and topics that should be addressed using FAQs.

16. The potential utility of establishing an advisory opinion program that would provide interpretations, in addition to or instead of an FAQ program, including the particular scope and benefits of advisory opinions that would be distinct from generalized FAQs and the types of questions or issues that could or could not be appropriately dealt with by advisory opinions.

17. The potential benefits and costs of memorializing over time any interpretations reflected in advisory opinions or other standalone guidance documents in the Official Interpretations to the underlying regulations, after notice and comment.

18. The tradeoffs between issuing FAQs or advisory opinions quickly and issuing written guidance after notice and comment. With respect to FAQs or advisory opinions, commenters should include, where possible, suggestions on how best to mitigate risks to stakeholders (*e.g.,* industry confusion, increased compliance costs, potential legal concerns) where there is a heightened risk that the Bureau may change its approach at a later date.

19. Other approaches, methods, or practices not currently employed by the Bureau that would enhance external stakeholders' ability to comprehend, implement, or comply with statutes and regulations subject to the Bureau's purview.

Disclaimers

The Bureau uses disclaimers on non-rule guidance materials to, among other things, describe the purpose of the material, note the legal limitations of the guidance in light of the APA and underlying Federal consumer financial laws, and emphasize that the rule and its Official Interpretations are the definitive sources regarding a rule's requirements in the event of a perceived conflict. In other words, these disclaimers are often used to clarify when guidance materials are non-rule materials that are intended only to aid understanding and implementation.

[32] As noted above, the guidance provided in the Bureau's Supervision and Examination Manuals or Supervisory Highlights publications is outside the scope of this RFI.

[33] 2016 Amendments to the 2013 Mortgage Rules Under the Real Estate Settlement Procedures Act (Regulation X) and the Truth in Lending Act (Regulation Z), 82 FR 29713 (June 30, 2017).

[34] Bureau of Consumer Fin. Prot., ''CFPB Compliance Bulletin 2016–03, Detecting and Preventing Consumer Harm from Production Incentives,'' (Nov. 28, 2016), *available at https://s3.amazonaws.com/files.consumerfinance.gov/f/documents/201611_cfpb_Production_Incentives_Bulletin.pdf.*

[35] Earlier iterations of the Bureau's Small Entity Compliance Guides utilized a question and answer format. *See, e.g.,* Bureau of Consumer Fin. Prot., ''Ability-to-Repay and Qualified Mortgage Rule: Small Entity Compliance Guide,'' (Mar. 2016), *available at https://files.consumerfinance.gov/f/201603_cfpb_atr-qm_small-entity-compliance-guide.pdf;* Bureau of Consumer Fin. Prot., ''Remittance Transfers: Small Entity Compliance Guide,'' (Jan. 31, 2017), *available at https://s3.amazonaws.com/files.consumerfinance.gov/f/documents/201701_cfpb_Intl_Money_Transfer_Small_Entity_Compliance_Guide.pdf.*

[36] Bureau of Consumer Fin. Prot., ''Mortgage Servicing FAQs,'' *https://s3.amazonaws.com/files.consumerfinance.gov/f/documents/cfpb_mortgage-servicing_frequently-asked-questions.pdf* (last updated Mar. 20, 2018).

[37] The HMDA FAQs may be accessed using a searchable web portal located on the Federal Financial Institutions Examination Council HMDA Help web page, which may be accessed from the Bureau's website. *See* Bureau of Consumer Fin. Prot., ''Frequently Asked Questions: HMDA Filing, FFIEC,'' *https://www.consumerfinance.gov/data-research/hmda/faq* (last visited Mar. 16, 2018); Bureau of Consumer Fin. Prot., FFIEC: HMDA Platform,'', *https://hmdahelp.consumerfinance.gov/knowledgebase/s/* (last visited Mar. 23, 2018).

[38] The Bureau has two other programs by which individual applicants can seek determinations from the Bureau, although the programs do not provide guidance on compliance with existing statutes and regulations. Rather, the Bureau's Trial Disclosure Waiver Policy sets forth procedures for the Bureau to exercise its authority pursuant to section 1032(e) of the Dodd-Frank Act to waive disclosure requirements for a set period to allow applicants flexibility in field testing alternative disclosures. 12 U.S.C. 5532(e). The Bureau has also developed a program setting forth the requirements and processes for the issuance of No Action Letters in cases in which Bureau staff do not intend to exercise their discretion to pursue supervision or enforcement activity concerning potentially consumer-friendly market innovations that involve significant regulatory uncertainty. These programs are not the focus of this RFI, which is focused on guidance to facilitate implementation of the Bureau's regulations and compliance with Federal law.

The Bureau has received feedback from industry indicating that the Bureau's use of disclaimers on its materials causes confusion as to the utility and reliability of the guidance and otherwise diminishes the usefulness of the guidance provided. The Bureau has also received feedback urging the Bureau to modify existing disclaimers.

Bureau disclaimers are printed on, for example, rule summaries, compliance guides, quick reference materials, and other compliance aids. These disclaimers are given orally to industry stakeholders when Bureau staff present in webinars or at industry conferences or respond to questions through the Regulatory Inquiries Function. The particular language used in disclaimers is tailored to the type of guidance being provided. For example, the disclaimers provided within the Bureau's regulatory implementation and compliance aids generally indicate that the explanation or summary of a regulatory requirement does not apply to all possible circumstances and is not legal advice. Oral disclaimers given through the Bureau's Regulatory Inquiries Function generally explain that Bureau staff only provide informal responses to regulatory inquiries and that the responses are not intended to serve as legal advice or considered to be an official interpretation of a regulation.

The Bureau has developed different disclaimers for different types of materials as its guidance function has evolved over time, and stakeholders have indicated that some historical formulations are particularly likely to cause confusion. For example, industry stakeholders point to language stating that webinar materials do not bind the Bureau, or create any rights, benefits, or defenses that are enforceable by other parties, as raising questions about whether material presented can be relied upon. They question whether the Bureau would change its interpretation without notice or take action against a party acting in conformity with an interpretation stated in a webinar.

The Bureau is seeking feedback on all aspects of its disclaimers, including the following areas of interest:

20. Taking into consideration the Bureau's purposes for providing guidance as well as APA requirements discussed above, whether disclaimers are transparent, understandable, and appropriate to the type of guidance being provided.

21. Desired changes to the Bureau's disclaimer language or approach to disclaimers generally, and whether other Federal agencies have adopted disclaimer language or approaches to disclaimers that would be useful to the Bureau.

22. The variety of Bureau disclaimers currently provided, and whether the Bureau should adopt a single, more generic disclaimer to be used in most instances.

23. Other feedback or suggestions related to the Bureau's disclaimers.

Authority: 12 U.S.C. 5511(c).

Dated: March 27, 2018.

Mick Mulvaney,

Acting Director, Bureau of Consumer Financial Protection.

[FR Doc. 2018–06674 Filed 3–30–18; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 17–52]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young, (703) 697–9107, *pamela.a.young14.civ@mail.mil* or Kathy Valadez, (703) 697–9217, *kathy.a.valadez.civ@mail.mil;* DSCA/DSA–RAN.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 17–52 with attached Policy Justification.

Dated: March 27, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

MAR 2 2 2018

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 17-52, concerning the Army's proposed Letter(s) of Offer and Acceptance to the Kingdom of Saudi Arabia for defense articles and services estimated to cost $106.8 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification

Transmittal No. 17–52

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Kingdom of Saudi Arabia

(ii) *Total Estimated Value:*

Major Defense Equipment *.	$ 0 million
Other	$106.8 million
Total	$106.8 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): None

Non-MDE:

Continuation of Maintenance Support Services (MSS) contract that supports the Royal Saudi Land Forces Aviation Command's (RSLFAC) fleet of AH–64D/E, UH–60L, Schweizer 333 and Bell 406CS helicopters. The MSS contract services includes the management and installation of engineering change proposals and modification work orders; Repair and Return (R&R) management services and component repairs; aircraft simulator logistics, maintenance and technical support; training; and maintenance management support for the RSLFAC Headquarters staff; and other related elements of logistics and program support.

(iv) *Military Department:* Army (SR–B–ZAU)

(v) *Prior Related Cases, if any:* SR–B–UAF; SR–B–UGZ; SR–B–WAL

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* March 22, 2018

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Kingdom of Saudi Arabia—Continuation of Maintenance Support Services (MSS)

The Kingdom of Saudi Arabia has requested the continuation of the Maintenance Support Services (MSS) contract that supports the Royal Saudi Land Forces Aviation Command's (RSLFAC) fleet of AH–64D/E, UH–60L, Schweizer 333 and Bell 406CS helicopters. The MSS contract services includes management and installation of engineering change proposals and modification work orders; Repair and Return (R&R) management services and component repairs; aircraft simulator logistics, maintenance and technical support; training; and maintenance management support for the RSLFAC Headquarters staff; and other related elements of logistics and program support. The estimated total case value is $106.8 million.

This proposed sale will support U.S. foreign policy and national security objectives by helping to improve the security of a friendly country which has been, and continues to be, an important force for political stability and economic growth in the Middle East. This potential sale is a continuation of current support. Saudi Arabia will have no difficulty absorbing this equipment and support into its armed forces.

The continuation of MSS services will aid in the maintenance support of Saudi Arabia's rotary wing aircraft fleet, engines, avionics, weapons, and missile components.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be DynCorps International, Mclean, VA. There are no known offset agreements in connection with this potential sale.

Implementation of this proposed sale will require the assignment of one (1) U.S. Government and up to three hundred twenty (320) contractor representatives to travel to Saudi Arabia for a period of two (2) years.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2018–06529 Filed 3–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 17–60]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young, (703) 697–9107, *pamela.a.young14.civ@mail.mil* or Kathy Valadez, (703) 697–9217, *kathy.a.valadez.civ@mail.mil;* DSCA/DSA–RAN.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 17–60 with attached Policy Justification.

Dated: March 27, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

MAR 2 2 2018

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 17-60, concerning the Army's proposed Letter(s) of Offer and Acceptance to Saudi Arabia for defense articles and services estimated to cost $300 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Regional Balance (Classified document provided under separate cover)

Transmittal No. 17–60

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Kingdom of Saudi Arabia

(ii) *Total Estimated Value:*

Major Defense Equipment * ..	$ 0 million
Other	$300 million
Total	$300 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): None

Non-MDE:

A new Foreign Military Sales Order (FMSO) II to provide funds for blanket order requisitions under a Cooperative Logistics Supply Support Agreement (CLSSA) for common spares/repair parts to support Saudi Arabia's fleet of M1A2 Abrams tanks, M2 Bradley Fighting Vehicles, High Mobility Multipurpose Wheeled Vehicles (HMMWVs), Light Armored Vehicles (LAVs), M198 Towed Howitzers, additional support, and other related elements of logistics and program support.

(iv) *Military Department:* Army (XX–B–KYN)

(v) *Prior Related Cases, if any:* SR–B–KYM, SR–B–KYL, SR–B–KSB, SR–B–KRK, SR–B-KRI, SR–B–KRE, SR–B–KRB, SR–B–KRA, SR–B–KLF, SR–B–KEZ, SR–B–UBW

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* March 22, 2018

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Saudi Arabia—Royal Saudi Land Forces Ordnance Corps Foreign Military Sales Order (FMSO) II Case

The Government of the Kingdom of Saudi Arabia has requested a possible purchase of a new Foreign Military Sales Order (FMSO) II to provide funds for blanket order requisitions under a Cooperative Logistics Supply Support Agreement (CLSSA) for common spares/repair parts to support Saudi Arabia's fleet of M1A2 Abrams tanks, M2 Bradley Fighting Vehicles, High Mobility Multipurpose Wheeled Vehicles (HMMWVs), Light Armored Vehicles (LAVs), M198 Towed Howitzers, additional support, and other related elements of logistics and program support. The total estimated program cost is $300 million.

This proposed sale will contribute to U.S. foreign policy and national security objectives by helping to improve the security of a friendly country which has been, and continues to be, an important force for political stability and economic growth in the Middle East. This potential sale is consistent with U.S. initiatives to provide key allies in the region with modern systems that will enhance interoperability with U.S. forces and increase stability.

The primary objective of this proposed sale is to allow the Royal Saudi Land Forces Ordnance Corps to continue to purchase needed spare/repair parts to maintain Saudi Arabia's fleet of M1A2 Abrams Tanks, M2 Bradley Fighting Vehicles, High Mobility Multipurpose Wheeled Vehicles (HMMWVs), Light Armored Vehicles (LAVs), M198 Towed Howitzers, additional support vehicles and other related logistics support as part of the Cooperative Logistics Supply Support Arrangement (CLSSA) program. Saudi Arabia will have no difficulty absorbing this equipment and support into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

There are no principal contractors involved with this potential sale. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the permanent assignment of any U.S. Government or contractor representatives to Saudi Arabia.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2018–06530 Filed 3–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Advisory Committee on Investigation, Prosecution, and Defense of Sexual Assault in the Armed Forces; Notice of Federal Advisory Committee Meeting

AGENCY: General Counsel of the Department of Defense.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Advisory Committee on Investigation, Prosecution, and Defense of Sexual Assault in the Armed Forces will take place. This meeting will be open to the public.

DATES: Open to the public, Friday, April 20, 2018 from 9:00 a.m. to 4:00 p.m.

ADDRESSES: One Liberty Center, 875 N Randolph Street, Suite 1432, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Dwight Sullivan, 703–695–1055 (Voice), dwight.h.sullivan.civ@mail.mil (Email). Mailing address is DACIPAD, One Liberty Center, 875 N Randolph Street, Suite 150, Arlington, Virginia 22203. Website: *http://dacipad.whs.mil/*. The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: In section 546 of the National Defense Authorization Act for Fiscal Year 2015 (Pub. L. 113–291), as modified by section 537 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92), Congress tasked the DAC–IPAD to advise the Secretary of Defense on the investigation, prosecution, and defense of allegations of rape, forcible sodomy, sexual assault, and other sexual misconduct involving members of the Armed Forces. This will be the seventh public meeting held by the DAC–IPAD. The purpose of the meeting is for the Committee to receive information to assess and make recommendations to the Secretary of Defense regarding the military justice data collection standards and criteria required by Article 140a, UCMJ. The Committee will receive testimony on best practices for data collection in the civilian criminal justice system from the Director, Office of Research and Data, U.S. Sentencing Commission; the Deputy Director, Incident-Based Statistics Unit, Bureau of Justice Statistics, U.S. Department of Justice; and a representative from the Administrative Office of the U.S. Courts. The Committee will also receive testimony from each of the Military Services regarding current data collection capabilities and requirements for military justice case management.

Agenda: 9:00 a.m.–9:15 a.m. Public Meeting Begins—Welcome and Introduction; 9:15 a.m.–12:00 p.m. Best Practices for Case Management and Data Collection in Civilian Criminal Courts; 12:00 p.m.–1:00 p.m. Lunch; 1:00 p.m.–2:30 p.m. Current Capabilities of the

Military Services' Case Management and Data Collection Programs; 2:30 p.m.–2:40 p.m. Break; 2:40 p.m.–3:40 p.m. Updates for the Committee from the Data, Case Review, and Policy Working Groups; 3:40 p.m.–4:00 p.m. Public Comment; 4:00 p.m. Public Meeting Adjourned.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is limited and is on a first-come basis. Visitors are required to sign in at the One Liberty Center security desk and must leave government-issued photo identification on file and wear a visitor badge while in the building. Department of Defense Common Access Card (CAC) holders who do not have authorized access to One Liberty Center must provide an alternate form of government-issued photo identification to leave on file with security while in the building. All visitors must pass through a metal detection security screening. Individuals requiring special accommodations to access the public meeting should contact the DAC–IPAD at *whs.pentagon.em.mbx.dacipad@mail.mil* at least five (5) business days prior to the meeting so that appropriate arrangements can be made. In the event the Office of Personnel Management closes the government due to inclement weather or for any other reason, please consult the website for any changes to the public meeting date or time.

Written Statements: Pursuant to 41 CFR 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written comments to the Committee about its mission and topics pertaining to this public session. Written comments must be received by the DAC–IPAD at least five (5) business days prior to the meeting date so that they may be made available to the Committee members for their consideration prior to the meeting. Written comments should be submitted via email to the DAC–IPAD at *whs.pentagon.em.mbx.dacipad@mail.mil* in the following formats: Adobe Acrobat or Microsoft Word. Please note that since the DAC–IPAD operates under the provisions of the Federal Advisory Committee Act, as amended, all written comments will be treated as public documents and will be made available for public inspection. Oral statements from the public will be permitted, though the number and length of such oral statements may be limited based on the time available and the number of such requests. Oral presentations by members of the public will be permitted from 3:40 p.m. to 4:00 p.m. on April 20, 2018, in front of the Committee members.

Dated: March 27, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–06566 Filed 3–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 17–62]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young, (703) 697–9107, *pamela.a.young14.civ@mail.mil* or Kathy Valadez, (703) 697–9217, *kathy.a.valadez.civ@mail.mil;* DSCA/DSA–RAN.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 17–62 with attached Policy Justification and Sensitivity of Technology.

Dated: March 27, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Paul D. Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

MAR 2 2 2018

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 17-62, concerning the Army's proposed Letter(s) of Offer and Acceptance to Saudi Arabia for defense articles and services estimated to cost $670 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified document provided under separate cover)

BILLING CODE 5001–06–C

Transmittal No. 17–62

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Kingdom of Saudi Arabia

(ii) *Total Estimated Value:*

Major Defense Equipment * ..	$647 million
Other	$ 23 million
Total	$670 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): Up to six thousand six hundred (6,600) TOW 2B Missiles (BGM–71F–Series) Ninety-six (96) TOW 2B (BGM–71F–Series) Fly-to-Buy Lot Validation Missiles

Non-MDE: Also included is government furnished equipment; technical manuals and publications; essential spares and repair parts; consumables; live fire exercise and ammunition; tools and test equipment; training; transportation; U.S. Government technical support and logistic support; contractor technical support; repair and return support; quality assurance teams; in-country Field Service Representative (FSR); other associated equipment and services in support of TOW 2B missiles; and other related elements of logistics and program support.

(iv) *Military Department:* Army (SR–B–VBQ).

(v) *Prior Related Cases, if any:* None.

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None.

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex.

(viii) *Date Report Delivered to Congress:* March 22, 2018.

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Saudi Arabia—TOW 2B (BGM–71F–Series) Missiles

The Government of the Kingdom of Saudi Arabia has requested to buy up to six thousand six hundred (6,600) TOW 2B missiles (BGM–71F–Series) and ninety-six (96) TOW 2B (BGM–71F–Series) fly-to-buy lot validation missiles. Also included is government furnished equipment; technical manuals and publications; essential spares and repair parts; consumables; live fire exercise and ammunition; tools and test equipment; training; transportation; U.S. Government technical support and logistic support; contractor technical support; repair and return support; quality assurance teams; in-country Field Service Representative (FSR); other associated equipment and services in support of TOW 2B missiles; and other related elements of logistics and program support. The total estimated program cost is $670 million.

This proposed sale will support U.S. foreign policy and national security objectives by improving the security of a friendly country which has been, and continues to be, an important force for political stability and economic growth in the Middle East. This potential sale is consistent with U.S. initiatives to provide key partners in the region with modern systems that will enhance interoperability with U.S. forces and increase stability.

The proposed sale of TOW 2B missiles and technical support will advance the Kingdom of Saudi Arabia's efforts to develop an integrated ground defense capability. A strong national defense and dedicated military force will assist Saudi Arabia to sustain itself in its efforts to maintain stability. Saudi Arabia will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor is Raytheon Missile Systems, Tucson, AZ. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the permanent assignment of any U.S. Government or contractor representatives to Saudi Arabia. There will be no more than two contractor personnel in the Kingdom of Saudi Arabia at any one time and all efforts will take less than two weeks in total.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 17–62

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The TOW 2B RF Missile is a fly-over-shoot-down missile designed to defeat armored vehicles. These missiles are fired from a variety of TOW launchers in the U.S. Army, USMC and FMS customer forces. The TOW 2B RF can be launched from the same launcher platforms as the existing wire-guided TOW 2B missiles without modification to the launcher. The TOW 2B missile (both wire & RF) contains two tracker beacons (xenon and thermal) for the launcher to track and guide the missile in flight. Guidance commands from the launcher are provided to the missile by an RF link contained within the missile case. The hardware, software and technical publications provided with the sale are unclassified; however, the system itself contains sensitive technology that instructs the system on how to operate in the presence of countermeasures.

2. If a technologically advanced adversary obtains knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent systems that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. A determination has been made that Saudi Arabia can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

4. All defense articles and services listed in this transmittal are authorized for release and export to the Kingdom of Saudi Arabia.

[FR Doc. 2018–06535 Filed 3–30–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0032]

Agency Information Collection Activities; Comment Request; U.S. Department of Education Grant Performance Report Form (ED 524B)

AGENCY: Office of the Secretary (OS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before June 1, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2018–ICCD–0032. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW, LBJ, Room 216–32, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Alfreida Pettiford, 202–245–6110.

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: U.S. Department of Education Grant Performance Report Form (ED 524B).

OMB Control Number: 1894–0003.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 5,300.

Total Estimated Number of Annual Burden Hours: 121,050.

Abstract: The ED 524B form and instructions are used in order for grantees to meet Department of Education (ED) deadline dates for submission of performance reports for ED discretionary grant programs. Recipients of multi-year discretionary grants must submit an annual performance report for each year funding has been approved in order to receive a continuation award. The annual performance report should demonstrate whether substantial progress has been made toward meeting the approved goals and objectives of the project. ED program offices may also require recipients of ''forward funded'' grants that are awarded funds for their entire multi-year project up-front in a single grant award to submit the ED 524B on an annual basis. In addition, ED program offices may also require recipients to use the ED 524B to submit their final performance reports to demonstrate project success, impact and outcomes. In both the annual and final performance reports, grantees are required to provide data on established performance measures for the grant program (*e.g.,* Government Performance and Results Act measures) and on project performance measures that were included in the grantee's approved grant application. The ED 524B also contains a number of questions related to project financial data such as Federal and non-Federal expenditures and indirect cost information. Performance reporting requirements are found in 34 CFR 74.51, 75.118, 75.253, 75.590 and 80.40 of the Education Department General Administrative Regulations.

The 524B is being revised to collect additional information to sufficiently monitor states on data security requirements for grant programs.

Dated: March 27, 2018.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–06560 Filed 3–30–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2018–ICCD–0033]

Agency Information Collection Activities; Comment Request; Federal Student Loan Program Deferment Request Forms

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before June 1, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2018–ICCD–0033. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW, LBJ, Room 216–34, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Ian Foss, 202–377–3681.

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: Federal Student Loan Program Deferment Request Forms.

OMB Control Number: 1845–0011.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 1,211,634.

Total Estimated Number of Annual Burden Hours: 193,861.

Abstract: These forms serve as the means by which borrowers in the William D. Ford Federal Direct Loan (Direct Loan), Federal Family Education Loan (FFEL) and the Federal Perkins Loan (Perkins Loan) Programs may request deferment of repayment on their loans if they meet certain statutory and regulatory criteria. The U.S. Department of Education and other loan holders uses the information collected on these forms to determine whether a borrower meets the eligibility requirements for the specific deferment type being submitted.

Dated: March 28, 2018.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–06634 Filed 3–30–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2018–ICCD–0034]

Agency Information Collection Activities; Comment Request; Federal Student Loan Program: Internship/Residency and Loan Debt Burden Forbearance Forms

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before June 1, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2018–ICCD–0034. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW, LBJ, Room 216–34, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Ian Foss, 202–377–3681.

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: Federal Student Loan Program: Internship/Residency and Loan Debt Burden Forbearance Forms.

OMB Control Number: 1845–0018.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 27,042.

Total Estimated Number of Annual Burden Hours: 6,393.

Abstract: These forms serve as the means by which borrowers in the William D. Ford Federal Direct Loan (Direct Loan), Federal Family Education Loan (FFEL) and the Federal Perkins Loan (Perkins Loan) Programs may request forbearance of repayment on their loans if they meet certain conditions. The U.S. Department of Education and other loan holders uses the information collected on these forms to determine whether a borrower meets the eligibility requirements for the specific type of forbearance.

Dated: March 28, 2018.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–06635 Filed 3–30–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Free Application for Federal Student Aid (FAFSA®) Information To Be Verified for the 2019–2020 Award Year

Correction

In notice document 2018–06278 beginning on page 13266 in the issue of Wednesday, March 28, 2018, make the following correction:

On page 13266 the table heading ''LTCH QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS'' should not have appeared.

[FR Doc. C1–2018–06278 Filed 3–30–18; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF EDUCATION

[Docket No. ED–2018–ICCD–0035]

Agency Information Collection Activities; Comment Request; Income Driven Repayment Plan Request for the William D. Ford Federal Direct Loans and Federal Family Education Loan Programs

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before June 1, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2018–ICCD–0035. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW, LBJ, Room 216–34, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Ian Foss, 202–377–3681.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in

public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Income Driven Repayment Plan Request for the William D. Ford Federal Direct Loans and Federal Family Education Loan Programs.

OMB Control Number: 1845–0102.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 6,090,000.

Total Estimated Number of Annual Burden Hours: 2,009,700.

Abstract: The Department is requesting an extension of the current information collection. We are updating this Income-Driven Repayment Plan Request form to make it more user friendly and allow for easier processing by the servicers. No new questions are being asked, some existing questions are being streamlined and there is reformatting to allow for readability and ease in completing the form. There is no burden change based on these changes.

Dated: March 28, 2018.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–06637 Filed 3–30–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0028]

Higher Education Hurricane and Wildfire Relief Program Application; Reopening of Comment Period

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice; reopening of comment period.

SUMMARY: On March 26, 2018, the U.S. Department of Education published an emergency comment period notice in the **Federal Register** on Monday, March 26, 2018 (83 FR 12945, Column 3; Page 12946, Column 1, 2) seeking public comment for an information collection entitled, ''Higher Education Hurricane and Wildfire Relief Program Application''.

DATES: The closing date for the comment period has been reopened and extended to April 5, 2018.

SUPPLEMENTARY INFORMATION: The Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management, hereby issues a notice as required by the Paperwork Reduction Act of 1995.

Dated: March 29, 2018.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–06729 Filed 3–30–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–1183–000]

Delta Solar I, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Delta Solar I, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 16, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 27, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–06627 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 7804–029]

Gerald and Glenda Ohs, Gerald Ohs; Notice of Application for Partial Transfer of License and Soliciting Comments, Motions To Intervene, and Protests

On July 14, 2017 and supplemented on November 2, 2017, Gerald Ohs and Glenda Ohs co-licensees (transferors) filed an application for the partial transfer of license for the North Willow Creek Project No. 7804, from Gerald and Glenda Ohs as co-licensees (transferors) to Gerald Ohs as sole licensee (transferee). The project is located on North Willow Creek in Madison County, Montana.

The applicants seek Commission approval to partially transfer the license for the North Willow Creek Project from the transferors as co-licensees to Gerald Ohs as sole-licensee.

Applicant's Contacts: For Transferors/Transferee: Mr. Gerald Ohs and Ms. Glenda Ohs, P.O. Box 625, 63 North Willow Creek Road, Pony, Montana 59747, Phone: 406–431–5450, Email: *klazysranch@yahoo.com.*

FERC Contact: Patricia W. Gillis, (202) 502–8735, *patricia.gillis@ferc.gov.*

Deadline for filing comments, motions to intervene, and protests: 30 days from the date that the Commission issues this notice. 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, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–7804–029.

Dated: March 27, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–06647 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR18–18–000]

CCPS Transportation, LLC; Notice of Petition for Declaratory Order

Take notice that on March 16, 2018, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2017), CCPS Transportation, LLC, filed a petition for a declaratory order seeking approval of the proposed capacity allocation and rate structure for a planned re-contracting of a portion of the capacity of the Spearhead Pipeline, all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on April 20, 2018.

Dated: March 27, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–06649 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC18–73–000.
Applicants: NextEra Energy Duane Arnold, LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act and Request for Expedited Action of NextEra Energy Duane Arnold, LLC.
Filed Date: 3/20/18.
Accession Number: 20180320–5259.
Comments Due: 5 p.m. ET 4/10/18.

Docket Numbers: EC18–74–000.
Applicants: Tenaska Hampden Partners, LLC, Berkshire Power Company, LLC.
Description: Joint Application of Tenaska Hampden Partners, LLC, et al. for Approval under Section 203 of the Federal Power Act and Request for Expedited Approval and Privileged Treatment.
Filed Date: 3/20/18.
Accession Number: 20180320–5269.
Comments Due: 5 p.m. ET 4/10/18.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG18–60–000.
Applicants: Walleye Energy, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Walleye Energy, LLC.
Filed Date: 3/20/18.
Accession Number: 20180320–5234.
Comments Due: 5 p.m. ET 4/10/18.

Docket Numbers: EG18–61–000.
Applicants: Pinal Central Energy Center, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Pinal Central Energy Center, LLC.
Filed Date: 3/20/18.
Accession Number: 20180320–5235.
Comments Due: 5 p.m. ET 4/10/18.

Docket Numbers: EG18–62–000.
Applicants: Trishe Wind Ohio, LLC.
Description: Self-Certification of EG Trishe Wind Ohio, LLC.
Filed Date: 3/22/18.
Accession Number: 20180322–5004.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: EG18–63–000.
Applicants: NRG Cottonwood Tenant LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of NRG Cottonwood Tenant LLC.
Filed Date: 3/22/18.
Accession Number: 20180322–5263.
Comments Due: 5 p.m. ET 4/12/18.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER17–217–005.
Applicants: Jersey Central Power & Light Company, PJM Interconnection, L.L.C.
Description: Compliance filing: JCPL submits a compliance filing per Feb. 20, 2018 order in Docket No. ER17–217 to be effective 6/1/2017.
Filed Date: 3/22/18.
Accession Number: 20180322–5139.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER17–1610–003.
Applicants: Southwest Power Pool, Inc.
Description: Compliance filing: Mountrail-Williams Electric Cooperative Formula Rate Compliance Filing to be effective 7/1/2017.
Filed Date: 3/22/18.
Accession Number: 20180322–5243.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–945–001.

Applicants: Mid-Atlantic Interstate Transmission, LLC, PJM Interconnection, L.L.C.
Description: Tariff Amendment: MAIT submits Supplemental Filing of IA SA No. 4577 in ER18–945 to be effective 5/22/2018.
Filed Date: 3/22/18.
Accession Number: 20180322–5250.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–938–000.
Applicants: Matador Power Marketing, Inc.
Description: Supplement to February 28, 2018 Matador Power Marketing, Inc. tariff filing.
Filed Date: 3/20/18.
Accession Number: 20180320–5248.
Comments Due: 5 p.m. ET 4/10/18.

Docket Numbers: ER18–1150–000.
Applicants: Trishe Wind Ohio, LLC.
Description: Baseline eTariff Filing: Market-Based Rate Tariff to be effective 5/21/2018.
Filed Date: 3/22/18.
Accession Number: 20180323–5000.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1151–000.
Applicants: Public Service Company of Colorado.
Description: § 205(d) Rate Filing: OATT–WAPA–NC NITS 325–0.1.0–NF PtP 425–0.0.0 to be effective 3/22/2018.
Filed Date: 3/22/18.
Accession Number: 20180323–5004.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1152–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2018–03–22_Definition 1.P True-Up Filing to be effective 10/3/2017.
Filed Date: 3/22/18.
Accession Number: 20180322–5110.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1153–000.
Applicants: ISO New England Inc.
Description: Compliance filing: Peak Energy Rent Settlement Compliance Filing; ER17–2153–000 et seq; EL16–120–000 to be effective 9/30/2016.
Filed Date: 3/22/18.
Accession Number: 20180322–5150.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1154–000.
Applicants: Southern California Edison Company.
Description: Tariff Cancellation: Notices of Cancellation of SGIA and Distrib Serv Agmt LACSD to be effective 11/27/2017.
Filed Date: 3/22/18.
Accession Number: 20180322–5182.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1155–000.
Applicants: Summer Energy Northeast, LLC.
Description: Baseline eTariff Filing: Summer Energy Northeast Baseline Tariff Filing to be effective 3/22/2018.
Filed Date: 3/22/18.
Accession Number: 20180322–5192.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1156–000.
Applicants: St. Joseph Energy Center, LLC.
Description: Baseline eTariff Filing: St. Joseph Energy Center Reactive Tariff to be effective 5/1/2018.
Filed Date: 3/22/18.
Accession Number: 20180322–5194.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1157–000.
Applicants: Idaho Power Company.
Description: Tariff Cancellation: Notice of Cancellation of Rate Schedule 165—Don-Blackfoot Thermal Relay to be effective 5/22/2018.
Filed Date: 3/22/18.
Accession Number: 20180322–5208.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1158–000.
Applicants: Louisville Gas and Electric Company.
Description: § 205(d) Rate Filing: OMU Amd and Rstd IA Rate Schedule 505 to be effective 2/23/2018.
Filed Date: 3/22/18.
Accession Number: 20180322–5209.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1159–000.
Applicants: Midcontinent Independent System Operator, Inc., Pioneer Transmission, LLC.
Description: § 205(d) Rate Filing: 2018–03–22_Pioneer Attachment O Filing to be effective 6/1/2018.
Filed Date: 3/22/18.
Accession Number: 20180322–5246.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1160–000.
Applicants: NRG Cottonwood Tenant LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authorization and Request for Waivers to be effective 4/1/2018.
Filed Date: 3/22/18.
Accession Number: 20180322–5254.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1161–000.
Applicants: New York Independent System Operator, Inc., Consolidated Edison Company of New York, Inc.
Description: § 205(d) Rate Filing: NYISO, Con Edison and Bayonne Energy Center Amended/Restated LGIA #1668 to be effective 2/22/2018.
Filed Date: 3/22/18.
Accession Number: 20180322–5256.
Comments Due: 5 p.m. ET 4/12/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 22, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–06620 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–1184–000]

Delta Solar II, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Delta Solar II, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 16, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access

who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 27, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–06628 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–1150–000]

Trishe Wind Ohio, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Trishe Wind Ohio, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 11, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 22, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–06623 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER03–179–014.
Applicants: FPL Energy New Mexico Wind, LLC.
Description: Notification of Change in Status of FPL Energy New Mexico Wind, LLC.
Filed Date: 3/23/18.
Accession Number: 20180323–5208.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: ER11–2192–011.
Applicants: Red Mesa Wind, LLC.
Description: Notification of Change in Status of Red Mesa Wind, LLC.
Filed Date: 3/26/18.
Accession Number: 20180326–5246.
Comments Due: 5 p.m. ET 4/16/18.

Docket Numbers: ER11–3635–009.
Applicants: Hatch Solar Energy Center I, LLC.
Description: Notification of Change in Status of Hatch Solar Energy Center I, LLC.
Filed Date: 3/26/18.
Accession Number: 20180326–5245.
Comments Due: 5 p.m. ET 4/16/18.

Docket Numbers: ER16–1277–004.
Applicants: White Pine Solar, LLC.
Description: Notification of Change in Status of White Pine Solar, LLC.
Filed Date: 3/26/18.
Accession Number: 20180326–5251.
Comments Due: 5 p.m. ET 4/16/18.

Docket Numbers: ER17–2270–001.
Applicants: Stuttgart Solar, LLC.
Description: Notification of Change in Status of Stuttgart Solar, LLC.
Filed Date: 3/23/18.
Accession Number: 20180323–5207.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: ER18–1174–000.
Applicants: Imperial Valley Solar 2, LLC.
Description: Initial rate filing: Normal filing MBR to be effective 12/31/9998.
Filed Date: 3/26/18.
Accession Number: 20180326–5224.
Comments Due: 5 p.m. ET 4/16/18.

Docket Numbers: ER18–1175–000.
Applicants: Duke Energy Progress, LLC, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Revisions to DEP–PJM JOA to Align Settlement Intervals to be effective 4/1/2018.
Filed Date: 3/26/18.
Accession Number: 20180326–5241.
Comments Due: 5 p.m. ET 4/16/18.

Docket Numbers: ER18–1176–000.
Applicants: Appalachian Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Wheeling Power Company.
Description: Formula Rate PBOP 2017 filing of American Electric Power Service Corporation under New Docket. Formula Rate Post-employment Benefits Other than Pensions filing of the AEP East Operating Companies.
Filed Date: 3/23/18.
Accession Number: 20180323–5205.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: ER18–1177–000.
Applicants: Brookfield Energy Marketing LP.
Description: Petition for Limited Waiver of Brookfield Energy Marketing LP.

Filed Date: 3/23/18.
Accession Number: 20180323–5211.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: ER18–1178–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original WMPA SA No. 5038; Queue No. AC1–036 to be effective 3/15/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5003.
Comments Due: 5 p.m. ET 4/17/18.

Docket Numbers: ER18–1180–000.
Applicants: South Carolina Electric & Gas Company.
Description: § 205(d) Rate Filing: Attachment F to be effective 7/27/2015.
Filed Date: 3/27/18.
Accession Number: 20180327–5036.
Comments Due: 5 p.m. ET 4/17/18.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH18–7–000.
Applicants: LS Power Development, LLC.
Description: LS Power Development, LLC submits FERC 65–B Non-Material Change in Fact of Waiver Notification.
Filed Date: 3/23/18.
Accession Number: 20180323–5210.
Comments Due: 5 p.m. ET 4/13/18.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RD18–5–000.
Applicants: North American Electric Reliability Corporation, Western Electricity Coordinating Council.
Description: Joint Petition of the North American Electric Reliability Corporation and Western Electricity Coordinating Council for Approval of Proposed Regional Reliability Standard FAC–501–WECC–2.
Filed Date: 3/16/18.
Accession Number: 20180316–5246.
Comments Due: 5 p.m. ET 4/26/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 27, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–06624 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14869–000]

Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications; RAMM Power Group, LLC

On February 28, 2018, RAMM Power Group LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Sacaton Energy Storage Project (Sacaton Project or project), a closed-loop pumped storage project to be located in Pinal County, Arizona. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following new facilities: (1) A 28-foot-high dam with a total crest length of 6,000 feet, creating a 1,300 acre-foot upper reservoir with a maximum surface elevation of 1,456 feet mean sea level (MSL); (2) a 200-foot-long, 12-foot-diameter steel penstock extending from the upper reservoir dam to the powerhouse; (3) an underground powerhouse with two 75-megawatt pump/turbine units; (4) a 2,200-foot-long, 14-foot-diameter low pressure draft tube extending from the powerhouse to the lower reservoir; (5) a 1,500 acre-foot lower reservoir with a maximum reservoir surface elevation of 455 feet MSL to be located within an existing pit mine (no dam needed); (6) a new 200-Megavolt-ampere substation located adjacent to the upper reservoir; (7) a 2,500-foot-long, 137-kilovolt (kV) transmission line extending from the project's substation to existing 137-kV transmission lines owned by Arizona Public Service; and (8) appurtenant facilities. The estimated average annual generation of the Sacaton Project would be 400,000 megawatt-hours

Applicant Contact: Dr. Michael A. Werner, RAMM Power Group, 7425 East Columbia Drive, Spokane, Washington 99212; phone: (509) 280–7486.

FERC Contact: Khatoon Melick, (202) 502–8433, *khatoon.melick@ferc.gov.*

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 Days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications 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, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. The first page of any filing should include docket number P–14869–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14869) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: March 26, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–06577 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–1174–000]

Imperial Valley Solar 2, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Imperial

Valley Solar 2, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 16, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 27, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–06626 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC18–76–000.
Applicants: Entergy Arkansas, Inc., Entergy Mississippi, Inc.
Description: Joint Application of Entergy Arkansas, Inc., et al. for Approval under Section 203 of the Federal Power Act.
Filed Date: 3/27/18.
Accession Number: 20180327–5079.
Comments Due: 5 p.m. ET 4/17/18.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–406–001.
Applicants: Brunner Island, LLC.
Description: Compliance filing: Reactive Service Rate Schedule Compliance Filing to be effective 2/25/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5075.
Comments Due: 5 p.m. ET 4/17/18.

Docket Numbers: ER18–564–001.
Applicants: South Central MCN LLC.
Description: Compliance filing: Wholesale Distribution ADIT Deficiency Response to be effective 1/1/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5158.
Comments Due: 5 p.m. ET 4/17/18.

Docket Numbers: ER18–1181–000.
Applicants: San Diego Gas & Electric, Energia Sierra Juarez 2 U.S., LLC.
Description: Joint Application of San Diego Gas & Electric Company, et al for Approval of Affiliate Transaction Pursuant to Section 205 of the Federal Power Act.
Filed Date: 3/26/18.
Accession Number: 20180326–5267.
Comments Due: 5 p.m. ET 4/16/18.

Docket Numbers: ER18–1182–000.
Applicants: System Energy Resources, Inc.
Description: § 205(d) Rate Filing: UPSA Amendment to Reflect Tax Cuts and Jobs Act of 2017 to be effective 6/1/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5074.
Comments Due: 5 p.m. ET 4/17/18.

Docket Numbers: ER18–1183–000.
Applicants: Delta Solar Power I, LLC.
Description: Baseline eTariff Filing: Initial Market Based Rate Tariff to be effective 5/21/2018.
Filed Date: 3/22/18.
Accession Number: 20180322–5321.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1184–000.
Applicants: Delta Solar Power II, LLC.
Description: Baseline eTariff Filing: Initial Market Based Rate Tariff to be effective 5/21/2018.
Filed Date: 3/22/18.
Accession Number: 20180322–5322.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1185–000.
Applicants: Duke Energy Progress, LLC.
Description: § 205(d) Rate Filing: DEP–PJM 2nd Amended and Restated JOA Concurrence to be effective 4/1/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5099.
Comments Due: 5 p.m. ET 4/17/18.

Docket Numbers: ER18–1186–000.
Applicants: Turtle Creek Wind Farm LLC.
Description: Baseline eTariff Filing: Market Based Rate Application to be effective 5/27/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5101.
Comments Due: 5 p.m. ET 4/17/18.

Docket Numbers: ER18–1187–000.
Applicants: Eagle's View Partners, Ltd.
Description: Baseline eTariff Filing: Eagles View MBR Application to be effective 3/28/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5102.
Comments Due: 5 p.m. ET 4/17/18.

Docket Numbers: ER18–1188–000.
Applicants: Prairie Queen Wind Farm LLC.
Description: Baseline eTariff Filing: Market Based Rate Application to be effective 5/27/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5103.
Comments Due: 5 p.m. ET 4/17/18.

Docket Numbers: ER18–1189–000.
Applicants: Meadow Lake Wind Farm VI LLC.
Description: Baseline eTariff Filing: Market Based Rate Application to be effective 5/27/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5110.
Comments Due: 5 p.m. ET 4/17/18.

Docket Numbers: ER18–1190–000.
Applicants: Entergy Arkansas, Inc.
Description: § 205(d) Rate Filing: Amended Distribution Agreement to Reflect Tax Cuts and Jobs Act of 2017 to be effective 6/1/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5111.
Comments Due: 5 p.m. ET 4/17/18.

Docket Numbers: ER18–1191–000.
Applicants: Wisconsin Public Service Corporation.

Description: § 205(d) Rate Filing: Notice of Termination for SA 43 to be effective 3/1/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5136.
Comments Due: 5 p.m. ET 4/17/18.

Docket Numbers: ER18–1192–000.
Applicants: The Connecticut Light and Power Company.
Description: § 205(d) Rate Filing: Interconnection Agreement with Fusion Solar Center, LLC to be effective 3/27/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5137.
Comments Due: 5 p.m. ET 4/17/18.

Docket Numbers: ER18–1193–000.
Applicants: Wisconsin Electric Power Company.
Description: § 205(d) Rate Filing: Notice of Termination for RS 106 to be effective 3/1/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5139.
Comments Due: 5 p.m. ET 4/17/18.

Docket Numbers: ER18–1194–000.
Applicants: CSOLAR IV West, LLC.
Description: § 205(d) Rate Filing: Market-Based Rate Tariff Revisions to be effective 3/28/2018.
Filed Date: 3/27/18.
Accession Number: 20180327–5157.
Comments Due: 5 p.m. ET 4/17/18.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES18–24–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Application of Midcontinent Independent System Operator, Inc. under Section 204 of the Federal Power Act for Authorization to Issue Securities.
Filed Date: 3/26/18.
Accession Number: 20180326–5266.
Comments Due: 5 p.m. ET 4/16/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 27, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–06625 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–1149–000]

Walleye Energy, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Walleye Energy, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 11, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 22, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–06622 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR18–38–000.
Applicants: Energy Transfer Fuel, LP.
Description: Tariff filing per 284.123(b),(e)/: Rate Election of Energy Transfer Fuel, LP Effective March 16, 2018.
Filed Date: 3/16/18.
Accession Number: 201803165131.
Comments/Protests Due: 5 p.m. ET 4/6/18.

Docket Numbers: RP13–459–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: Report Filing: 2017 Penalty Revenue Credit Report.
Filed Date: 3/19/18.
Accession Number: 20180319–5130.
Comments Due: 5 p.m. ET 4/2/18.

Docket Numbers: RP18–570–000.
Applicants: Northern Natural Gas Company.
Description: Petition of Northern Natural Gas Company for Limited Waiver of Tariff Provisions.
Filed Date: 3/19/18.
Accession Number: 20180319–5201.
Comments Due: 5 p.m. ET 4/2/18.

Docket Numbers: RP18–571–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Amendment to Neg Rate Agmt (Colorado Bend 46260–4) to be effective 3/21/2018.
Filed Date: 3/20/18.
Accession Number: 20180320–5084.

Comments Due: 5 p.m. ET 4/2/18.

Docket Numbers: RP18–572–000.

Applicants: Trailblazer Pipeline Company LLC.

Description: § 4(d) Rate Filing: Neg Rate 2018–03–15 MS, Macquaire, Citadel, CIMA to be effective 4/1/2018.

Filed Date: 3/20/18.

Accession Number: 20180320–5183.

Comments Due: 5 p.m. ET 4/2/18.

Docket Numbers: RP18–573–000.

Applicants: LLOG Bluewater Holdings, LLC, Beacon Offshore Energy Operating, LLC, LLOG Exploration & Production Company, LLC.

Description: Joint Petition of LLOG Bluewater Holdings, LLC, et al. for Limited Waiver, et al.

Filed Date: 3/20/18.

Accession Number: 20180320–5197.

Comments Due: 5 p.m. ET 4/2/18.

Docket Numbers: RP18–574–000.

Applicants: Elba Express Company, L.L.C.

Description: Compliance filing Annual Interruptible Revenue Crediting Report 2018.

Filed Date: 3/22/18.

Accession Number: 20180323–5001.

Comments Due: 5 p.m. ET 4/3/18.

Docket Numbers: RP18–575–000.

Applicants: Transcontinental Gas Pipe Line Company.

Description: § 4(d) Rate Filing: Rate Schedule LSS and SS–2 Tracker-Eff. 04/01/2018 to be effective 4/1/2018.

Filed Date: 3/22/18.

Accession Number: 20180323–5008.

Comments Due: 5 p.m. ET 4/3/18.

Docket Numbers: RP18–576–000.

Applicants: Tennessee Gas Pipeline Company, L.L.C.

Description: § 4(d) Rate Filing: Volume No. 2—Neg Rate Agmt—Sequent Enegy Management SP100239 to be effective 4/1/2018.

Filed Date: 3/22/18.

Accession Number: 20180323–5009.

Comments Due: 5 p.m. ET 4/3/18.

Docket Numbers: RP18–577–000.

Applicants: Gulf South Pipeline Company, LP.

Description: § 4(d) Rate Filing: Amendment to Neg Rate Agmt (Jera 46437–1) to be effective 3/22/2018.

Filed Date: 3/22/18.

Accession Number: 20180322–5001.

Comments Due: 5 p.m. ET 4/3/18.

Docket Numbers: RP18–578–000.

Applicants: Panhandle Eastern Pipe Line Company, LP.

Description: Compliance filing Flow Through of Cash Out Revenues filed on 3–21–18.

Filed Date: 3/22/18.

Accession Number: 20180322–5002.

Comments Due: 5 p.m. ET 4/3/18.

Docket Numbers: RP18–579–000.

Applicants: Enable Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Fuel Tracker Filing Effective May 1, 2018 to be effective 5/1/2018.

Filed Date: 3/22/18.

Accession Number: 20180322–5143.

Comments Due: 5 p.m. ET 4/3/18.

Docket Numbers: RP18–580–000.

Applicants: Trailblazer Pipeline Company LLC.

Description: § 4(d) Rate Filing: Fuel Tracker 2018 to be effective 5/1/2018.

Filed Date: 3/22/18.

Accession Number: 20180322–5229.

Comments Due: 5 p.m. ET 4/3/18.

Docket Numbers: RP18–581–000.

Applicants: Vector Pipeline L.P.

Description: Annual Fuel Use Report for 2017 of Vector Pipeline L.P.

Filed Date: 3/22/18.

Accession Number: 20180322–5292.

Comments Due: 5 p.m. ET 4/3/18.

Docket Numbers: RP18–582–000.

Applicants: Millennium Pipeline Company, LLC.

Description: § 4(d) Rate Filing: Negotiated Rate Amendments—BKV to be effective 11/22/2017.

Filed Date: 3/23/18.

Accession Number: 20180323–5108.

Comments Due: 5 p.m. ET 4/4/18.

Docket Numbers: RP18–583–000.

Applicants: High Island Offshore System, L.L.C.

Description: § 4(d) Rate Filing: NGL Bank Revision to be effective 12/1/2017.

Filed Date: 3/23/18.

Accession Number: 20180323–5136.

Comments Due: 5 p.m. ET 4/4/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 26, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–06576 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commission Staff Attendance

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission's staff may attend the following meetings related to the transmission planning activities of the New York Independent System Operator, Inc. (NYISO):

NYISO Business Issues Committee Meeting

April 11, 2018, 10:00 a.m.–2:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: *http://www.nyiso.com/public/committees/documents.jsp?com=bic&directory=2018-04-11.*

NYISO Operating Committee Meeting

April 12, 2018, 10:00 a.m.–4:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: *http://www.nyiso.com/public/committees/documents.jsp?com=oc&directory=2018-04-12.*

NYISO Electric System Planning Working Group Meeting

April 18, 2018, 10:00 a.m.–4:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: *http://www.nyiso.com/public/committees/documents.jsp?com=bic_espwg&directory=2018-04-18.*

NYISO Management Committee Meeting

April 25, 2018, 10:00 a.m.–2:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: *http://www.nyiso.com/public/committees/documents.jsp?com=mc&directory=2018-04-25.*

NYISO Electric System Planning Working Group Meeting

April 30, 2018, 10:00 a.m.–4:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: *http://www.nyiso.com/public/committees/documents.jsp?com=bic_espwg&directory=2018-04-30.*

The discussions at the meetings described above may address matters at issue in the following proceedings:

New York Independent System Operator, Inc., Docket No. ER13–102.

New York Independent System Operator, Inc., Docket No. ER15–2059.

New York Independent System Operator, Inc., Docket No. ER17–2327.

For more information, contact James Eason, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (202) 502–8622 or *James.Eason@ferc.gov.*

Dated: March 26, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–06578 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR18–19–000]

Green River Devco LP; Notice of Request for Temporary Waiver

Take notice that on March 23, 2018, pursuant to Rule 204 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.204, Green River Devco LP filed a petition for temporary waiver of the tariff filing and reporting requirements of sections 6 and 20 of the Interstate Commerce Act and parts 341 and 357 of the Commission's regulations with respect to a crude petroleum gathering system it owns in Weld County, Colorado, as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on April 6, 2018.

Dated: March 27, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–06646 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–1160–000]

NRG Cottonwood Tenant LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of NRG Cottonwood Tenant LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 12, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 23, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–06619 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–3643–000.

Applicants: PacifiCorp.

Description: Report Filing: FERC Audit Refund Report to be effective N/A.

Filed Date: 3/23/18.

Accession Number: 20180323–5024.

Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: ER17–419–005.
Applicants: Transource Pennsylvania, LLC, Transource Maryland, LLC, PJM Interconnection, L.L.C.
Description: Compliance filing: Transource PA and MD submit Amendments to 1/1/18 Compliance Filing in ER17–419 to be effective 2/1/2017.
Filed Date: 3/23/18.
Accession Number: 20180323–5115.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: ER18–836–000.
Applicants: Energia Sierra Juarez 2 U.S., LLC.
Description: Supplement to February 9, 2018 Energia Sierra Juarez U.S. 2, LLC tariff filing (Corrected Attachment B).
Filed Date: 3/22/18.
Accession Number: 20180322–5291.
Comments Due: 5 p.m. ET 4/2/18.

Docket Numbers: ER18–1162–000.
Applicants: Orange and Rockland Utilities, Inc.
Description: § 205(d) Rate Filing: Attachment J—Municipal Underground Surcharge Revision to be effective 4/1/2018.
Filed Date: 3/22/18.
Accession Number: 20180322–5281.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER18–1163–000.
Applicants: Avista Corporation.
Description: § 205(d) Rate Filing: Avista Corp NITSA SA T–1092 Low Voltage Facilities Revisions to be effective 4/1/2018.
Filed Date: 3/23/18.
Accession Number: 20180323–5025.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: ER18–1165–000.
Applicants: Shoreham Solar Commons LLC.
Description: § 205(d) Rate Filing: Amendments to MBR Tariff to Reflect Affiliation to be effective 3/7/2018.
Filed Date: 3/23/18.
Accession Number: 20180323–5027.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: ER18–1166–000.
Applicants: Wisconsin Public Service Corporation.
Description: § 205(d) Rate Filing: Filing of Amended and Restated Service Agreement with MG&E to be effective 1/1/2018.
Filed Date: 3/23/18.
Accession Number: 20180323–5091.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: ER18–1167–000.
Applicants: Nevada Power Company.
Description: Compliance filing: OATT Revisions Attachments N–v6 and O–v8 to be effective 5/15/2018.
Filed Date: 3/23/18.
Accession Number: 20180323–5097.
Comments Due: 5 p.m. ET 4/13/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 23, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–06621 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC18–75–000.
Applicants: Stuttgart Solar, LLC.
Description: Application of Stuttgart Solar, LLC for Authorization under Section 203 of the Federal Power Act.
Filed Date: 3/23/18.
Accession Number: 20180323–5194.
Comments Due: 5 p.m. ET 4/13/18.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG18–64–000.
Applicants: SP Sandhills Solar, LLC.
Description: Self-Certification of EG or FC of SP Sandhills Solar, LLC.
Filed Date: 3/23/18.
Accession Number: 20180323–5159.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: EG18–65–000.
Applicants: SP Butler Solar, LLC.
Description: Self-Certification of EG or FC of SP Butler Solar, LLC.
Filed Date: 3/23/18.
Accession Number: 20180323–5160.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: EG18–66–000.
Applicants: SP Pawpaw Solar, LLC.
Description: Self-Certification of EG or FC of SP Pawpaw Solar, LLC.
Filed Date: 3/23/18.
Accession Number: 20180323–5161.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: EG18–67–000.
Applicants: SP Decatur Parkway Solar, LLC.
Description: Self-Certification of EG or FC of SP Decatur Parkway Solar, LLC.
Filed Date: 3/23/18.
Accession Number: 20180323–5162.
Comments Due: 5 p.m. ET 4/13/18.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1437–006.
Applicants: Tampa Electric Company.
Description: Supplement to June 30, 2017 Triennial Market Power Update for the Southeast Region [Exhibit TEC11] of Tampa Electric Company.
Filed Date: 3/22/18.
Accession Number: 20180322–5304.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER10–2465–010; ER11–2657–011; ER11–2107–015; ER11–2108–015.
Applicants: Milford Wind Corridor Phase I, LLC., Milford Wind Corridor Phase II, LLC., North Community Turbines LLC., North Wind Turbines LLC.
Description: Notice of Non-Material Change in Status of Milford Wind Corridor Phase I, LLC., et al.
Filed Date: 3/22/18.
Accession Number: 20180322–5306.
Comments Due: 5 p.m. ET 4/12/18.

Docket Numbers: ER17–775–003.
Applicants: PJM Interconnection, L.L.C.
Description: Compliance filing: Further Compliance Filing Pursuant to 2/21/18 Order in Docket No. ER17–775 to be effective 5/11/2017.
Filed Date: 3/23/18.
Accession Number: 20180323–5158.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: ER18–1168–000.
Applicants: New York Independent System Operator, Inc.
Description: § 205(d) Rate Filing: NYISO 205 filing re: market party fuel cost adjustments to be effective 5/23/2018.
Filed Date: 3/23/18.
Accession Number: 20180323–5148.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: ER18–1169–000.
Applicants: California Independent System Operator Corporation.
Description: § 205(d) Rate Filing: 2018–03–23 Commitment Cost Enhancements Phase 3 Amendment to be effective 11/1/2018.
Filed Date: 3/23/18.
Accession Number: 20180323–5168.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: ER18–1170–000.
Applicants: NSTAR Electric Company.
Description: § 205(d) Rate Filing: Transfer Agreement between NSTAR and NEMC for the transfer of CMEEC's Use Rights to be effective 5/23/2018.
Filed Date: 3/23/18.
Accession Number: 20180323–5173.
Comments Due: 5 p.m. ET 4/13/18.

Docket Numbers: ER18–1171–000.
Applicants: Tampa Electric Company.
Description: § 205(d) Rate Filing: LGIA IRS Update to be effective 3/27/2018.
Filed Date: 3/26/18.
Accession Number: 20180326–5109
Comments Due: 5 p.m. ET 4/16/18.

Docket Numbers: ER18–1172–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: GIA & DSA Santa Ana Storage Project SA Nos. 1006–1007 to be effective 3/14/2018.
Filed Date: 3/26/18.
Accession Number: 20180326–5114
Comments Due: 5 p.m. ET 4/16/18.

Docket Numbers: ER18–1173–000.
Applicants: Midcontinent Independent System Operator.
Description: § 205(d) Rate Filing: 2018–03–26_Enhance Locational Aspect of Resource Adequacy Construct to be effective 5/30/2018.
Filed Date: 3/26/18.
Accession Number: 20180326–5174.
Comments Due: 5 p.m. ET 4/16/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 26, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–06575 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP18–116–000]

Texas Gas Transmission, LLC; Notice of Application

Take notice that on March 14, 2018, Texas Gas Transmission, LLC (Texas Gas), 9 Greenway Plaza, Suite 2800, Houston, Texas 77046, filed in Docket No. CP18–116–000, an application pursuant to section 7(b) of the Natural Gas Act (NGA) requesting to abandon approximately 11.0 miles of its 16-inch-diameter North Lake Pagie pipeline and approximately 5.7 miles of its 16-inch-diameter Bay Junop-Bay Round pipeline, including all appurtenant and auxiliary facilities. The facilities are located approximately 22.1 miles southwest of Houma, Louisiana, extending offshore in Terrebonne Parish, Louisiana, as part of Texas Gas' Southeast Supply Lateral, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application may be directed to Juan Eligio Jr, Supervisor of Regulatory Affairs, Texas Gas Transmission, LLC, 9 Greenway Plaza, Suite 2800, Houston, Texas 77046, by telephone at (713) 479–3480, by fax at (713) 479–1818, or by email at *Juan.Eligio@bwpmlp.com.*

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.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit seven copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right

to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on April 17, 2018.

Dated: March 27, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–06648 Filed 3–30–18; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 30, 2018.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *TYME Bancshares, Inc., Dallas, Texas;* to become a bank holding company by acquiring 100 percent of Groom Bancshares, Inc., and therefore indirectly acquire The State National Bank, both of Groom, Texas.

Board of Governors of the Federal Reserve System, March 28, 2018.

Ann Misback,

Secretary of the Board.

[FR Doc. 2018–06602 Filed 3–30–18; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or to Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 17, 2018.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23219. Comments can also be sent electronically to or *Comments.applications@rich.frb.org:*

1. *First Bankshares, Inc., Barboursville, West Virginia;* to engage through a subsidiary, Community Mortgage Network, Inc., Huntington, West Virginia, in extending credit and servicing loans pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, March 28, 2018.

Ann Misback,

Secretary of the Board.

[FR Doc. 2018–06601 Filed 3–30–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC and the Health Resources and Services Administration (HRSA), announce the following meeting for the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT). This meeting is open to the public, limited only by 100 room seating and 100 ports for audio phone lines. Time will be available for public comment. The public is welcome to submit written comments in advance of the meeting. Comments should be submitted in writing by email to the contact person listed below. The deadline for receipts is Monday, May 7, 2018. Persons who desire to make an oral statement, may request it at the time of the public comments period on May 9, 2018 at 4:15 p.m. EDT. This meeting is accessible by web conference: 1–877–603–4228, Participant code: 42598858.

DATES: The meeting will be held on May 9, 2018, 8:30 a.m. to 5:00 p.m., EDT and May 10, 2018, 8:30 a.m. to 12:00 p.m., EDT.

ADDRESSES: CDC Corporate Square, Building 8, Conference Room 1–ABC, 8 Corporate Boulevard, Atlanta, Georgia 30329.

FOR FURTHER INFORMATION CONTACT: Margie Scott-Cseh, Committee Management Specialist, CDC, 1600 Clifton Road NE, Mailstop: E–07, Atlanta, Georgia 30333, telephone (404) 639–8317; *zkr7@cdc.gov*

SUPPLEMENTARY INFORMATION:

Purpose: This committee is charged with advising the Director, CDC and the Administrator, HRSA, regarding activities related to prevention and control of HIV/AIDS, Viral Hepatitis and other STDs, the support of health care services to persons living with HIV/AIDS, and education of health professionals and the public about HIV/AIDS, Viral Hepatitis and other STDs.

Matters To Be Considered: The agenda will include discussions on (1) HIV, Viral Hepatitis, and Sexually Transmitted Disease consequences of

the opioid crisis; (2) Perspectives on, and experiences with, syringe services program (SSP); (3) Continued discussion on HIV transmission risk in the context of Antiretroviral Therapy (ART) use and Viral Suppression (Treatment as Prevention or TasP); (4) Anti-bullying policies in schools; and (5) Updates from Workgroups. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2018–06547 Filed 3–30–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Office of Infectious Diseases (BSC, OID)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, Office of Infectious Diseases (BSC, OID). This meeting is open to the public, limited only by the space available; the meeting room will accommodate up to 100 people. The public is also welcome to listen to the meeting by telephone, limited only by the number of ports available (50); the toll-free dial-in number is 1–888–998–7892, with a pass code of 1252535.

DATES: The meeting will be held on May 2, 2018, 8:30 a.m. to 5:00 p.m., EDT, and May 3, 2018, 8:30 a.m. to 12:00 p.m., EDT.

ADDRESSES: CDC, Global Communications Center, 1600 Clifton Road NE, Building 19, Auditorium B1/B2, Atlanta, Georgia 30329; also 1–888–998–7892.

FOR FURTHER INFORMATION CONTACT: Sarah Wiley, MPH, Designated Federal Officer, OID, CDC, 1600 Clifton Road NE, Mailstop D10, Atlanta, Georgia 30329, Telephone (404) 639–4840; *sed5@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The BSC, OID, provides advice and guidance to the Secretary, Department of Health and Human Services; the Director, CDC; the Director, OID; and the Directors of the National Center for Immunization and Respiratory Diseases, the National Center for Emerging and Zoonotic Infectious Diseases, and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC, in the following areas: Strategies, goals, and priorities for programs; research within the national centers; and overall strategic direction and focus of OID and the national centers.

Matters To Be Considered: The agenda will include discussions on priority issues for the national centers, including influenza, foodborne infections, antimicrobial resistance, and viral hepatitis, as well as public health workforce development. A report back from the Board's Infectious Disease Laboratory Working Group will also be given. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2018–06545 Filed 3–30–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Office of Public Health Preparedness and Response, (BSC, OPHPR)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, Office of Public Health Preparedness and Response, (BSC, OPHPR). This meeting is open to the public, limited only by the room seating. The meeting room accommodates up to 80 people. Public participants should pre-register for the meeting as described below. Members of the public that wish to attend this meeting in person should pre-register by submitting the following information by email, facsimile, or phone (see Contact Person for More Information) no later than 12:00 noon (EDT) on Wednesday, May 2, 2018:

- Full Name
- Organizational Affiliation
- Complete Mailing Address
- Citizenship
- Phone Number or Email Address

The public is also welcome to listen to the meeting by via Adobe Connect. Pre-registration is required by clicking the links below.

WEB ID: May 9, 2018 (100 Seats) *https://adobeconnect.cdc.gov/e9teo9x7k41/event/registration.html.*

WEB ID: May 10, 2018 (100 Seats) *https://adobeconnect.cdc.gov/e2jt3r7tvlj/event/registration.html.*

Dial in number: 800–857–9618; Participant code: 6838980. (100 Seats).

DATES: The meeting will be held on May 9, 2018, 10:00 a.m.–5:30 p.m., EDT and May 10, 2018, 8:30 a.m.–3:30 p.m., EDT.

ADDRESSES: Centers for Disease Control and Prevention (CDC), Global Communications Center, Building 19, Auditorium B3, 1600 Clifton Road NE, Atlanta, Georgia 30329.

FOR FURTHER INFORMATION CONTACT: Dometa Ouisley, Office of Science and Public Health Practice, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop D–44, Atlanta, Georgia 30329, Telephone: (404) 639–7450; Facsimile: (404) 471–8772; Email: *OPHPR.BSC.Questions@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: This Board is charged with providing advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health (ASH), the Director, Centers for Disease Control and Prevention (CDC), and the Director, Office of Public Health Preparedness and Response (OPHPR), concerning strategies and goals for the programs and research within OPHPR, monitoring the overall strategic direction and focus of the OPHPR Divisions and Offices, and administration and oversight of peer review for OPHPR scientific programs. For additional information about the Board, please visit: *http://www.cdc.gov/phpr/science/counselors.htm.*

Matters To Be Considered: The agenda will include discussions on Day one of

the meeting that will cover briefings and BSC deliberation on the following topics: Interval updates from the OPHPR Director and OPHPR Divisions and Offices; updates from the Biological Agent Containment working group; discussion of Industry, Private Sector, and Public Health Interactions Supporting Emergency Preparedness and Response; and Preparedness Updates from Liaison Representatives.

Day two of the meeting will cover briefings and BSC deliberation on the following topics: OPHPR Office of Policy, Planning and Evaluation activities; CDC's Data Preparedness activities; Public Health System Perspectives on Hurricanes Response; and Excellence in Response Operations Initiative. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2018–06546 Filed 3–30–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10191]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by *June 1, 2018.*

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs Division of Regulations Development Attention: Document Identifier/OMB Control Number __ Room C4–26–05 7500 Security Boulevard Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10191 Medicare Parts C and D Program Audit and Timeliness Monitoring Data Requests

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Parts C and D Program Audit and Timeliness Monitoring Data Requests; *Use:* Medicare Part D plan sponsors and Medicare Advantage organizations (collectively referred to as sponsoring organizations) are required to comply with all Medicare Parts C and D program requirements. In 2010, the explosive growth of these sponsoring organizations precipitated the need for CMS to develop an annual audit strategy to ensure that we evaluate sponsoring organizations compliance with the program requirements. In addition to describing how sponsoring organizations are selected for audit and which program areas will be audited, CMS' annual audit strategy reflected a move to a more targeted, data-driven, and risk-based audit approach. Since 2010, CMS has continued to focus on assisting the industry with improving their operations to ensure beneficiaries receive appropriate access to care. CMS has developed audit protocols that focus on high-risk areas that have the greatest potential for beneficiary harm.

CMS' program audit protocols are posted to the CMS website each year for use by sponsoring organizations to prepare for their audit. Currently CMS utilizes the following 5 protocols to audit sponsoring organizations' performance: Compliance Program Effectiveness (CPE), Formulary Administration (FA); Coverage Determinations, Appeals, and Grievances (CDAG); Organization Determinations, Appeals, and Grievances (ODAG), Special Needs Program Model of Care (SNP–MOC) (only administered on organizations who operate SNPs). Beginning in audit

year 2019, the SNP–MOC program area has been more accurately renamed Special Needs Program Care Coordination Quality Improvement Performance Evaluation (SNP–CCQIPE). In addition, the Medication Therapy Management (MTM) pilot protocol has been suspended until further notice. For that reason, it is no longer posted to the CMS website.

Beginning in audit year 2019, the data collected via program-specific record layouts, and collected via impact analyses on an as-needed basis, will be consolidated into each program area data request document. The pre-audit issue summary was updated for technical terminology changes. Three of the questionnaires and the power point template that previously have been distributed as part of our CPE audits will remain. However, the CPE self-assessment questionnaire and the CDAG and ODAG questionnaires have been removed. We have added new questionnaires for FA and SNP–CCQIPE. A revised template for collecting root cause analyses from organizations on an as-needed basis during the program audit has been included in this package.

We have also included a new independent validation audit work plan template that will be collected from sponsors that are required to undergo an independent validation audit. The validation audit is part of our robust audit process where CMS requires sponsoring organizations that have been audited and found to have deficiencies to undergo a validation audit to ensure correction. The validation audit utilizes the same audit protocols, but only tests the elements where deficiencies were found, as opposed to re-administering the entire audit. This validation audit work plan template will be populated by the sponsoring organization's independent auditing firm to describe how it plans to test for correction of the deficiencies identified during the program audit.

To assist in improving the audit process, we have also included an audit feedback questionnaire that is representative of the survey link we send to sponsoring organizations at the end of each program audit. Completion of this questionnaire is optional for sponsoring organizations to provide feedback on the audit process.

The proposed changes to each data collection instrument, along with the new FA and SNP–CCQIPE questionnaires, root cause template, validation audit work plan template and audit feedback questionnaire are included in the posted PRA package.

Finally, separate from the audit process and in order to address sponsoring organizations' concerns regarding undue harm in Star Ratings during audit years. The number of sponsoring organizations that are required to submit universes annually for their coverage/organization determinations and appeals increased. In 2016, CMS expanded this annual collection to all MA and Part D sponsoring organizations. The universes are submitted in the same format as required for audits under the Part D CDAG protocol and the Part C ODAG protocol. The universes are then analyzed for timeliness on an annual basis, across all sponsoring organizations, to allow a more comprehensive review of the accuracy of Part C and D appeals data to calculate Star Ratings. *Form Number:* CMS–10191 (OMB control number: 0938–1000); *Frequency:* Yearly; *Affected Public:* Private Sector (business or other for-profit and not-for-profit institutions); *Number of Respondents:* 166; *Total Annual Responses:* 211; *Total Annual Hours:* 51,548. (For policy questions regarding this collection contact Brenda Hudson at 443–743–9299.)

Dated: March 28, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–06645 Filed 3–30–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; Older American Act Title III and Title VII (Chapters 3 and 4) Annual State Program Reporting (Annual Performance Data Collection); This is a Revision to the Existing State Program Report (OMB Approval 0985–0008)

AGENCY: Administration for Community Living (ACL), HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to annual performance data from State grantees under the Older Americans Act related to Title III and Title VII (Chapters 3 and 4) of that act. Title III includes, for example, home delivered and congregate meal services, transportation and caregiver service; and Title VII includes Elder Abuse Prevention and Legal Assistance Development (ICR Rev).

DATES: Submit written comments on the collection of information by May 2, 2018.

ADDRESSES: Submit written comments on the collection of information by:

(a) *Email to: OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL;

(b) Fax to 202.395.5806, Attn: OMB Desk Officer for ACL; or

(c) By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: ACL's Office of Performance and Evaluation at *SPRredesign.comments@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. This collection is a revision of the 2016 approved version of the State Program Report and incorporates significant reduction in data collected. This data collection is essential to provide performance measures as required by Congress and the GPRA Modernization Act of 2010 (GPRAMA). Significant revisions to the SPR were last implemented in 2005. This proposed collection is a revision of the currently approved version (effective 2016–2019). The factors that influenced the proposed revision of the SPR, include: (1) The need to modernize the data structure to allow for more efficient reporting and the ability to use current technology for reporting and analysis; (2) the interest in aligning data elements within and across data collections; (3) the need to consider alternative data elements that reflect the current Aging Network and long-term care services and supports; and (4) the need to reduce reporting burden while enhancing data quality. The proposed SPR revision reduces the number of data elements reported by 70% and the amount of time for completion by 30% as compared to the current 2016–2019 SPR. This is a reduction of 874 hours from the previous version.

Reductions in data elements are found throughout the data collection but are concentrated in the consumer demographic components. Due to the aggregate level nature of the SPR, information on combinations of demographic characteristics (*e.g.,* number of women served who are 65 years or older and have 2 activity of daily living limitations) require exponentially larger numbers of data elements compared to single demographic characteristics (*e.g.* number of women served). To reduce the reporting burden associated with the number of data elements ACL is proposing to limit data element combinations. For example, the revised SPR asks for demographic characteristic such as age, race, and gender for three or more ADL and IADLs rather than for zero, one, two and three or more ADLs and IADLs. The remaining proposed demographic data elements include indicators of priority populations (*i.e.,* social and economic vulnerability and frailty) found in the OAA and will allow ACL to continue to measure efforts to target services.

Limited expansions in data elements are found in the Title III–E National Family Caregiver Support Program service component. The proposal separates out three service areas that were reported as a whole (*i.e.,* counseling, training and support group services). Separation allows for support group services to be categorized as a non-registered service for which consumer demographic details are no longer reported. Additional information regarding the types of respite services provided under the OAA is sought. The proposal separates assistance services into two types: (1) Case management, and (2) information and assistance. Case management assistance services are categorized as registered, meaning caregiver demographic data are reported while information and assistance services do not include reporting of demographic data. Supplemental services are reported in the same manner as ''other service'' under Title III–B, Home and Community-based Services (HCBS) program. Across the OAA services, greater detail regarding expenditure data is proposed. Under Title III–B, HCBS program, the proposed data collection expands data regarding Title VII legal assistance services. The ACL seeks data on the OAA identified priority legal issues for closed cases.

Comments in Response to the 60-Day *Federal Register* Notice

A 60-day **Federal Register** Notice was published in the **Federal Register** on June 1, 2017, Vol. 82, No. 104, pp. 25293–25294.

ACL received comments from fourteen (14) organizations and one (1) individual about the State Performance Report (SPR) redesign. ACL reviewed all of the comments, but some of the comments were deemed not relevant because they were: (a) About the data submission process itself (b) did not request a change (c) only commented on the format (d) indicated topics for technical assistance and training for the final data collection or (e) provided commentary without referencing the SPR. Regarding concerns about the:

- Timeline-ACL proposes moving the effective date back by 12 months,
- Cost, burden, and changes to data elements-ACL recognizes that there is always a cost to changing data systems, but believes that the anticipated improvement in the data justifies the proposed changes,
- New items related to Legal Services-ACL worked closely with program staff and stakeholders to develop a reasonable data collection to measure the contribution of this important program about which performance data were not previously collected,
- Need for additional elements including sub-state and individual level data-ACL is not adding more elements or more granular data collection at this time but will consider those suggestions for future data collections,
- Need for improved definitions and language-ACL made several changes to specific elements and is using these comments to inform the training and technical assistance it provides, and
- Caregiver program-ACL made revisions to several items and is using these comments to inform the training and technical assistance it provides.

A detailed analysis of the comments and responses can be found at (*https://www.reginfo.gov/public/do/PRAMain.*

The proposed data collection template may be found on the ACL website at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: ACL estimates the burden of this collection of information as follows: 56 State Agencies on Aging respond annually and it will take an average of 33.5 hours for a total of 1,876 hours. This is a reduction of 874 hours from the previous version. The burden estimate of 33.5 hours was derived from feedback from grantees.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Older American Act Title III and Title VII (Chapters 3 and 4) Annual State Program Reporting	56	1	33.5	1,876
Total	56	1	33.5	1,876

Dated: March 26, 2018.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2018–06662 Filed 3–30–18; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1010]

Food and Drug Administration Prescription Drug User Fee Act VI Benefit-Risk Implementation Plan; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft 5-year plan describing the Agency's approach to further the implementation of structured benefit-risk assessment, including the incorporation of the patient's voice in drug development and decision-making, in the human drug review program and the opportunity for public comment on the draft plan. This new draft plan is an update to the 5-year plan published in February 2013 on FDA's website. This new draft plan is

part of FDA's commitments that were made as part of the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI). FDA has published the draft plan on its website.

DATES: Submit either electronic or written comments by June 1, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 1, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of June 1, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–1010 for ''Food and Drug Administration Prescription Drug User Fee Act VI Benefit-Risk Implementation Plan; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 301–796–5003, Fax: 301–847–8443, *Graham.Thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft 5-year plan describing the Agency's approach to further the implementation of structured benefit-risk assessment into human drug and biologics review. This draft plan is intended to meet a performance goal included in the sixth authorization of PDUFA (PDUFA VI). This reauthorization, part of the FDA Reauthorization Act of 2017 signed by the President on August 18, 2017, includes a number of performance goals and procedures that are documented in the PDUFA VI Commitment Letter, which is available at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.*

This new draft plan is an update to the 5-year plan published in February 2013 on FDA's website: *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf.*

FDA's commitments to meet certain performance goals under PDUFA VI were developed in consultation with patient and consumer advocates, health care professionals, and other public stakeholders, as part of negotiations with regulated industry. Section J.2 of the commitment letter, ''Enhancing Benefit-Risk Assessment in Regulatory Decision-Making'' (*https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf*) outlines FDA's commitments in this area, including publication of an update to the implementation plan published in 2013 entitled ''Structured Approach to Benefit-Risk Assessment in Drug Regulatory Decision-Making'' (*https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf*). The update includes a report on the progress made during PDUFA V and a plan for continued implementation during Fiscal Years (FY) 2018–2022. The publication and implementation of this plan are intended to fulfill the commitments described in Section J of the PDUFA VI Commitment Letter.

II. FDA Draft PDUFA VI Benefit-Risk Implementation Plan

Benefit-risk assessment is the foundation for FDA's regulatory review of human drugs and biologics. In PDUFA V, FDA's Center for Drug

Evaluation and Research and Center for Biologics and Research committed to further our efforts to enhance benefit-risk assessment and communication in the human drug review process in FY 2013–2017. Enhancing and communicating benefit-risk assessment continues to be an Agency priority in PDUFA VI. The draft plan describes the progress made on PDUFA V in benefit-risk assessment. This progress includes revision of FDA's review/decision templates and manuals to incorporate FDA's approach to benefit-risk assessment, training review and management of staff on the revised templates and manuals, developing an evaluation plan to ascertain the impact of FDA's implementation of the Benefit-Risk Framework in drug review, holding two public workshops on benefit-risk considerations from the regulator's perspective, and advancing FDA's Patient-Focused Drug Development initiative. This draft plan also summarizes the third-party evaluation of FDA's implementation of the Benefit-Risk Framework into FDA's new drug review.

The plan also includes an overview of FDA's commitments in PDUFA VI for continued implementation of structured benefit-risk assessment during FY 2018–2022. These commitments include participating in a meeting to gather stakeholder input on key topics, publishing a draft guidance on benefit-risk assessment for new drugs and biologics, continuing to revise relevant Manuals for Policies and Procedures and Standard Operating Practices and Procedures to incorporate benefit-risk assessment approaches, and conducting a second evaluation of the implementation of the Benefit-Risk Framework beginning in 2021. In addition to these commitments, FDA also plans to explore additional opportunities to enhance our use and communication of benefit-risk assessments.

III. Electronic Access

FDA has published the draft plan on its website: *https://www.fda.gov/ForIndustry/UserFees/Prescription DrugUserFee/ucm326192.htm.* The period for public comment on the draft plan will remain open for 60 days following the publication of this notice. After consideration of public comments, FDA will finalize the plan. Throughout PDUFA VI, the Agency will update the plan as necessary and post all updates on FDA's website.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06531 Filed 3–30–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0369]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Under the Federal Import Milk Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements of our regulations implementing the Federal Import Milk Act (FIMA).

DATES: Submit either electronic or written comments on the collection of information by June 1, 2018.

ADDRESSES: You may submit comments as follows: Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 1, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of June 1, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2012–N–0369 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations under the Federal Import Milk Act.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available

for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Regulations Under the Federal Import Milk Act (FIMA)—21 CFR Part 1210

OMB Control Number 0910–0212—Extension

Under FIMA (21 U.S.C. 141–149), milk or cream may be imported into the United States only by the holder of a valid import milk permit (21 U.S.C. 141). Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50 °F (21 U.S.C. 142).

Our regulations in part 1210 (21 CFR part 1210), implement the provisions of FIMA. Sections 1210.11 and 1210.14 require reports on the sanitary conditions of, respectively, dairy farms and plants producing milk and/or cream to be shipped to the United States. Section 1210.12 requires reports on the physical examination of herds, while § 1210.13 requires the reporting of tuberculin testing of the herds. In addition, the regulations in part 1210 require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22). Section 1210.20 requires that an application for a permit to ship or transport milk or cream into the United States be made by the actual shipper. Section 1210.23 allows permits to be granted based on certificates from accredited officials.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1210.11	1996/Farm Inspection Report	2	200	400	1.5	600
1210.12	1995/Report of Physical Examination of Cows.	1	1	1	.5 (30 minutes)	.5
1210.13	1994/Report of Tuberculin Tests of Cattle	1	1	1	.5 (30 minutes)	.5
1210.14	1997/Score Card for Sanitation Inspections of Milk Plants.	2	1	2	2	4
1210.20	1993/Application for Permit to Ship or Transport Milk and/or Cream into US.	2	1	2	.5 (30 minutes)	1
1210.23	1815/Certificate/Transmittal for an Application.	2	1	2	.5 (30 minutes)	1
Total						607

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1210.15	2	1	2	.05 (3 minutes)	.10 (6 minutes)

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Upon review of the information collection, we have retained the currently approved estimated burden. The estimated number of respondents and hours per response are based on our experience with the import milk permit program and the average number of import milk permit holders over the past 3 years. Assuming two respondents will submit approximately 200 Form FDA 1996 reports annually for a total of 600 responses, and that each response requires 1.5 hours, we estimate the total burden is 600 hours.

The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FDA 1994 and 1995. To date, Form FDA 1815 has been submitted in lieu of these forms. Because we have not received any Forms FDA 1994 or 1995 in the last 3 years, we assume no more than one will be submitted annually. We also assume each submission requires 0.5 hour for a total of 0.5 burden hour annually.

We estimate that two respondents will submit one Form FDA 1997 report annually, for a total of two responses. We estimate the reporting burden to be 2.0 hours per response, for a total burden of 4 hours. We estimate that two respondents will submit one Form FDA 1993 report annually, for a total of two responses. We estimate the reporting burden to be 0.5 hour per response, for a total burden of 1 hour. We estimate that two respondents will submit one Form FDA 1815 report annually, for a total of two responses. We estimate the reporting burden to be 0.5 hour per response, for a total burden of 1 hour.

With regard to records maintenance, we estimate that approximately two recordkeepers will spend 0.05 hour annually maintaining the additional pasteurization records required by § 1210.15, for a total of 0.10 hour annually.

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by us (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not subject to review by the Office of Management and Budget under the Paperwork Reduction Act. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of business activities.

Dated: March 27, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06595 Filed 3–30–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0549]

Prescription Polyethylene Glycol 3350; Denial of a Hearing and Order Withdrawing Approval of Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Commissioner of Food and Drugs (the Commissioner) is denying requests for a hearing and issuing an order withdrawing approval of abbreviated new drug applications (ANDAs) for certain prescription laxatives with the active ingredient polyethylene glycol 3350 (PEG 3350), listed in this document, because the drug products are misbranded under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: This order is applicable May 2, 2018.

ADDRESSES: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Julie Finegan, Office of Scientific Integrity, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4218, Silver Spring, MD 20993–0002, 301–796–8618.

SUPPLEMENTARY INFORMATION:

I. Background

A. Procedural Background

On February 18, 1999, the U.S. Food and Drug Administration (FDA or the Agency) approved a new drug application (NDA) submitted by Braintree Laboratories, Inc., (Braintree) for prescription (or ''Rx'') PEG 3350 (MiraLAX) (NDA 20–698). Subsequently, FDA approved five ANDAs for prescription PEG 3350.[1] On October 6, 2006, FDA approved a new NDA (NDA 22–015) submitted by Braintree, removing their PEG 3350 laxative drug product from prescription dispensing requirements of section 503(b) of the FD&C Act (21 U.S.C. 353(b)).[2]

Section 503(b)(1) of the FD&C Act requires that a drug which: (1) Because

[1] The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the Hatch-Waxman Amendments) created new section 505(j) of the FD&C Act, which established the current ANDA approval process. To obtain approval, an ANDA applicant is not required to submit evidence to establish the clinical safety and effectiveness of the drug product; instead, an ANDA relies on FDA's previous finding that the reference listed drug is safe and effective. To rely on a previous finding of safety and effectiveness, an ANDA applicant must demonstrate, among other things, that the drug product described in an ANDA has the same active ingredient(s), indications for use, route of administration, dosage form, strength, and labeling as the reference listed drug (section 505(j)(2)(A)(i)–(v) and (j)(4) of the FD&C Act). In addition, the ANDA applicant must submit evidence that its proposed drug product is bioequivalent to the reference listed drug (section 505(j)(2)(A)(iv) of the FD&C Act).

[2] On October 10, 2008, Braintree requested that FDA withdraw approval of the NDA for prescription MiraLAX (NDA 20–698) under 21 CFR 314.150(c) because it had stopped marketing the product. On February 11, 2009, FDA withdrew approval of the NDA for prescription MiraLAX in a **Federal Register** notice (effective March 13, 2009)(74 FR 6896 at 6899 (February 11, 2009)).

of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug or (2) is limited by an approved application under section 505 of the FD&C Act (21 U.S.C. 355) to use under the professional supervision of a practitioner licensed by law to administer such drug, be dispensed only upon prescription of a practitioner licensed to administer such drug. Under section 503(b)(4)(B) of the FD&C Act, a drug, to which the prescription dispensing provisions of section 503(b)(1) do not apply, shall be deemed to be misbranded if at any time prior to dispensing, the label of the drug bears the ''Rx only'' symbol.

Likewise, at section 503(b)(4)(A), drugs that are subject to the prescription dispensing provisions of section 503(b)(1) must bear the ''Rx only'' symbol; if not, they would be misbranded. These provisions mean that nonprescription (over-the-counter (OTC)) drugs must not bear the ''Rx only'' symbol and prescription drugs must bear the ''Rx only'' symbol; otherwise, they each would be misbranded. FDA has long interpreted these provisions to mean that section 503(b) of the FD&C Act does not permit the same active ingredient to be simultaneously marketed in both a prescription drug product and a nonprescription drug product, unless a meaningful difference exists between the two that makes the prescription product safe only under the supervision of a licensed practitioner.[3]

FDA's regulation at § 310.200 (21 CFR 310.200) sets forth the procedure for exempting a drug approved for prescription use from the prescription dispensing requirements of section 503(b)(1)(B) of the FD&C Act. A drug limited to prescription use under section 503(b)(1)(B) shall be exempt from the prescription dispensing requirements if FDA determines that the prescription dispensing requirements are ''not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and [FDA] finds that the drug is safe and effective for use in self-medication as directed in proposed labeling.'' (See § 310.200(b).) In this instance, based on studies submitted by the sponsor, FDA determined that the original prescription MiraLAX product no longer met the criteria in section 503(b)(1) of the FD&C Act for prescription use. Therefore, FDA changed MiraLAX's status from prescription to nonprescription (commonly referred to as an ''Rx to OTC switch''). When FDA concludes, as it did with MiraLAX, that no prescription indications remain, FDA describes the Rx to OTC switch as a ''full'' or ''complete'' switch. The Braintree product continued to use the trade name MiraLAX when it switched from prescription to nonprescription.

Due to this change in MiraLAX's status from prescription to nonprescription, in an April 20, 2007, letter to the ANDA holders, FDA noted that the approved ANDAs were based on a reference listed drug (RLD) with labeling for prescription only use (NDA 20–698) and that MiraLAX had recently switched from ''Rx-only'' to OTC marketing. FDA explained that the FD&C Act does not permit both prescription and nonprescription versions of the same drug product to be marketed at the same time. The Agency notified the PEG 3350 ANDA holders that their prescription products, which bear the ''Rx only'' symbol, are misbranded and may not be lawfully marketed. FDA explained that if the ANDA holders wished to continue marketing PEG 3350, they may not do so pursuant to the ANDAs referencing prescription MiraLAX. FDA informed the ANDA holders that they must file new ANDAs referencing NDA 22–015 and the new ANDAs must include the same OTC labeling as the RLD. FDA also explained that under section 505(j)(2)(D)(i) of the FD&C Act, the ANDA holders were not permitted to supplement their ANDAs to reference NDA 22–015, which was not the RLD identified in their ANDAs. The ANDA holders did not seek voluntary withdrawal of their applications.

In the **Federal Register** of October 24, 2008 (73 FR 63491), the Center for Drug Evaluation and Research (CDER) published a notice of opportunity for a hearing (NOOH) proposing to withdraw approval of the ANDAs for drug products containing the active ingredient, PEG 3350, approved for prescription use. Schwarz Pharma Inc. (Schwarz), ANDA 76–652; Paddock Laboratories, Inc. (Paddock), ANDA 77–893; Gavis Pharmaceuticals, LLC (Gavis), ANDA 77–736; and Nexgen Pharma Inc. (Nexgen), ANDA 77–706 (collectively, the ''ANDA holders''), each submitted timely requests for a hearing and each submitted evidence in support of their requests. Teva Pharmaceutical Industries, Ltd., now Teva Pharmaceuticals USA, (Teva), ANDA 77–445, did not submit a request for a hearing. Teva's Rx PEG 3350 product has been discontinued. On May 22, 2014, consistent with § 314.200(g)(3) (21 CFR 314.200(g)(3)), CDER served upon the ANDA holders a proposed order denying their requests for hearing and withdrawing approvals of their ANDAs and providing the ANDA holders 60 days to respond with sufficient data, information, and analysis to demonstrate that there is a genuine and substantial issue of fact that justifies a hearing. CDER subsequently extended this 60-day deadline. Breckenridge Pharmaceutical Inc. (Breckenridge) (ANDA 77–736); Kremer's Urban Pharmaceuticals, Inc. (Kremer's) (ANDA 76–652); Nexgen; and Paddock submitted objections to the proposed order. The Commissioner has reviewed the ANDA holders' objections and is denying their requests for hearing and withdrawing approval of their ANDAs.

B. The October 24, 2008, NOOH

The NOOH proposed the withdrawal of the PEG 3350 ANDAs on the basis of the switch of MiraLAX from Rx to OTC. The NOOH noted that the FD&C Act does not permit both Rx and OTC versions of the same drug product to be marketed at the same time. Under the FD&C Act, a drug to which the prescription dispensing requirements do not apply (*i.e.,* an OTC drug) shall be deemed misbranded if at any time prior to its dispensing, the label of the product bears the ''Rx only'' symbol. The NOOH explained that the ANDA products' labels, which bear the ''Rx only'' symbol, are false or misleading because the same PEG 3350 product was approved for OTC use. The NOOH proposed the withdrawal of the ANDAs under section 505(e) of the FD&C Act.

The Background section of the NOOH described the original approval of prescription MiraLAX and the subsequent approval of the OTC product. The NOOH summarized the two studies that formed the basis for approval of NDA 20–698, the prescription MiraLAX product for the treatment of occasional constipation, as follows:

- Study 851–6 was a double-blind, parallel trial that enrolled 151 subjects who were randomized to placebo or MiraLAX 17 grams (g). The treatment lasted 14 days. The primary efficacy endpoint was bowel movement frequency with success defined as more

[3] In an advanced notice of proposed rulemaking (ANPRM), FDA previously solicited public comment on the factors that it generally would consider in determining whether there is a meaningful difference between prescription and OTC drug products. See ''Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Product'' (70 FR 52050, September 1, 2005).

than 3 bowel movements per 7-day period, and failure defined as fewer than 3 bowel movements per 7-day period, use of a laxative or enema, or withdrawal from the trial. A total of 133 subjects completed this study.

• Study 851–3 was a single-center, double-blind, triple-crossover trial that randomized 50 constipated patients to a first period (10 days) of either 17 or 34 g of MiraLAX therapy. Subsequently, without a washout interval, subjects were randomized to second or third periods (also 10 days) of placebo or the alternate MiraLAX dose. The primary endpoints of efficacy were stool frequency and stool weight. All 50 patients completed the trial. This study helped to define a dose-response for MiraLAX.

TABLE 1—DAYS TO FIRST BOWEL MOVEMENT MIRALAX RX PIVOTAL STUDIES

Study	Measure	Day 1	Day 2	Day 3	Day 4
851–3	Pt w/BM *	23	35	42	45
(n=48)	%	47.9	72.9	87.5	93.8
851–6	Pt w/BM	28	48	59	63
(n=76)	%	36.8	63.2	78.9	84.2

* Pt w/BM = The cumulative number of patients who had at least one bowel movement up to the fourth day of therapy with 17 g MiraLAX daily. For both studies, the majority of patients (72.9% and 63.2%, respectively) had at least one bowel movement by the second day of therapy.

Table 1 illustrates that in both studies submitted to support the prescription MiraLAX NDA at least one-third of subjects taking 17 g of MiraLAX had a bowel movement by Day 1 and at least three-fourths had a bowel movement by Day 3. Based on the results of these studies, a length of treatment of 2 weeks or less was recommended.

To support approval of the nonprescription application for MiraLAX for occasional constipation, Braintree submitted three studies (described in bullets below) evaluating safety and efficacy in adults (including a subset of elderly subjects) for a period longer than the previously approved period of up to 14 days of use. Although nonprescription MiraLAX is indicated for a period of up to 1 week, the submitted long-term studies supported a determination that the product would be safe for use in the OTC setting, where repeated purchase and use may be likely. Subjects who participated in these long-term studies were constipated, but otherwise healthy, adults with no documented organic cause for constipation who met protocol-specified modified Rome Criteria [4] for constipation. The primary endpoint(s) for these three studies were all longer term assessments of safety and effectiveness, not the number of days to first bowel movement.

• 851–CR1: A randomized, double-blind, placebo-controlled, parallel-group, multicenter study of 304 subjects comparing 6 months of treatment with MiraLAX 17 g per day to daily treatment with a matched placebo. Of the patients enrolled in this study 75 (25 percent) were 65 years of age or older. This was an efficacy study in which efficacy was measured by outcomes of more than 3 satisfactory stools per week and the occurrence of one or fewer of the following symptoms: Straining in more than 25 percent of defecations; lumpy or hard stools in more than 25 percent of defecations; or sensation of incomplete evacuation in more than 25 percent of defecations. More than 80 percent of patients in this study experienced a bowel movement within 1 to 3 days of starting therapy.

• 851–ZCC: An open-label, randomized, parallel-arm, multicenter study of constipated adult patients randomized to treatment with either 17 g per day MiraLAX or Zelnorm (tegaserod maleate, indicated for the short-term treatment of women with irritable bowel syndrome whose primary bowel symptom is constipation) for 28 days. This study excluded elderly and male patients because of Zelnorm labeling restrictions. This study demonstrated that MiraLAX is more effective than Zelnorm at treating constipation over a 4-week period. Overall, patients who were having fewer than three bowel movements per week began having approximately one bowel movement per day by weeks 1 and 2.

• 851–CR3: An open-label, extended use, multicenter, single-treatment study of 311 subjects using MiraLAX 17 g per day for 12 months. Of the patients enrolled in this study 117 (38 percent) were 65 years of age or older. This was a 1-year safety study of MiraLAX use, and no placebo arm was included. Patients treated with MiraLAX for up to 12 months achieved similar benefits to those previously reported in shorter studies. According to the self-assessment measure used, 80 to 88 percent of patients (and 84 to 94 percent of elderly patients) rated themselves successfully treated during the course of the study.

According to CDER, after reviewing the results of these studies, FDA determined that the three studies provided evidence that nonprescription MiraLAX could be used by consumers effectively in the OTC setting, concluding that OTC MiraLAX is efficacious for the vast majority of users with constipation within 7 days and generally produces a bowel movement by day 3, and would also be safe if repeatedly used over time. FDA determined that the criteria in section 503(b)(1) of the FD&C Act were no longer met and that the criteria for switching prescription MiraLAX to nonprescription status under § 310.200 were met. Thus, the Agency approved MiraLAX as a nonprescription product for occasional constipation.

As CDER stated in the NOOH, for the prescription and nonprescription versions of PEG 3350 to be lawfully marketed simultaneously, there must be some meaningful difference between the two products (*e.g.,* indication, strength, route of administration, dosage form, patient population) that makes the prescription product safe only under the supervision of a practitioner licensed by law. The NOOH then described the evidence CDER considered in determining that there is no meaningful difference between the prescription and nonprescription versions of the PEG 3350 laxative products.

CDER explained that it determined that there is no meaningful difference between the prescription PEG 3350 ANDA holders' laxative products and the nonprescription MiraLAX product based upon an evaluation of the active ingredient, dosage form, strength, route of administration, indications, and patient population for both versions. As stated in the NOOH, CDER found that

[4] The Rome Criteria is a system developed to classify the functional gastrointestinal disorders (disorders of the digestive system in which symptoms cannot be explained by the presence of structural or tissue abnormality), based on clinical symptoms. Some examples of these types of disorders include irritable bowel syndrome, functional dyspepsia, functional constipation, and functional heartburn. See *https://therome foundation.org/.*

the nonprescription and prescription PEG 3350 products are the same. They have: (1) The same active ingredient, PEG 3350; (2) the same dosage form, a powder for solution; (3) the same strength, a 17g dose in 4 to 8 ounces of liquid; (4) the same route of administration, oral; (5) the same indication, *i.e.* for patients with occasional constipation; and (6) the same patient population, patients that are 17 years of age or older. With regard to any differences in the labeling between the prescription and nonprescription products, CDER concluded that any differences are non-meaningful and are based upon the Agency's practice under the OTC drug monograph system of having consistent labeling for OTC laxative groups. For example, CDER found that the differences in duration of use between the prescription and nonprescription products were not meaningful and were related only to advice from the OTC laxative monograph panel that labeling for a 7-day duration of use helps to promote safety in case the consumer is constipated from a serious condition for which he or she should seek care from a physician. The NOOH noted that the OTC MiraLAX labeling included the phrase ''relieves occasional constipation'' for consistency with other OTC products and to avoid consumer confusion that may result from differences in the indication statement among OTC laxative products. A comparison of the two products' labels is set forth in table 2.

TABLE 2—COMPARISON OF THE PRESCRIPTION AND NONPRESCRIPTION LABELS

	Prescription MiraLAX/PEG 3350	Nonprescription MiraLAX
Indication	For the treatment of occasional constipation	Relieves occasional constipation (irregularity).
Strength	17g	17g.
Route of Administration	For oral administration after dissolution in water. The cap on each bottle is marked with a measuring line and may be used to measure a single MiraLAX dose of 17 g (about one heaping tablespoon).	The bottle top is a measuring cap marked to contain 17g of powder when filled to the indicated line. Stir and dissolve in any 4 to 8 ounces of beverage (cold, hot, or room temperature) then drink.
Dosage Form	Powdered form	Powdered form.
Duration of Use	This product should be used for 2 weeks or less or as directed by a physician.	Use no more than 7 days. Ask a doctor if you need to use a laxative for longer than 1 week.
Effectiveness	Treatment for 2 to 4 days may be required to produce a bowel movement.	Generally produces a bowel movement in 1 to 3 days.
Population	Adults	For adults and children 17 years of age and over.

CDER concluded that, where there is no meaningful difference between nonprescription MiraLAX and the prescription PEG 3350 products, the continued marketing of the same PEG 3350 product could result in the consumer confusion that Congress intended to prevent through section 503(b)(4)(B) of the FD&C Act. CDER reasoned that the display of the Rx-only symbol on the ANDA holders' PEG 3350 products rendered the labeling of those products false or misleading where the same PEG 3350 product was approved for OTC use. Accordingly, CDER concluded that the labeling of the prescription PEG 3350 products is false and misleading, and the products are thus misbranded under section 502 of the FD&C Act (21 U.S.C. 352) because they continue to bear the ''Rx only'' symbol.[5] CDER thus proposed withdrawal of the ANDAs pursuant to section 505(e) of the FD&C Act. Under section 505(e), FDA may, after due notice and an opportunity for a hearing, withdraw the approval of an application submitted under section 505(j) of the FD&C Act if the Secretary finds that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

The NOOH informed the PEG 3350 ANDA holders that if they requested a hearing they would have to present data and information showing that there is a genuine and substantial issue of fact requiring a hearing. The NOOH also stated that if it conclusively appeared from the face of the data, information, and factual analyses submitted in support of a hearing request that there was no genuine and substantial issue of fact precluding the withdrawal of the PEG 3350 ANDAs, or if the requests for a hearing were not made in the required format or with the required analyses, the Commissioner would enter summary judgment against the holders of the PEG 3350 ANDAs, making findings and conclusions, and denying a hearing (73 FR 63491).

II. Statutory and Regulatory Framework Regarding 21 CFR Part 12 Hearings

The specific criteria considered when determining whether a hearing is justified are set out in § 12.24(b) (21 CFR 12.24(b)). Under that regulation, a hearing will be granted if the material submitted by the requester shows, among other things, the following: (1) There is a genuine and substantial factual issue for resolution at a hearing; a hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence; a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requestor; a hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate; (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested (*e.g.,* if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the FD&C Act or any FDA regulation; and (6) the requirements in other applicable regulations, *e.g.,* 21 CFR 10.20, 12.21, 12.22, and 314.200, and in the notice issuing the final regulation or the NOOH are met.

[5] See section 502(a) of the FD&C Act (deeming a drug to be misbranded if its labeling is false or misleading in any particular); see also section 503(b)(4) and § 310.200(d).

A party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing.'' (*Costle* v. *Pacific Legal Found.,* 445 U.S. 198, 214 (1980), *reh'g denied*, 446 U.S. 947 (1980) (citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc., 412* U.S. 609, 620–21 (1973).) A party's argument that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' does not meet this test. (*Georgia Pacific Corp.* v. *U.S. EPA,* 671 F.2d 1235, 1241 (9th Cir. 1982)). If a hearing request fails to identify any factual evidence that would be the subject of a hearing, FDA will not provide one (*Hynson,* 412 U.S. at 620). FDA may deny a hearing and enter an order withdrawing approval of an application when it appears from the request for hearing that there is no genuine and substantial issue of fact. (See § 314.200(g); *Hynson,* 412 U.S. at 620; *John D. Copanos & Sons, Inc. and Kanasco, Ltd.* v. *FDA,* 854 F.2d 510, 522 (D.C. Cir. 1988).)

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held (*Pineapple Growers Ass'n* v. *FDA,* 673 F.2d 1083, 1085–86 (9th Cir. 1982).) When the issues raised in the objection are, even if true, insufficient to alter the decision, the Agency need not grant a hearing. (See *Dyestuffs & Chemicals, Inc.* v. *Flemming,* 271 F.2d 281, 286 (8th Cir. 1959), cert. denied, 362 U.S. 911 (1960).) A hearing need not be held to resolve questions of law. (See *Citizens for Allegan County, Inc.* v. *FPC,* 414 F.2d 1125, 1128 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC,* 256 F.2d 233, 240 (5th Cir. 1958), cert. denied, 358 U.S. 872 (1958).) Mere allegations or conclusory statements are not sufficient to justify a hearing (§ 12.24(b)(2); 39 FR 9750 at 9755, March 13, 1974). In determining whether a hearing is justified, FDA will analyze the data and information underlying a conclusion by the person requesting a hearing that a hearing is necessary (39 FR 9750 at 9755; see also *Evers* v. *General Motors Corp.,* 770 F.2d 984, 986 (11th Cir. 1985) (It is settled that ''a party may not avoid summary judgment solely on the basis of an expert's opinion that fails to provide specific facts from the record to support its conclusory allegations.''); accord *United States* v. *Various Slot Machines On Guam,* 658 F.2d 697, 700 (9th Cir. 1981) (''in the context of a motion for summary judgment, an expert must back up his opinion with specific facts''); *Merit Motors, Inc.* v. *Chrysler Corp.,* 569 F.2d 666, 673 (D.C. Cir. 1977)).

In summary, a hearing request must present sufficient credible evidence to raise a genuine and substantial issue of fact and the evidence presented by the requestor, if established at a hearing, must be adequate to resolve the issue as requested and to justify the action requested.

III. Analysis

The Commissioner has reviewed the evidence submitted by the holders of the PEG 3350 ANDAs and finds that they have not raised a genuine and substantial issue of fact requiring a hearing under §§ 12.24(b) and 314.200(g), that the legal objections offered are without merit and cannot justify a hearing, and that summary judgment should be granted against them. The Commissioner also orders that, under section 505(e) of the FD&C Act, approval of the PEG 3350 ANDAs, including all related amendments and supplements, are hereby withdrawn, effective May 2, 2018.

The reasons for the Commissioner's decision are described more fully below.

A. Hearing Request

As noted, each of the PEG 3350 ANDA holders, except Teva, requested a hearing and submitted evidence, including information and factual analyses, as to why FDA should grant a hearing regarding their requests. As § 12.24(b) makes clear, FDA requires ''specifically identified reliable evidence'' to grant a hearing. FDA will not grant a hearing based solely upon ''mere allegations or denials or general descriptions of positions and contentions.'' Furthermore, courts have held that ''general and unsupported statements . . . of experts . . . [that] fail to address the specific problems identified by the FDA . . . do not create a genuine issue of fact.'' (*Copanos*, 854 F.2d at 526.) Similarly, the Supreme Court noted that it was appropriate to withdraw a drug from the market if the only evidence presented in opposition to its withdrawal is ''clinical impressions of practicing physicians,'' as that does not constitute the type of evidence upon which FDA bases its regulatory decisions. (*Hynson,* 412 U.S. at 630.)

None of the PEG 3350 ANDA holders submitted data or other information in support of their requests for a hearing that presents a genuine and substantial issue of fact that would be determinative with respect to whether there is some meaningful difference between the prescription and nonprescription products approved by FDA that makes the prescription product safe only under the supervision of a licensed practitioner. Instead, they made numerous assertions and included anecdotal evidence in the form of declarations from practicing physicians, published medical literature, and trade publications on issues that are not material to this proceeding. Much of the information submitted by the PEG 3350 ANDA holders overlapped, and some ANDA holders chose to reference other submissions. Nexgen submitted five declarations from practicing physicians, one news release, and one document outlining objections to the medical review of NDA 22–015 (nonprescription MiraLAX). Nexgen also submitted a bibliography of journal articles cited by its medical experts in their declarations. Paddock submitted a wide variety of documents, including labeling for different products, published medical literature, letters sent to the company by FDA, a copy of the NOOH, a copy of the tentative final monograph (TFM) for OTC laxatives, and various web publications on constipation and its comorbidities. Paddock also referenced a number of online resources in its footnotes and cross-referenced three of the declarations submitted by Nexgen—those of Thomas Quincy Garvey III, M.D., Paul Erick Hyman, M.D., and Irvin Wechsler, B.Sc Pharm. Schwarz did not submit any original evidence, but rather chose to incorporate all of Nexgen's arguments and evidence by reference. Gavis submitted no evidence in support of its assertions.

The ANDA holders object to the proposed order's treatment of their evidentiary submissions. They maintain that the proposed order misapplied the summary judgment standard and misinterpreted FDA regulations and precedent relevant to summary judgment. Nexgen and Breckenridge submitted a joint objection to the proposed order in which they maintain that FDA cannot impose summary judgment where it has not issued a regulation setting forth the standard on which summary judgment will be based (Nexgen/Breckenridge Joint Objection (hereafter Nexgen Objection) at 13–17). Nexgen and Paddock contend that summary judgment is inappropriate where the term meaningful difference has not been defined and the determination of meaningful difference is inherently factual (Paddock Comments at 19; Nexgen Objection at 21–22). Nexgen complains that FDA applied the concept of material fact so narrowly that no issue is likely to satisfy those criteria (Nexgen Objection at 19). Kremers maintains that the proposed order's application of the summary judgment standard violates due process

because it holds that FDA will not allow its scientific judgment to be challenged in an administrative hearing (Kremers Objection at 13–14). Likewise, Paddock complains that the proposed order impermissibly assessed the persuasiveness of the evidence, which is more appropriately done at a hearing (Paddock Objection at 11–12, 15–17). The ANDA holders argue that FDA erred in rejecting the expert affidavits because language in the preamble to part 12 (21 CFR part 12) suggests that expert disagreement is sufficient to create a factual dispute for which a hearing is needed (Kremer's Objection at 8–10). They contend that the expert affidavits contain facts and analysis that, if proven at a hearing, demonstrate meaningful differences between Rx and OTC PEG 3350 products. They maintain that basing the hearing denial on the lack of clinical data was improper in this particular proceeding, where the efficacy of PEG 3350 is not at issue (Nexgen Objection at 18–19; Kremers Objection at 8–9; Paddock at 13–14).

The Commissioner has reviewed the evidence presented and finds that it either fails to address the specific problems identified by FDA and/or that it does not constitute specifically identified reliable evidence. In the ANPRM and the NOOH, FDA stated that in determining whether the same active ingredient can be simultaneously marketed in prescription and OTC products, FDA would consider whether there is a meaningful difference between two drug products, such as active ingredient, dosage form, strength, route of administration, indications, or patient population that makes the prescription product safe only under the supervision of a licensed practitioner. Much of the evidence submitted by the ANDA holders does not warrant granting a hearing because the evidence is not relevant to the above factors. A significant portion of the evidence submitted by the ANDA holders in support of the hearing includes published medical literature and affidavits summarizing the impressions of practicing physicians regarding unapproved uses of PEG 3350, such as chronic constipation, opioid-induced constipation, and use in pediatric patients (see, *e.g.,* Waymack Declaration ¶¶ 17–25, 28; Waymack Bibliography 1–2, 5–6, 8–9); Hyman Declaration ¶¶ 8–23; Hyman Bibliography 1–2, 4, 6–14; Weschler Declaration ¶¶ 9–14). The indication for both OTC MiraLAX and the generic prescription PEG 3350 products is occasional constipation. Neither the prescription products nor OTC MiraLAX are indicated for treatment of chronic constipation or opioid-induced constipation or for treatment of pediatric patients. Evidence regarding these unapproved uses of PEG 3350 is not relevant and does not raise a material issue of fact regarding the factors FDA set forth in the ANPRM or the NOOH.

The expert statements regarding duration of use likewise fail to meet the criteria at § 12.24 for granting a hearing. The NOOH explained that, in previous switches, a drug remained prescription for one duration of use while becoming OTC for the other duration only when there was an additional and more fundamental difference between the products, such as a different indication, dose, duration of therapy, and/or target population (73 FR 63491 at 63493 n.1), none of which are present here. The NOOH further explained that the 7-day duration of use for OTC MiraLAX was based upon the labeling intended for the OTC audience and to ensure consistent labeling among OTC laxative products. The ANDA holders did not dispute this. Nevertheless, they made arguments and submitted affidavits of impressions of practitioners citing review documents and approved labeling related to duration of use. The ANDA holders focus on PEG 3350's alleged increased efficacy after 2 to 4 weeks and maintained efficacy from 4 weeks to up to 6 months of use, based upon the ''or as directed by a physician'' language in the prescription labeling. Also relying upon the ''or as directed by a physician'' phrase in the prescription labeling, the ANDA holders contend that such language indicates that prescription MiraLAX has an unlimited duration of use. They further maintain that OTC MiraLAX has a maximum duration of use of 7 days.

Prescription PEG 3350 is approved for a duration of use of ''2 weeks *or less* or as directed by a physician.'' Nonprescription MiraLAX's labeled duration of use states: ''use *no more* than 7 days''; ''Stop use and ask a doctor if . . . you need to use a laxative for longer than 1 week''; and ''do not take more than directed *unless* advised by your doctor.'' The labeling of both products states that the patient may use the product for less than the 7-day or 14-day duration the ANDA holders cite. In addition, the labeling for both products explicitly states that the products can be expected to be effective in producing a bowel movement in less than 7 days,[6] which is consistent with the fact that both products are indicated for occasional constipation and not chronic constipation. Both products' labeling also acknowledges the discretion of a treating physician to recommend a duration of use beyond the labeled duration.[7] For this reason, the ANDA holders' attempts to show that there is increasing efficacy over an extended period of time is not determinative of whether there is a meaningful difference between the prescription and OTC products as approved by FDA. Moreover, although the PEG ANDA holders complain that the proposed order improperly relied upon a lack of data, the ANDA holders raised the issue of comparative efficacy over time based upon a misplaced reliance on the data from the MiraLAX application and without submitting supporting data.

Duration of use alone was not set forth in the ANPRM or the NOOH as a factor the Agency considers in determining whether there is a meaningful difference between a prescription product and an OTC product. Moreover, the NOOH made clear that the duration of use on the OTC label resulted from the intended audience (consumers) and the need to maintain consistency with the labeling of other OTC laxative products, and not from any difference necessitated by science. The plain language of the labeling provides discretion to patients and physicians with regard to duration of use. Considering all these factors, the Commissioner in this proceeding declines to conclude that duration of use alone, without an additional more fundamental difference between the products, is sufficient to establish a meaningful difference. As such, the evidence and affidavits regarding duration of use do not raise material issues of fact that would be determinative with respect to this action, and thus do not justify a hearing. Additional discussion of the meaningful difference standard and duration of use is found in section III.D.

Other evidence submitted by the ANDA holders consists of expert statements or impressions of practitioners that challenge FDA's 2006 decision to approve MiraLAX—or, in some instances, any laxative product—as an OTC product (see, *e.g.,* Garvey Declaration ¶¶ 10–17, 21–25; Waymack Declaration ¶¶ 9–10, 26–27, 29; Beier Declaration ¶¶ 8, 10–17; Weschler Declaration ¶¶ 15–17); see also Nexgen

[6] The prescription labeling states, ''Treatment for 2 to 4 days may be required to produce a bowel movement.'' The nonprescription labeling states, ''Generally, produces a bowel movement in 1 to 3 days.''

[7] FDA does not seek to interfere with the exercise of the professional judgment of health care providers in prescribing or administering, for unapproved uses for individual patients, most legally marketed medical products.

Comments at 46–48 (contrasting FDA's approval of OTC MiraLAX with a prior decision to approve OTC Plan B only for individuals 16 years of age and older); Nexgen Objection at 37–40, 47 (raising arguments related to a lack of labeling comprehension, self-selection, and actual use studies and an advisory committee meeting prior to MiraLAX's OTC approval). Other statements focus on issues such as whether the clinical trials were adequate to support the efficacy of MiraLAX within 7 days, whether constipation is a self-limiting condition suitable for treatment with an OTC drug, and whether FDA correctly concluded that MiraLAX may be used safely for up to 7 days (with certain exceptions set forth in the OTC label) without the supervision of a licensed practitioner.

This evidence challenges FDA's decision to approve MiraLAX as an OTC product. As explained in the Background section, the PEG 3350 ANDAs were approved based upon FDA's finding that the generic PEG 3350 products have the same active ingredient, indication for use, route of administration, dosage form, strength, and labeling as, and that they were bioequivalent, to prescription MiraLAX. The PEG ANDA holders were not required to submit evidence to establish the safety and efficacy of their products. Rather, the ANDAs relied upon FDA's prior finding of MiraLAX's safety and efficacy for approval, which was supported by the evidence submitted in the previously approved NDA for prescription MiraLAX (NDA 20–698). Subsequently, FDA approved NDA 22–015 for OTC MiraLAX, which has the same active ingredient, indication for use, route of administration, dosage form, and strength as prescription MiraLAX. The ANDA holders now challenge the decisions made in the course of the approval of NDA 22–015 and seek a hearing on these issues. Neither the FD&C Act nor its implementing regulations require that the ANDA holders be afforded a hearing on FDA's decision to approve the NDA for OTC MiraLAX, and that issue is not determinative in this proceeding, which is only to decide whether OTC MiraLAX as already approved by FDA is meaningfully different from the approved prescription products. Accordingly, the Commissioner finds that a hearing on this evidence submitted with regard to these issues is not warranted. (See § 12.24(b); *Hynson,* 412 U.S. at 620; *Capanos,* 854 F.2d at 522, 526).

The Commissioner further concludes that a hearing may be denied in this proceeding, even in the absence of a regulation setting forth the standard for determining whether there is a meaningful difference between prescription and nonprescription products containing the same active ingredient. This is so because the meaningful difference standard was set forth in the ANPRM and the NOOH, and the NOOH discussed in detail the facts and evidence that formed the basis for CDER's proposed withdrawal of the ANDAs. Where the NOOH provides such information, precise regulations specifying the type of evidence necessary to justify a hearing are not required (*Capanos,* 854 F.2d at 520; cf. *American Cyanamid Co.* v. *FDA,* 606 F.2d 1307, 1312–13 (D.D.C. 1979); *Hess & Clark, Inc.* v. *FDA*, 495 F.2d 975, 984 (D.C. Cir. 1974)). Furthermore, the factors set forth in the ANPRM and the NOOH, which FDA will consider in determining whether there is a meaningful difference between prescription and nonprescription drug products containing the same active ingredient (indication, strength, route of administration, dosage form, patient population), are clearly set forth in the products' labeling.

As to the complaint that the proposed order ''applied the concept of 'material fact' '' so narrowly that no issue is likely to satisfy that standard (Nexgen Objection at 17), the ANDA holders' requests for hearing and objections to the proposed order do not dispute that the active ingredient, dosage form, strength, route of administration, indication, and patient population are the same for the original prescription MiraLAX product approved in NDA 20–698, the prescription generic PEG 3350 products, and OTC MiraLAX approved in NDA 22–015, as reflected on the products' labeling. Contrary to their assertions, the Agency is not construing substantial and genuine issue of fact narrowly. Rather, any data or information presented by the ANDA holders purporting to establish facts that do not relate to the factors set forth in the ANPRM and NOOH is immaterial because those are the factors that are relevant to determining if there is a meaningful difference between the products. In addition, the factors the Agency set forth as relevant to determining a meaningful difference between the products largely align with those the Agency relied upon in approving the PEG 3350 ANDAs (see 21 U.S.C. 355(j)(2)(A)(i) to (v)). Under these circumstances, it would be difficult for the ANDA holders to raise a genuine and substantial issue of fact requiring a hearing. Considering the relevant issues in this proceeding, the evidence submitted combined with the mere assertions of fact advanced by the PEG 3350 ANDA holders is insufficient to raise a genuine and substantial issue of fact requiring a hearing. The Commissioner therefore denies the PEG 3350 ANDA holders' request for a hearing and is entering summary judgment (§§ 12.24(b)(1) and (2), and 314.200(g)).

B. New Evidence Submitted With the Objections to the Proposed Order

In addition to submitting evidence intended to support its arguments in its request for hearing, Nexgen's objection to CDER's proposed order included new evidence and allegations. Nexgen maintains the new information and allegations raise genuine and substantial issues of fact requiring a hearing. The new information includes medical literature describing the use of PEG 3350 for chronic constipation and for a duration longer than 14 days, and literature discussing the physician's role in PEG 3350 use. Also included in the Objection are allegations that FDA was long ''aware'' of the tension between the safe duration of use period for OTC laxatives and the use of laxatives for prolonged periods in certain populations with physician supervision. Nexgen also alleges for the first time that OTC MiraLAX has a new indication because FDA's approval letter referenced required pediatric studies for OTC MiraLAX. Nexgen also raises allegations regarding: additional active ingredients for which FDA has permitted simultaneous prescription and nonprescription products; the lack of a labeling comprehension study and advisory committee meeting prior to approval of OTC MiraLAX; a U.S. Department of Health and Human Services (HHS) announcement of a grant to study PEG 3350 in the pediatric population; and the cost of OTC MiraLAX. Nexgen submitted survey results of physician perceptions of the OTC and prescription MiraLAX labeling, data on reported adverse events for MiraLAX after the OTC approval, and data on continued sales of prescription MiraLAX (Nexgen Objection at 23–43; Nexgen Objection Exhibits 5–7).

Under § 314.200(c), an applicant who wishes to participate in a hearing shall file the studies on which the person relies to justify a hearing within 60 days after the date of publication of the notice of opportunity for hearing. FDA will not consider data or analyses submitted after that 60-day timeframe when determining whether a hearing is warranted unless they are derived from well-controlled studies begun before the

date of the notice of opportunity for hearing and the results of the studies were not available within 60 days after the date of publication of the notice. Under those circumstances, the person requesting a hearing shall list all studies in progress, the results of which the person intends later to submit in support of the request for a hearing. Additionally, such person must submit a copy of the complete protocol, a list of participating investigators, and a brief status report of the studies within 60 days of the notice of hearing. Further, FDA may consider studies submitted outside the 60-day timeframe when the person requesting a hearing makes a showing of an inadvertent omission and hardship (§ 314.200(c)(1) and (2)).

In the preamble to 21 CFR 130.14, the predecessor to § 314.200, FDA rejected a comment suggesting that FDA should permit later submission of material ''not known'' to exist at the time a request for hearing is due. FDA stated on numerous occasions in the past, persons requesting a hearing have subsequently supplemented that request with multiple submissions of data and information culled from the literature and other sources, all of which were available at the time of the original request for hearing. This has resulted in lengthy delays while the newly submitted information has been assessed. In the interest of administrative efficiency, it is essential that this type of continuous submission be precluded. Accordingly, the new regulations require that any submission of existing information be made within the 60-day time period permitted in the regulations. (39 FR 9750 at 9757.) Likewise, in the preamble to the predecessor to part 12, FDA stated it would be impracticable to permit supplementation at any time prior to the Commissioner's ruling on an objection or request for hearing, for the Commissioner would then be required to defer his ruling whenever supplemental material was received. This would seriously disrupt the process of ruling on objections and requests, would frustrate efforts of persons to respond in support of denial of a hearing, and could prolong action indefinitely. (41 FR 51706 at 51707, November 23, 1976.)

In its request for a hearing, Nexgen stated, ''Nexgen is submitting herein substantial facts and legal analyses controverting FDA's position, and intends to supplement this information in its '60 day' submission pursuant to 21 CFR 12.22 and 314.200.'' (Nexgen Comment at 2). Regarding the new information and allegations Nexgen submitted in its Objection, Nexgen made no attempt to supplement its request for hearing in a manner that comports with the requirements of § 314.200(c)(2). Nexgen did not show that the information includes data derived from well-controlled studies that began before the date of the notice of opportunity for hearing and that the results were not available within 60 days of the date of publication of the notice. Nexgen did not list the studies in progress, nor did it submit the protocols, the participating investigators, or a status report of the studies. Nexgen made no showing that any of the data or analyses or cited publications are derived from well-controlled studies. Even if FDA were to consider information not derived from well-controlled studies submitted after 60 days, Nexgen made no attempt to inform FDA that it would be submitting the results of a telephonic survey, adverse event data, labeling analysis of products for which FDA has permitted simultaneous prescription and nonprescription marketing, cost data, or continued sales data for prescription MiraLAX. Additionally, Nexgen did not show that the new information and allegations submitted in the Objections were not included in its Request for Hearing due to an inadvertent omission and hardship. Nexgen's failure to submit this new evidence in conformance with § 314.200 gives the Commissioner sufficient reason to decline to review it.

Even if the Commissioner were to consider the submissions in Nexgen's objection, Nexgen's new information and analyses are not relevant to the issue of whether there is a meaningful difference between the prescription and nonprescription versions of MiraLAX approved by FDA such that PEG 3350 could be marketed simultaneously in both a prescription and nonprescription MiraLAX product. The data and analyses submitted by Nexgen, such as the physician survey, studies of PEG 3350 for chronic constipation, the approval process for OTC MiraLAX, adverse event reports for MiraLAX, sales data for prescription MiraLAX, the cost of OTC MiraLAX, and HHS funding to study PEG 3350 in the pediatric population, are not related to the factors set forth in the ANPRM and the NOOH as material to determining meaningful difference. In light of the requirements in § 314.200 for submitting data and analyses after the 60-day deadline, FDA's rationale for imposing restrictions on the submission of data and analyses after 60 days, and the lack of relevance of this information, the Commissioner will not further consider the information Nexgen and Breckenridge submitted with their objections to the proposed order.

C. Legal Arguments Offered by the ANDA Holders

The ANDA holders have failed to raise a genuine and substantial issue of fact that requires a hearing, and a hearing will not be granted on issues of law (§ 12.24(b)(1)). In addition, the Commissioner does not find the arguments advanced by the PEG 3350 ANDA holders persuasive and is entering summary judgment against them. The Commissioner will address each argument and assertion made by the PEG 3350 ANDA holders in support of their hearing requests to explain the finding of summary judgment.

The arguments addressed in section III.C of this order challenge the statutory and regulatory requirements of the FD&C Act that govern prescription and nonprescription marketing status, the withdrawal of approval of a drug application, generic drugs and exclusivity, and FDA enforcement. The arguments challenge the regulatory requirements of the Administrative Procedure Act (APA) and FD&C Act with regard to notice and comment rulemaking. The arguments also challenge the statutory and regulatory requirements for summary judgment. As such, they are legal arguments, which do not raise a genuine and substantial issue of fact. Thus, these arguments cannot form the basis for granting a hearing (see §§ 12.24(b)(1) and 314.200(g)). In addition, these arguments do not have any legal merit.

1. The Agency's Authority Under Section 503(b)(4)(B) of the FD&C Act

Nexgen, Paddock, and Gavis all submitted arguments regarding the Agency's authority under section 503(b)(4)(B) of the FD&C Act. Specifically, they argue that because their ANDAs were approved as prescription products, they are required to bear the ''Rx only'' symbol and therefore cannot be deemed misbranded under section 503(b)(4)(B) of the FD&C Act (Nexgen Comments at 37–39). As the basis for this argument, they suggest that the provisions in section 503(b)(1)(A) are independent of those in section 503(b)(1)(B) of the FD&C Act, and a drug is a prescription drug if it is covered under section 503(b)(1)(B), regardless of whether it is covered under section 503(b)(1)(A) (Nexgen Comments at 38; Gavis Comments at 002; Paddock Comments at 6). Thus, they contend that once a drug is approved as prescription under section 503(b)(1)(B) of the FD&C Act, it is

always prescription and that status cannot be taken away, regardless of a change from prescription to nonprescription status of the RLD.

Likewise, they argue that the Durham-Humphrey Amendments (Pub. L. 82–215 (1951)) were not intended to address the situation in which a prescription drug product is forced to change to nonprescription because a separate NDA for the same active ingredient was approved as a nonprescription product (Nexgen Comments at 39–40). They further argue that if Congress intended generic prescription drugs to become misbranded immediately when their referenced products are approved for nonprescription use, it should have written that explicitly into the FD&C Act (Gavis Comments at 003; Paddock Comments at 6; Nexgen Comments at 39–40).

A basic rule of statutory construction is that ''a statute is to be read as a whole . . . since the meaning of statutory language, plain or not, depends on context.'' (*King* v. *St. Vincent's Hosp.,* 502 U.S. 215, 220 (1991) (citations omitted).) ''A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme . . . .'' (*United Savings Ass'n* v. *Timbers of Inwood Forest Associates,* 484 U.S. 365, 371 (1988) (citations omitted)). In line with the notion that the statute should be read in a holistic manner, congressional silence on a particular point does not lend more credence to one interpretation if much of the evidence would point to another interpretation. ''An inference drawn from congressional silence certainly cannot be credited when it is contrary to all other textual and contextual evidence of congressional intent.'' (See *Burns* v. *United States,* 501 U.S. 129, 136 (1991) (internal citation omitted).) Further, where Congress does not explicitly include language addressing a particular situation, it is appropriate for FDA to form an interpretation of the proper application of the statute based on the legislative history (see *Wilder* v. *Virginia Hosp. Ass'n,* 496 U.S. 498, 515 (1990) (referencing to Senate report for evidence of ''the primary objective'' of the Boren amendment to the Medicaid law)).

The ANDA holders' argument that once a product is approved as a prescription product, it is always a prescription product, cannot withstand a holistic reading of section 503(b) of the FD&C Act. Section 503(b)(3) states that FDA may ''remove drugs subject to section 505 [of the FD&C Act] from the requirements of [section 503(b)(1)] . . . when such requirements are not necessary for the protection of the public health.'' On its face, the statute authorizes the Secretary to exempt a product from the prescription-dispensing requirements when such requirements are not necessary for the protection of the public health. Further, section 503(b)(3) of the FD&C Act references 503(b)(1) in its entirety and thus applies to drugs that are limited by an application approved under section 505 of the FD&C Act to prescription use under section 503(b)(1)(B). FDA set forth this interpretation when it issued § 310.200 in 1963 (28 FR 6377, June 20, 1963). That regulation states that any drug limited to prescription use under section 503(b)(1)(B) of the act shall be exempted from prescription dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling. (§ 310.200(b).) Therefore, the ANDA holders' general contention that once a product is approved as a prescription product under section 503(b)(1)(B) of the FD&C Act, it can never lose its prescription status, is incorrect.

Section 503(b)(4) of the FD&C Act describes when a drug product is required to bear the ''Rx only'' symbol on its label and when a drug product may not bear the ''Rx only'' symbol. Under section 503(b)(4)(A), any drug product that is subject to 503(b)(1) ''shall be deemed misbranded if at any time prior to dispensing the label of the drug fails to bear . . . the symbol 'Rx only'.'' Under section 503(b)(4)(B) of the FD&C Act, any drug product that is not subject to 503(b)(1), *i.e.,* a nonprescription product, shall be deemed to be misbranded if it bears the ''Rx only'' symbol on its label any time prior to the dispensing of the drug product. The purpose of section 503(b)(4) of the FD&C Act is to eliminate the marketing of both prescription and nonprescription versions of the same drug product at the same time (see Pub. L. 82–215 (1951)).

While considering the Durham-Humphrey Amendments, Congress noted that retail pharmacists shelved one and the same drug product made by various manufacturers, but with different labels. Some drug products bore prescription labeling while the same drug product manufactured by a different firm bore nonprescription labeling, leading to confusion for both pharmacists and the public. (See H.R. Rep. No. 82–700, at 3 (1951); S. Rep. No. 82–946, at 2 (1951); 97 Cong. Rec. 9235 (1951); see also 97 Cong. Rec. 9321 (1951).) Congress stated that the purpose of the amendments was to change that ''uncertain situation'' into a ''certain situation.'' (See 97 Cong. Rec. 9330 (1951).) The amendments were also meant to ''relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician.'' (S. Rep. No. 82–946, at 1–2 (1951); see also 97 Cong. Rec. 9235 (1951).)

If section 503(b)(4) of the FD&C Act were construed the way Nexgen, Paddock, and Gavis describe, the Durham-Humphrey Amendments would be rendered meaningless. If a prescription generic drug product were allowed to remain on the market by virtue of its approval as a prescription product, which approval was based, among other things, on its bioequivalence to an RLD, despite that RLD's switch from prescription to nonprescription, there would be simultaneous marketing of prescription and nonprescription versions of the same drug product. This result conflicts with a holistic reading of section 503(b) of the FD&C Act. Further, this result would negate a central purpose of the Durham-Humphrey Amendments as set forth in the legislative history: avoiding confusion for pharmacists and the public.

Additionally, the ANDA holders' argument with respect to Congress's failure to include specific language in the FD&C Act describing the exact situation in which the PEG 3350 ANDA holders find themselves is not persuasive. In the absence of express statutory language, FDA is permitted to put forth a reasonable interpretation of the statute. The courts have long held that FDA's interpretation of the FD&C Act governs as long as it is ''a permissible construction of the statute.'' (See *Chevron, U.S.A., Inc.* v. *Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–44(1984); *Novartis Pharm. Corp.* v. *Leavitt*, 435 F.3d 344, 349 (D.C. Cir. 2006) (''FDA interpretations of the FDCA receive deference''); cf. *Pharmanex* v. *Shalala*, 221 F.3d 1151, 1160 (10th Cir. 2000) (FDA's interpretation that a ''new drug'' includes active ingredients as well as finished drug products is entitled to deference); *Nat'l Pharm. Alliance* v. *Henney*, 47 F. Supp. 2d 37, 39–40 (D.D.C. 1999) (because Congress's use of ''drug'' in section 505 did not clearly speak to the relevant issue, courts must defer to FDA's interpretation).) As described above, Congress expressed

clear concerns about the same products being marketed as both prescription and nonprescription products and the ensuing confusion for both pharmacists and the public at large. FDA's interpretation of the application of the Durham-Humphrey Amendments is not only a permissible construction of section 503(b) of the FD&C Act when reading that section as a whole, but a logical interpretation in light of the legislative history behind the amendments. Additionally, based on those concerns, Congress could not have intended the interpretation that the ANDA holders put forth.

Furthermore, the PEG 3350 ANDA holders' interpretation of section 503(b)(4) of the FD&C Act is inconsistent with that held by the United States Court of Appeals for the Seventh Circuit (Seventh Circuit). The PEG 3350 ANDA holders were the Defendants-Appellees in a case under section 43(a)(1)(B) of the Lanham Act (15 U.S.C. 1125(a)(1)(B)) concerning the marketing of generic prescription PEG 3350 products, which was appealed to the Seventh Circuit after the District Court dismissed the case pending a decision by FDA regarding the misbranding of their products (*i.e.,* the publication of this notice). In its opinion, the Seventh Circuit upheld the lower court's decision and clearly explained that ''the Food, Drug, and Cosmetic Act does not permit both by-prescription-only and over-the-counter versions of the same drug to be sold at the same time.'' (*Schering-Plough Healthcare Products, Inc.* v. *Schwarz Pharma, Inc.*, 586 F.3d 500, 505 (7th Cir. 2009) (citing section 503(b)(4) of the FD&C Act).) The Seventh Circuit also explained that, in light of this provision of the FD&C Act, ''the FDA is conducting a proceeding to determine whether [the PEG 3350 ANDA products] are misbranded now that there is an over-the-counter version of the drug . . . [and] if the FDA determines that they are 'the same,' the result will be that the generic drug can no longer be sold.'' (Id.).

In this case, CDER concluded, and the Commissioner affirms, that there is not a meaningful difference between the prescription and nonprescription versions of MiraLAX; *i.e.,* that they are essentially the ''same.'' And, once a drug product is fully switched from prescription to nonprescription use, the previous prescription drug product may no longer be legally marketed as per section 503(b) of the FD&C Act, as the prescription product would be misbranded under section 503(b)(4)(B). Had Braintree continued to market prescription MiraLAX following FDA's approval of OTC MiraLAX, the prescription MiraLAX would have been misbranded. It follows that the PEG 3350 ANDA products that reference prescription MiraLAX and that were approved based upon a finding that they met the requirements of section 505(j)(2)(A)(i) to (v) and (j)(4) of the FD&C Act cannot avoid being misbranded under section 503(b)(4) and § 310.200(d) simply because they were initially approved as prescription drugs and continue to be marketed as prescription products.

2. The Agency's Authority Under Section 505(e) of the FD&C Act

a. False or misleading. Nexgen and Paddock submitted comments arguing that the prescription version of the labeling is not false or misleading; therefore, the Agency does not have the authority to withdraw the product under section 505(e) of the FD&C Act. Nexgen and Paddock argue that the PEG 3350 labeling is not false or misleading because it still meets the standards under which it was initially approved as a prescription drug product referencing NDA 20–698. They maintain that the approval of their products as prescription drugs did not depend upon PEG 3350's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use. Rather, they maintain that their PEG 3350 products are entitled to prescription status under section 503(b)(1)(B) of the FD&C Act because the ANDA required that their products be dispensed by prescription. They also contend that because the NOOH provides no evidence of new information that would indicate that the labeling is false or misleading, section 505(e)(3) of the FD&C Act does not apply (see Nexgen Comments at 41; Paddock Comments at 9–10).

These legal arguments are based upon an incorrect assertion that the products are not misbranded under section 503(b)(4) of the FD&C Act. In this instance, neither criterion under 503(b)(1) applies to the generic PEG 3350 products. FDA previously determined, at the time OTC MiraLAX was approved, that the supervision of a licensed practitioner is no longer necessary for the use of MiraLAX and that no prescription indications remained. After FDA made that determination with regard to the RLD, the legal status of the RLD as a prescription product and the medical and scientific basis underlying the approval of both the RLD and the generic PEG 3350 products as prescription drugs no longer existed. Where, as here, the legal and scientific underpinnings of the approval of the generic PEG 3350 products as prescription drugs have ceased to exist, FDA concludes that section 503(b)(1)(B) of the FD&C Act no longer applies to those products. This interpretation is supported by a reading of section 503(b) as a whole and is consistent with the purpose of the statute as set forth in the legislative history, as discussed in the above subsection of this order. In addition, the labeling of the ANDA PEG 3350 products is false or misleading. By bearing the ''Rx only'' symbol, the labeling implies that the products can be dispensed safely only with a licensed practitioner's prescription. Yet, FDA has determined that MiraLAX can be used safely and effectively in the nonprescription setting and specifically does not meet the criteria in 503(b)(1) of the FD&C Act. In section III. D. of this order, FDA has determined that the generic PEG 3350 products are the same drug product as nonprescription MiraLAX (*i.e.,* there is no meaningful difference between them) for purposes of determining whether they are misbranded under section 503(b)(4) of the FD&C Act. Thus, the contention that the generic prescription labeling is not false or misleading because the applications were originally approved as prescription products is without merit.

Because the labeling for the PEG 3350 prescription products is false or misleading, the Agency has the authority to withdraw approval of the products under section 505(e)(3) of the FD&C Act. The ''new information'' in this case is the October 2006 approval of MiraLAX as an OTC drug, the change in status of MiraLAX from prescription to nonprescription, and the fact that the PEG 3350 ANDA holders have not submitted new ANDAs referencing OTC MiraLAX and including the same OTC labeling as the RLD after receiving written notice from FDA. Accordingly, the standard for withdrawal in section 505(e)(3) of the FD&C Act has been met.

b. Written notice. Schwarz submitted comments arguing that the April 20, 2007, letters are not sufficient ''written notice'' under the FD&C Act to justify the NOOH. Schwarz argues that because neither the Secretary, nor anyone with properly delegated authority, provided written notice to Schwarz, the April 20, 2007, letter does not constitute an advisory opinion or represent the formal position of FDA. Further, Schwarz claims that there is no evidence that Schwarz did not attempt to correct the issues identified in the April 20, 2007, letter. Because of this, Schwarz contends that FDA has not satisfied the prerequisites to withdrawal under

section 505(e)(3) of the FD&C Act and the NOOH is invalid (Schwarz Comments at 2–3).

This argument is unavailing. Section 505(e) states that the Secretary may, ''after due notice and opportunity for hearing to the applicant,'' withdraw approval of a drug application if the Secretary finds that the labeling of such drug is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Schwarz's assertions regarding the April 20, 2007, letter are unavailing, as even if the Commissioner were to assume that the Buehler letter failed to satisfy the requirements of section 505(e), the NOOH itself also satisfies this requirement.

The NOOH issued in October 2008 proposed the withdrawal of the PEG 3350 ANDAs on the basis of the switch of MiraLAX from Rx to OTC. The NOOH noted that the FD&C Act does not permit both Rx and OTC versions of the same drug product to be marketed at the same time. Under the FD&C Act, a drug to which the prescription dispensing requirements do not apply (*i.e.,* an OTC drug) shall be deemed misbranded if at any time prior to its dispensing, the label of the product bears the ''Rx only'' symbol. The NOOH explained that the ANDA products' labels, which bear the ''Rx only'' symbol, are false or misleading because the same PEG 3350 product was approved for OTC use. Thus the NOOH, which was issued by the Associate Commissioner for Policy and Planning pursuant to delegated authority,[8] also satisfies the requirement in section 505(e) of the FD&C Act that there be written notice specifying the matter complained of.

Contrary to Schwarz's suggestion, there is nothing in the statute that requires written notice to ''justify'' the NOOH; the statute only requires written notice as a prerequisite to the withdrawal itself. The NOOH did not withdraw the applications; it merely initiated this proceeding during which the applicants were given ample opportunity to contest the proposed withdrawals. The Commissioner is withdrawing approval of the applications via this order, and the NOOH serves as written notice prior to this withdrawal under section 505(e) of the FD&C Act.[9]

3. The Agency's Authority Under Hatch-Waxman

Paddock's comments contend that the Hatch-Waxman amendments do not authorize FDA to withdraw approval of an ANDA for nonsafety or noneffectiveness reasons. In fact, Paddock argues, by removing the prescription PEG 3350 products from the market, FDA is effectively awarding Braintree 6 years of exclusivity for its prescription product, which contravenes the Hatch-Waxman Amendments in section 505(c) and (j) of the FD&C Act. Paddock further argues that FDA's award of 3 years of exclusivity to OTC MiraLAX must have been based on studies in a new patient population and thus contravenes the proposal to find that there is not a meaningful difference between the prescription and OTC products (Paddock Comments at 5–6).

These allegations make incorrect statements about the Agency's authority under the FD&C Act regarding withdrawal of generic drug products and granting of market exclusivity. The Hatch-Waxman Amendments established new section 505(j) of the FD&C Act, which sets forth the ANDA approval process for generic drugs. The NOOH proposed withdrawal based upon the second sentence of section 505(e) of the FD&C Act, which explicitly references section 505(j), and vests the Secretary with the authority to withdraw an ANDA whenever new information establishes that ''the labeling of such drug . . . is false or misleading in any particular.'' The prescription PEG 3350 ANDAs are misbranded under section 503(b)(4)(B) of the FD&C Act and FDA's regulations because they are marketed for prescription use at the same time as a nonprescription product that FDA determines in this order is not meaningfully different. In this case, the use of the ''Rx only'' symbol on the labeling of the prescription PEG 3350 products is false or misleading because it implies that the products are required to be dispensed only with a prescription; whereas FDA has determined that the same product does not meet the criteria in section 503(b)(1) of the FD&C Act and can be used safely and effectively in the nonprescription setting.

FDA did not award Braintree 6 years of exclusivity for its prescription product. Braintree received 3 years of exclusivity under section 505(j)(5)(F) of the FD&C Act when the initial approval of prescription MiraLAX was supported by new clinical studies essential to its approval conducted by or on behalf of Braintree. It also received 3 years of exclusivity under the same provision when the OTC switch NDA was approved because Braintree supported its OTC MiraLAX application with new clinical studies conducted by or on behalf of Braintree that were essential to its approval. These are two separate awards of exclusivity earned by Braintree under the criteria set forth in the FD&C Act. Contrary to Paddock's contention, there were two separate bases for granting two 3-year periods of exclusivity, as is often the case when products switch from prescription to nonprescription status.

4. Arguments Regarding the Administrative Procedure Act

a. Notice and comment rulemaking. Paddock argues that the Agency's withdrawal of the Rx PEG 3350 ANDAs following MiraLAX's switch from Rx to OTC would violate the APA when MiraLAX's switch was not accomplished through the notice and comment rulemaking process. Paddock argues that the Durham-Humphrey Amendments preclude withdrawal of a generic product based on a change of the RLD to nonprescription status unless the RLD's prescription status was changed through rulemaking (Paddock Comments at 2–3). Therefore, Paddock contends that because the Agency did not engage in notice and comment rulemaking to change the status of MiraLAX from prescription to nonprescription, it does not have the authority to withdraw approval of the PEG 3350 ANDAs (Paddock Comments at 2–3, 7). Paddock further argues that the approval of OTC MiraLAX and the later decision to propose withdrawal of

[8] The Secretary delegated authority to the Commissioner, with authority to redelegate, all functions vested in the Secretary under the FD&C Act, as set forth in the FDA Staff Manual Guide, Volume II, Number 1410.10 (effective May 18, 2005). Available at: *https://web.archive.org/web/20070701125239/http://www.fda.gov:80/smg/1410_10.html* (accessed December 15, 2017). At the time the NOOH was issued, the Commissioner had redelegated the authority to perform all functions of the Commissioner to certain specified officials including the Associate Commissioner for Policy and Planning, as set forth in the FDA Staff Manual Guide, Volume II, Number 1410.21 (effective May 15, 2007). Available at: *https://web.archive.org/web/20070705185904/http://www.fda.gov:80/smg/1410_21.html* (accessed December 15, 2017).

[9] The ANDA holders have received additional notice prior to this withdrawal order that their products' labeling was false or misleading, as required by section 505(e) of the FD&C Act. In May 2014, Dr. Janet Woodcock, CDER Director, wrote to the ANDA holders and attached a copy of the proposed order, which specified CDER's basis for concluding that the prescription MiraLAX labeling is false or misleading. The ANDA holders have not corrected the misbranding within a reasonable time of receiving Dr. Woodcock's letter. In May 2014, Dr. Woodcock had the properly delegated authority to take regulatory actions for drugs for human use for which approved applications submitted under section 505 of the FD&C Act are in effect. See FDA Staff Manual Guide 1410.104 ¶ 1.A (effective June 12, 2012). Available at: *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM336918.pdf.*

the prescription PEG 3350 ANDAs from the market is essentially a legislative rule issued without notice and comment in violation of the APA (Paddock Comments at 7–8). In addition, Paddock argues that because the Agency has never defined how it assesses a meaningful difference, it is in effect issuing a legislative rule without engaging in notice and comment rulemaking (Paddock Comments at 19).

These allegations are inaccurate regarding the Agency's authority under the FD&C Act and the APA, neither of which requires the issuance of regulations before FDA can determine that a drug no longer meets the criteria at section 503(b)(1) of the FD&C Act. Paddock seemingly relies upon section 503(b)(3), which describes one procedure for exempting a drug from the prescription drug requirements of section 503(b)(1) of the FD&C Act. Specifically, section 503(b)(3) provides that FDA may, by regulation, remove a drug from the prescription dispensing requirements in section 503(b)(1) of the FD&C Act when the prescription status mandated by its NDA approval is no longer ''necessary for the protection of the public health.'' FDA has interpreted section 503(b) of the FD&C Act to allow the Agency to switch a drug product from prescription to nonprescription by approving an NDA submitted by a sponsor seeking such a change. In practice, FDA has exercised that authority and changed the status of numerous products from prescription to nonprescription through the submission of NDAs.

Further, in the absence of express statutory language requiring rulemaking, government agencies possess broad discretion in deciding whether to proceed by general rulemaking or case-by-case adjudication. (See, *e.g.*, *NLRB* v. *Bell Aerospace*, 416 U.S. 267, 293–94 (1974) (stating that ''the choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency.'' (internal citation omitted)); see generally *Cellnet Commc'n, Inc.* v. *FCC*, 965 F.2d 1106, 1111 (D.C. Cir. 1992) (reviewing the FCC's refusal to initiate a rulemaking and stating that ''an agency's refusal to initiate a rulemaking is evaluated with a deference so broad as to make the process akin to non-reviewability.'').) While the Agency may proceed through rulemaking, FDA also has the authority to exempt a drug from the prescription dispensing requirements without rulemaking. Switching a product through the NDA holder's submission of an NDA is an example of the Agency exercising its authority to proceed on a case-by-case basis.

As noted above, Paddock argues that withdrawal of the PEG 3350 ANDAs in the absence of notice and comment rulemaking constitutes a legislative rule. Under section 505(e) of the FD&C Act, FDA may withdraw approval of applications through adjudication, as the Agency is doing here; therefore, FDA's withdrawal of the PEG 3350 ANDAs does not constitute a legislative rule. Further, the issue of whether an FDA action involving an interpretation of the FD&C Act constitutes a legislative rule has been previously considered. In a matter challenging FDA's implementation of the pediatric exclusivity provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA), one of the arguments maintained that the ''Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act'' was a legislative rule that should have been enacted through notice and comment rulemaking. To determine whether the rule in that case was legislative or interpretive, the court used the four-part test from *American Mining Congress* v. *Mine Safety & Health Admin.*, 995 F.2d 1106 (D.C. Cir. 1993). The court first asked ''whether in the absence of the rule there would not be an adequate legislative basis for . . . agency action.'' (*Nat'l Pharm. Alliance* v. *Henney,* 47 F. Supp. 2d 37, 41 (D.D.C. 1999).) The court reasoned that, ''[FDAMA] on its face provides all the 'legislative basis' that is necessary for the agency's action,'' (Id.) and did not reach the remaining questions. As explained in section III.C.1 of this order, Congress explicitly added the Durham-Humphrey Amendments to the FD&C Act to eliminate the marketing of both prescription and nonprescription versions of the same drug product at the same time. Thus, as with FDAMA, sections 503 and 505(e) of the FD&C Act provide the legislative basis for FDA to withdraw the PEG 3350 ANDAs; therefore, FDA's withdrawal action does not constitute a legislative rule. To the extent that Paddock argues that FDA's interpretation of meaningful difference, as set forth in the NOOH and ANPRM, is a legislative rule, applying the *American Mining Congress* four-part test again supports that FDA's interpretation does not constitute a legislative rule. As explained earlier in section I.B of this order, in the 2005 **Federal Register** notice referenced above, FDA explained that the Agency has interpreted the language in section 503(b)(1) and (4) of the FD&C Act to allow marketing of the same active ingredient in products that are both prescription and nonprescription, assuming some meaningful difference exists between the two that makes the prescription product safe only under the supervision of a licensed practitioner (70 FR 52050 at 52051). FDA noted such a difference could be, for example, in indication, strength, route of administration, and/or dosage form. This is a permissible interpretation of the FD&C Act by FDA (see, *e.g.*, *Shalala* v. *Guernsey Mem'l Hosp.*, 514 U.S. 87, 110 (1995) (5–4 decision) (O'Connor, J., dissenting)). The interpretation of ''meaningful difference'' does not require notice and comment rulemaking because the Durham-Humphrey Amendments provide an adequate legislative basis on its face to make such an interpretation.

b. Burden of proof. Paddock argues that the Agency also violates the APA in its application of evidentiary requirements with regard to summary judgment. Paddock argues that the APA places the burdens of persuasion and production on the party seeking an order, which in this case is the Secretary (Paddock Comments at 14). Here, Paddock contends that the Agency has to present evidence that the labeling of the prescription PEG 3350 products is false and misleading and that FDA's action to withdraw the ANDAs is based on new information (Paddock Comments at 14).

It is inappropriate, Paddock argues, for the Agency to issue a summary judgment order absent a hearing because the APA only authorizes a hearing officer to do so, and the Agency should be the party demonstrating that there is no genuine and substantial issue of fact (Paddock Comments at 16). If the Agency proceeds as it plans to according to the NOOH and issues an order for summary judgment, Paddock argues, it would be acting as prosecutor, judge, and jury, which is not authorized under the APA (Paddock Comments at 16).

Furthermore, both Nexgen and Paddock request that the Agency make all of the data from the clinical studies in the nonprescription MiraLAX NDA (22–015) available to the PEG 3350 ANDA holders (Nexgen Comments at 40 n. 37; Paddock Comments at 17–19; Nexgen Objection at 76–77). Not doing so, they claim, deprives them of due process because the data cited in the NOOH is not sufficient to understand the basis upon which FDA is acting to remove the PEG 3350 ANDAs from the market. Paddock argues that, under Rule 56(f) of the Federal Rules of Civil Procedure (FRCP), it has the right to review the protocols and data

underlying the OTC MiraLAX approval (Paddock Comments at 17–19).

These allegations mischaracterize the Agency's authority to issue summary judgment orders as set forth under the FD&C Act, its implementing regulations, and the APA, and as reflected in case law. The Agency is authorized under section 505(e) of the FD&C Act to withdraw a drug from the market, after notice and opportunity for a hearing, if its labeling is false and misleading. In addition, FDA's regulations set forth a regulatory procedure for withdrawing approval of drug marketing applications under 505(e) that is designed to provide due process, including notice and opportunity for a hearing, to application holders (see § 314.200(a)). FDA's regulations governing formal evidentiary public hearings set forth the grounds upon which a hearing may be denied and summary decision granted (see § 12.24). FDA regulations explicitly require the person requesting a hearing to show that the criteria in § 12.24(b) for granting a hearing are met. Likewise, where FDA serves a proposed order denying a hearing, the burden remains on the person requesting the hearing to respond with sufficient data, information, and analysis to justify a hearing (§§ 12.24 and 314.200(g)).

In fact, these administrative procedures have been previously upheld by the Supreme Court (*see Hynson*, 412 U.S. at 622 (''we find FDA hearing regulations unexceptionable on any statutory or constitutional ground.'')). Likewise, the courts have held that summary judgment is available to FDA if hearing requests fail to raise a genuine and substantial issue of fact. (*See Hynson*, 412 U.S. at 621 (''We cannot impute to Congress the design of requiring, nor does due process demand, a hearing when it appears conclusively from the applicant's 'pleadings' that the application cannot succeed.''); *Hess & Clark,* 495 F.2d at 983 (''When the FDA issues a Notice of Opportunity for Hearing, its summary judgment procedures are available if the requesting party fails to raise material issues of fact.'').) Contrary to Paddock's contentions, FDA is authorized to act as the final arbiter on issues of summary judgment. In issuing the predecessor regulation to § 314.200, FDA rejected comments asserting that an Administrative Law Judge should determine whether there is an issue of fact justifying a hearing. FDA noted that the same legal arguments were raised in the pharmaceutical industry briefs in *Hynson* and were rejected by the Supreme Court holding that the present summary judgment procedures met all statutory and constitutional requirements (39 FR 9750 at 9754). Not all of the constraints inherent in Rule 56 of the FRCP apply to this proceeding. (*See Smithkline Corp.* v. *FDA*, 587 F.2d 1107, 1119 (D.C. Cir. 1978) (''The Supreme Court has made clear, however, that, because these circumstances do not involve the Seventh Amendment right to a trial by jury, we need not engage in the sharp limitations on summary judgment required by Rule 56 of the Federal Rules of Civil Procedure.''); *Copanos,* 854 F.2d at 518 (''It is well settled that this provision does not guarantee the applicant a hearing in all circumstances; the agency may by regulation provide for summary withdrawal of approvals. . . .'').)

Based on the requirements of the FD&C Act, FDA's regulations, and the APA, Paddock and the other PEG 3350 ANDA holders have been afforded an appropriate opportunity to justify a hearing on the factual basis for the proposed withdrawal of approval for the ANDAs. They have been given specific instructions as to the type and detail of evidence required to support a request for hearing. As explained elsewhere in this order, the ANDA holders' approval relies on FDA's prior safety and efficacy findings for the RLD. The issue for resolution in this proceeding is whether there is a meaningful difference between OTC MiraLAX and the prescription PEG 3350 products as approved by FDA. Whether or not FDA should have approved MiraLAX Rx or MiraLAX OTC in the first place is not at issue here. Due process does not require FDA to provide the underlying data supporting the approval of prescription or OTC MiraLAX. The Agency is not obligated to provide the PEG 3350 ANDA holders additional or more detailed information with regard to its issuance of the NOOH.

5. Other Legal Arguments or Claims

Nexgen argues in its request for a hearing that FDA has never taken enforcement action to require the withdrawal of a prescription drug product simply because it lacks a meaningful difference from a later-approved nonprescription drug product (Nexgen Comments at 43). Thus, they contend that ''*FDA has no regulatory standards in place and no enforcement history to cite as a body of law establishing the foundation or the basis for its extraordinary proposed withdrawal*'' of the prescription PEG 3350 ANDAs (Nexgen Comments at 43 (emphasis in original)).[10]

This argument does not have any legal merit. It is within FDA's purview to determine when and what enforcement actions are appropriate regarding specific drug products, taking into account Agency resources and public health priorities. Such individual enforcement-related decisions have no bearing on the lawfulness of the marketing of any particular product. Even if FDA were enforcing provisions of the FD&C Act it had not previously, FDA is not estopped from enforcing those provisions (*see Scott Paper Co.* v. *Marcalus Mfg. Co.*, 326 U.S. 249, 257 (1945); *Donovan* v. *Daniel Marr & Son, Co.*, 763 F.2d 477, 484 (1st Cir. 1985); *United States* v. *Undetermined Quantities of Clear Plastic Bags of an Article of Drug for Veterinary Use*, 963 F. Supp. 641, 646–647, *aff'd*, No. 97–3467, 1998 U.S. App. LEXIS 9320, at *3–4 (6th Cir. May 4, 1998); *United States* v. *789 Cases of Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1296–97 (D.P.R. 1992)). Companies marketing drug products in the United States have the responsibility to ensure that their products are safe and effective and marketed in compliance with the law. Any product, including a product that is misbranded under the FD&C Act, which is being marketed illegally is subject to enforcement action at any time.[11]

Gavis submitted comments arguing that changing their prescription PEG 3350 product to nonprescription status would open them up to product liability in many States because they would not have the benefit of the learned intermediary defense, which exists for prescription products (Gavis Comments at 005). Nexgen argues for the first time in its objection that the ANDA holders could be subject to design defect liability for use beyond 7 days and misbranding charges for promoting use beyond 7 days. Nexgen also maintains that physicians may be subject to tort

[10] Counsel for Nexgen, Buchanan, Ingersoll & Rooney PC, also raised this issue in a Citizen Petition to the Agency (unrelated to the subject of this notice). See Docket No. FDA–2009–P–0589, Citizen Petition from Edward John Allera, Request to Confirm Dihydrocodeine Bitartrate as Generally Recognized as Safe and Effective for Use as a Liquid Antitussive in Prescription Cough/Cold Drug Products, dated December 1, 2009. The Agency denied the Citizen Petition in its entirety noting that ''The fact that FDA has not taken enforcement action against particular products in the past has no bearing on the lawfulness of the marketing of such products. FDA is not estopped from enforcing the requirements of the FD&C Act because the Agency has not previously enforced those requirements with respect to certain unapproved and violative products.'' (See Response to Citizen Petition FDA–2009–P–0589, issued March 9, 2012.)

[11] FDA, Guidance for FDA Staff and Industry Marketed Unapproved Drugs Manual of Compliance Policy Guides 440.100 at 5–6 (2011), available at *https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074382.htm.*

liability for instructing patients to use OTC MiraLAX for a duration longer than 7 days (Nexgen Objection at 77–78).

Potential liability issues are not among the factors FDA considers in determining whether an active ingredient may be simultaneously marketed in a prescription and nonprescription product. With regard to the decision to approve OTC MiraLAX, the Agency does not consider individual State tort law liability in its decisions regarding the safety and efficacy of drug products and whether the criteria for prescription products at section 503(b)(1) of the FD&C Act are met. As a matter of Federal law, FDA determines when approving an NDA whether a product meets the criteria for prescription drugs in the FD&C Act at section 503(b), or whether it can be safely and effectively marketed as a nonprescription product.

D. Evidence and Arguments Regarding Meaningful Difference Between the Prescription and Nonprescription PEG 3350 Products

As noted in section III.A, the PEG 3350 ANDA holders submitted evidence and arguments to support the contention that there is a meaningful difference between the prescription and nonprescription PEG 3350 products and assert that FDA is incorrect in proposing to withdraw the prescription version from the market. The evidence and arguments submitted by the PEG 3350 ANDA holders are further addressed in this section.

1. Duration of Use

Despite the fact that FDA considered the change of MiraLAX from prescription to nonprescription to be a ''full'' switch (and MiraLAX is no longer a RLD eligible to be marketed on a prescription basis), Nexgen, Gavis, and Paddock all assert that the difference in duration of use between the prescription and nonprescription versions of the PEG 3350 labeling constitutes a meaningful difference between the two products.

TABLE 3—LABELING REGARDING DURATION OF USE FOR PRESCRIPTION AND NONPRESCRIPTION PEG 3350

	Prescription MiraLAX	Nonprescription MiraLAX
Duration of Use	This product should be used for 2 weeks or less or as directed by a physician.	Use no more than 7 days. Stop use and ask a doctor if you need to use a laxative for longer than 1 week.

Nexgen and Gavis both argue that the words ''or as directed by a physician'' in the prescription MiraLAX labeling can be construed to mean that the PEG 3350 ANDA prescription products can be prescribed by a physician for an indefinite period of time or for chronic use; whereas the wording of the nonprescription MiraLAX labeling implies that FDA determined that use of PEG 3350 for longer than 7 days is unsafe for the consumer without supervision of a practitioner licensed by law (Gavis Comments at 003–004; Nexgen Comments at 6). Thus, they assert that because the prescription ANDA products are labeled for a longer duration of use with physician oversight, those products must be dispensed pursuant to prescription. They argue that because the PEG 3350 ANDAs are approved for prescription use, they should be allowed to remain on the market for those patients who need physician supervision (Gavis Comments at 003–004; Nexgen Comments at 8–9).

Furthermore, Nexgen and Gavis assert that the data submitted as part of the NDA for nonprescription MiraLAX support long-term use of the product, and withdrawing the prescription PEG 3350 ANDAs from the market would leave patients without a long-term option (see Gavis Comments at 004–005). Paddock and Nexgen claim that the data supporting the application for nonprescription use show that consumers taking PEG 3350 will experience increasing levels of effectiveness between 10 days and 1 month of use (Paddock Comments at 24; Nexgen Comments at 9; Nexgen Objection at 49–58). They believe this change in effectiveness over time is a material difference between the prescription and nonprescription products and shows that longer-term use with physician supervision is medically necessary (Nexgen Comments at 12; Paddock Comments at 20). Furthermore, Nexgen argues that the studies used to support the nonprescription MiraLAX NDA were conducted in chronically constipated patients and were designed to evaluate chronic use over the long term (Nexgen Comments at 14–15; Nexgen Objection at 49–58).

Nexgen also contends that FDA arbitrarily chose 7 days as a duration of use for the nonprescription MiraLAX product. This duration of use, Nexgen argues, was not based on FDA's medical judgment, but instead was a recommended time for OTC laxatives generally (Nexgen Comments at 7; Nexgen Objection at 56–57). Paddock agrees and claims that the statements in the NOOH are contrary to the recommendation in the TFM [12] on OTC laxatives (50 FR 2124 at 2131, January 15, 1985)), which states that ''constipation lasting more than 1 week could be a sign of a more serious condition for which proper diagnosis and treatment may be warranted. Therefore, the 1-week use limitation warning will be retained for bulk-forming laxatives as well as all other OTC laxative drug products,'' which Paddock believes indicates that the Agency found there to be a significant difference between 1- and 2-weeks duration of use (Paddock Comments at 22–23). Nexgen maintains that FDA must address at a hearing why it approved a 7-day duration of use consistent with the TFM in light of the NDA studies and literature (Nexgen Objection at 56–57). The ANDA holders' arguments regarding duration of use are not persuasive.

When FDA approved nonprescription MiraLAX, it considered the change from prescription to nonprescription to be complete, *i.e.,* no prescription indications remained. As set forth explicitly in the approved labeling, both the prescription and nonprescription products are indicated for occasional constipation, not chronic constipation, and the duration of use must be read in concert with that approved indication. Thus, FDA did not consider there to be any meaningful differences between the prescription and nonprescription labeling, and FDA considered any minor wording changes to simply be due to the different audiences (*i.e.,* learned intermediary versus lay consumer) and the difference in setting (*i.e.,* use with a physician's supervision versus consumer self-directed use).

Although the words ''or as directed by a physician'' in the prescription ANDA labeling may be interpreted as contemplating extended use, in the prescription setting a physician would have been involved in making that determination. Thus, according to the

[12] *See generally* 21 CFR part 330 (describing the public rulemaking process resulting in the establishment of standards (drug monographs) for an OTC therapeutic drug class).

labeling, a physician may choose, in his or her discretion as a medical professional, to prescribe the product for longer than 2 weeks. Contrary to the arguments posited by the ANDA holders, this recognition of physician discretion did not change the approved indication to chronic constipation. In any event, the nonprescription product also recognizes such discretion, so in that regard the products are the same, as well. Nonprescription MiraLAX describes a shorter duration of use and recommends seeing a physician if the patient needs to use a laxative for longer than 7 days, and, if so, a physician can direct the OTC consumer to continue using the product for a longer duration.

Although the studies supporting the approval of both the prescription and nonprescription versions of MiraLAX were of a longer duration than the duration of use for which the nonprescription product is labeled, when evaluating nonprescription labeling FDA determines what it believes to be the appropriate duration of use before recommending consumers seek assistance from a physician. The studies themselves are only one aspect of that determination. Furthermore, for approvals of both prescription and nonprescription products generally, long-term studies are often used to establish safety of the product. (See ''Guidance for Industry: Premarketing Risk Assessment,'' available at *https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126958.pdf*.) For nonprescription MiraLAX, the purpose of the longer duration of the studies was to assess the safety of the product for use in the OTC setting in which the potential exists for consumers to use the product repeatedly without consulting a physician.

FDA acknowledges that the study designs used in the trials that supported the change from prescription to nonprescription status were similar to study designs that could be used to support an indication of chronic idiopathic constipation, which is a long-term use indication that FDA would likely consider to be a prescription use. While the trials conducted to support the approval of MiraLAX as a nonprescription product were sufficiently long in duration to potentially have supported an indication for chronic idiopathic constipation (in addition to occasional constipation), such an indication was not sought by the sponsor. Because Braintree did not seek a chronic idiopathic constipation indication as a prescription product, and the ANDA prescription products were not approved for and are not labeled for that use, any argument that the studies support this use, or that their approvals should not be withdrawn because the product is used off-label, is irrelevant.

In determining whether a complete change from prescription to nonprescription status was appropriate, FDA found that there was no evidence in the three studies submitted in the MiraLAX NDA for nonprescription use that showed a different efficacy or safety profile in the treated population, compared with the studies that supported the prescription indication. With regard to the ANDA holders' assertions that the data supporting the nonprescription use demonstrates increased efficacy between 14 days and 1 month, the trials for the original prescription product were not designed to evaluate comparative efficacy over time. Therefore, there is no evidence from the studies that were used to support the approval of the prescription indication that establishes that MiraLAX is most effective when used for more than 7 days as the PEG 3350 ANDA holders claim. As to the longer-term studies supporting the nonprescription approval, as explained above, FDA considered the longer-term studies for nonprescription MiraLAX primarily to provide safety information. Specifically, these studies confirm that the drug would still be considered safe if a consumer chose to use it repeatedly before seeking advice from a physician. The studies cannot be used to support the assertions made by the PEG 3350 ANDA holders that the prescription product is most effective when used for a longer period of time. As reflected in their respective labeling, both products were expected to be effective in producing a bowel movement in less than 7 days, further confirming that there is no meaningful difference with respect to duration of use.

The ANDA holders also challenge decisions made during the course of FDA approval of OTC MiraLAX. They maintain that FDA's decision, made at the time of the OTC approval, to include a 7-day duration of use in the OTC labeling was arbitrary and was not based on FDA's medical judgment. As discussed above, the ANDA holders are not entitled to a hearing with regard to the decision to approve OTC MiraLAX or to decisions related to the content of the OTC label; those decisions are not at issue in this proceeding. Based on its studies and analyses submitted to support the nonprescription MiraLAX NDA, Braintree's proposed nonprescription labeling contained a 14-day duration of use, like the labeling for the prescription product. However, FDA, in conducting its own analysis, determined that the appropriate duration of use for the nonprescription MiraLAX product was 7 days with an instruction to consult a physician after that time. FDA determined that the 7-day duration of use was appropriate for a consumer self-medicating in the nonprescription setting and concluded that the nonprescription labeling should be consistent with earlier FDA determinations for other nonprescription laxatives. FDA issued a TFM for nonprescription laxative products in 1985. In this proposed regulation, the Agency agreed with the advisory panel regarding duration of use for laxatives in the OTC setting. The panel had previously stated that the reason for this recommendation is that a sudden change in bowel habits may be due to serious disease (*e.g.,* cancer, stricture), and the continued use of a laxative may delay diagnosis of such conditions. The panel is of the opinion that the available scientific evidence shows that very few indications warrant the use of any laxative beyond 1 week, except under the advice of a physician (40 FR 12902 at 12906, March 21, 1975). In the preamble to the TFM, FDA stated that ''the [A]gency considers the recommended 1-week limitation on the use of laxatives to be a necessary warning for the safe use of these products.'' (50 FR 2124 at 2130). This decision regarding the appropriate duration of use for laxative products in the OTC setting was not arbitrary, as the ANDA holders contend, but rather was based on FDA's scientific judgment regarding laxative products and its determination regarding how best to protect and promote the health of consumers using laxatives in the OTC setting. In any event, however, this decision regarding the OTC label was not based on any meaningful difference between the prescription and nonprescription products.

Gavis and Nexgen also attempt to fashion an argument out of a typographical error in the NOOH (Nexgen Comments at 5–6; Gavis Comments at 003–004). FDA wrote in the NOOH that the prescription indication is the following: ''This product should be used for 2 weeks or less as directed by a physician.'' The correct wording of the ANDA prescription labeling is, ''This product should be used for 2 weeks or less *or* as directed by a physician'' (emphasis added to indicate omitted word). Gavis and Nexgen both argue that FDA's conclusion that there is no meaningful difference is faulty because they contend that the Agency relied on the misstated indication for the prescription

PEG 3350 labeling. The Commissioner acknowledges that FDA unintentionally omitted the word ''or'' from the description of the ANDA prescription labeling in the NOOH. No meaning should be ascribed to this omission. FDA's analysis was based on the actual ANDA prescription labeling.

Nexgen also argues that the approval of nonprescription MiraLAX was an ''Initial Marketing of a Drug Product OTC'' and not an ''Rx to OTC Switch'' under the Center for Drug Evaluation and Research's Manual of Policies and Procedures (MAPP) 6020.5. Similar to their arguments described above, Nexgen contends that an ''Rx to OTC switch'' did not occur because the nonprescription MiraLAX has a different duration of use from the prescription product, which they suggest points to a meaningful difference between the two (Nexgen Comments at 16). Further, Nexgen accuses FDA of making an ''after-the-fact effort to revise or re-write the actual history relating to the OTC application and its review, apparently to rationalize its unfounded and unprecedented proposed enforcement action [withdrawing the PEG 3350 ANDAs]'' (Nexgen Comments at 17). Nexgen maintains that the switch of MiraLAX from prescription to nonprescription was not a complete switch because OTC MiraLAX was approved under a different NDA number, while, for other products, FDA has effectuated a partial switch with a new NDA and a complete switch with a supplemental NDA (Nexgen Objection at 44–46). Nexgen also maintains that the switch was not a complete switch because Breckenridge's prescription ANDA was approved only a few months prior to approval of OTC MiraLAX, Nexgen's prescription ANDA was approved 10 days prior to the approval of OTC MiraLAX, and the prescription MiraLAX NDA was not withdrawn until March 2009 (Nexgen Objection at 46).

These arguments have no validity. Nexgen's characterizations of FDA's actions are unfounded and incorrect. In assessing whether section 503(b)(4) allows the same active ingredient in products that are both prescription and nonprescription, FDA considers the products' approved indication, strength, route of administration, dosage form, and patient population and not the definitions in MAPP 6020.5 or MAPP processes that may have been followed prior to the approval. Facts related to the timing of a generic prescription PEG 3350 approval and the withdrawal of the prescription NDA likewise are not relevant to those considerations. While Braintree's NDA for nonprescription MiraLAX has a different NDA number, the issuance of a new NDA number is an administrative issue, which is irrelevant to the question of whether there is a meaningful difference between the prescription and nonprescription versions. Despite the difference in NDA numbers, FDA did consider the nonprescription MiraLAX NDA to be an ''Rx to OTC switch'' according to the MAPP.

In sum, the Commissioner has concluded that that there is not a meaningful difference between the prescription and nonprescription products based on the duration of use. The Commissioner does not find the arguments advanced by the PEG 3350 ANDA holders on this topic persuasive and is entering summary judgment against them.

2. Difference in Patient Populations

Nexgen, Gavis, and Paddock also submitted comments regarding the use of PEG 3350 in high-risk populations. They argue that their prescription approvals should not be withdrawn because, in their opinion, the supervision of a licensed practitioner is necessary for the safe and effective use of this drug in high-risk populations (Nexgen Comments at 26–30). They believe that patients in higher-risk populations cannot self-diagnose and self-treat their constipation. Therefore, they argue that the product should be dispensed upon a prescription and that a physician should be involved in the care of such patients (Paddock Comments at 24–26).

Furthermore, they do not believe that the nonprescription product can be used correctly by all of the patients that regularly use PEG 3350 and contend that eliminating the prescription version promotes self-medication by chronically ill individuals (Nexgen Comments at 47; Paddock Comments at 20). Specifically, they argue that the studies submitted to support the approval of MiraLAX for nonprescription use do not reflect how the product will be used in high-risk populations because high-risk subjects were excluded from the study population (Nexgen Comments at 21; Paddock Comments at 24). The studies excluded children and patients with a history of heart failure, diabetes, kidney failure, gastrointestinal disease, and surgeries or obstruction. Paddock argues that these groups represent large segments of the population who need laxative therapy (Paddock Comments at 24). In addition, Nexgen, Paddock, and Gavis note that subpopulations like children and the elderly require close monitoring when using laxatives and are at risk when taking a nonprescription product (Paddock Comments at 25; Gavis Comments at 007; Nexgen Comments at 31–33).

Finally, Nexgen notes that FDA failed to consider the needs of pediatric patients in its analysis. The prescription labeling stated that ''safety and effectiveness in pediatric patients has not been established''; whereas, the nonprescription labeling states, ''children 16 years of age or under: ask a doctor.'' Nexgen argues that the nonprescription labeling fails to consider that a physician's supervision is required for use in children. Nexgen also conjectures that by allowing Braintree to defer pediatric studies until 2016, FDA contemplated use of nonprescription MiraLAX in children (Nexgen Comments at 7–8).

FDA disagrees with the PEG 3350 ANDA holders' argument that there should be a prescription version of PEG 3350 available. As an initial matter, the ANDA holders' allegations regarding potential misuse by chronically ill individuals are simply a new iteration on their prior arguments about an off-label use of MiraLAX: Chronic constipation associated with these chronic illnesses. The data submitted by Braintree met the statutory and regulatory criteria for changing the product's status from prescription to nonprescription. In making this determination, FDA found that the product is safe and effective for use for self-medication as directed in the proposed nonprescription labeling. In this instance, and with all other nonprescription drug products, the labeling describes the patient population for which the product was found to be safe and effective, and suggests that other populations, such as children, should consult a physician. Nonprescription labeling is designed to assist consumers in appropriate self-selection and use. In addition, the nonprescription labeling is designed to instruct consumers regarding when they should seek the advice of a physician. Further, a physician is free to instruct a patient on how and whether to use a nonprescription product.

FDA disagrees with the contention that nonprescription MiraLAX is unsafe for use by elderly patients. In fact, the long-term clinical studies conducted to support the approval of MiraLAX as a nonprescription product enrolled a significant number of patients aged 65 years or older. In one study, 25 percent of the patients were over 65 years old, and in another study, 38 percent of

patients were over 65 years old.[13] The ANDA holders present their experts' observations related to the risk of MiraLAX use in the elderly but do not challenge the results of these studies. Furthermore, the risk information in the prescription labeling on geriatric use (''In geriatric nursing home patients a higher incidence of diarrhea occurred at the recommended 17 g dose. If diarrhea occurs MiraLAX should be discontinued'') is reflected in the risk information in the nonprescription ''Drug Facts'' label (''When using this product you may have loose, watery, more frequent stools; Stop use and ask a doctor if . . . [bullet] you get diarrhea''). Based on available data and information, FDA determined that the product is safe and effective for use in geriatric patients without a prescription if used as directed in the approved labeling and disagrees with Nexgen and Paddock's contentions that only having a nonprescription version available puts elderly patients at risk.

With regard to pediatric patients, the approved nonprescription MiraLAX labeling, like the prescription labeling, indicates that the product is for those 17 and older and explains that children under 16 should consult with a physician. No randomized, controlled studies were performed to properly assess the efficacy and safety of nonprescription MiraLAX in pediatric patients. In the absence of such data, it is common for nonprescription labeling to include age cutoffs and instruct consumers to talk to their doctor. Based on a particular patient's medical condition, a physician can choose to direct him or her on how to use a nonprescription product.

3. Difference in Labeling

Nexgen and Paddock also argue that removing the prescription PEG 3350 products from the market would deprive physicians of important information that is included in the prescription labeling but not in the nonprescription labeling. Nexgen argues that the quality of information provided in the prescription labeling and package insert is helpful in treating high-risk patients (Nexgen Comments at 21). Paddock notes that the package insert more fully discusses the efficacy, safety, and risk profile of PEG 3350 for long-term use and in high-risk patients (Paddock Comments at 20). Nexgen maintains that FDA's TFM for laxative products proposed to require professional labeling for OTC laxatives (Nexgen Objection at 72). These differences, they argue, constitute a meaningful difference between the products and require that prescription PEG 3350 remain on the market.

It is true that prescription labeling contains more detailed information than is included on nonprescription products (see §§ 201.57 and 201.66 (21 CFR 201.57 and 201.66)). However, when FDA determines that a product meets the statutory and regulatory criteria for changing its status from prescription to nonprescription, the new nonprescription labeling is designed for consumer use as per § 201.66. Prescription labeling is designed to inform medical practitioners and thus contains more information than OTC labeling. Such additional detail would not be appropriate or useful in the OTC setting. Because FDA considered the change from prescription to nonprescription status to be a ''full'' switch, the prescription labeling is no longer appropriate. The fact that the prescription labeling is more detailed does not establish a meaningful difference between the prescription and nonprescription versions.

The factors FDA generally considers in determining whether there is a meaningful difference are indication, strength, route of administration, population, and dosage form. As the labeling for the prescription and nonprescription PEG 3350 products shows, they have the same indication, strength, route of administration, population, and dosage form. As explained in the NOOH, if FDA were to include the differences between prescription and nonprescription labeling requirements as a factor in determining whether there is a meaningful difference sufficient to allow the same active ingredient to be marketed in prescription and nonprescription products, FDA would never be able to exempt a drug product from the prescribing requirements of section 503(b). This result would be in contravention of the plain language of section 503 of the FD&C Act and the purpose of Congress in enacting that provision. Further, Nexgen's contention that FDA proposed to require professional labeling for nonprescription laxatives in the TFM for those products fails to establish a meaningful difference between the prescription and nonprescription PEG 3350 products.[14]

4. Other Active Ingredients Marketed in Prescription and Nonprescription Drug Products Simultaneously

Nexgen and Paddock do not agree that the examples FDA cited in the NOOH of active ingredients that are simultaneously marketed in prescription and nonprescription drugs that FDA considers to be meaningfully different (ranitidine hydrochloride (HCl), omeprazole, and ibuprofen) can be distinguished from PEG 3350. In addition, Nexgen and Paddock identified other examples of active ingredients that are simultaneously marketed in prescription and nonprescription products (butenafine HCl, terbinafine HCl, cimetidine, and loperamide) that they believe are analogous to PEG 3350. They argue that all of the examples of active ingredients being simultaneously marketed for prescription and nonprescription uses have less significant differences in conditions of use than those between the prescription and nonprescription versions of MiraLAX (Paddock Comments at 2 and 21; Nexgen Comments at 49–53). Furthermore, Nexgen argues that in the examples FDA cited in its NOOH, each of the active ingredients has a prescription version because of a need for continued physician oversight to treat certain patient populations. In this way, they contend, those products are analogous to the prescription PEG 3350 products. Thus, they argue that the ANDA PEG 3350 approvals should be retained to ensure the intervention and supervision of a physician of certain patients for which physicians commonly prescribe PEG 3350 (geriatric patients, pediatric patients, patients with chronic constipation) and for whom a serious disease or condition is the cause of constipation. They argue that, although PEG 3350 is not approved for chronic use and pediatric patients, FDA must consider that PEG 3350 is commonly prescribed for these uses (Nexgen Comments at 49–50). Nexgen also argues that meaningful differences exist between the prescription and nonprescription labels of MiraLAX and ranitidine products because the prescription labeling for the prescription MiraLAX and ranitidine includes information describing dosing in elderly patients, while the OTC labeling for both products does not (Nexgen Comments at 50).

Nexgen and Paddock's arguments that FDA's determinations regarding whether there are meaningful differences between the prescription and nonprescription versions of ranitidine HCl, omeprazole, and

[13] Ruyi He, GI Team Leader AP Comments on NDA 22–015, dated August 14, 2006.

[14] Should a physician wish to access more detailed information about the efficacy, safety, and risk profile of nonprescription MiraLAX for long-term use and/or use in high-risk patients, such information is available in the medical literature.

ibuprofen do not support the conclusion that the prescription PEG 3350 products also have meaningful differences from nonprescription MiraLAX. Nexgen's and Paddock's meaningful difference arguments largely compare uses for which the ANDA holders assert PEG 3350 is commonly prescribed, but for which it is not approved, (*e.g.,* pediatric patients and patients with chronic constipation) with indications for which ranitidine HCl, omeprazole, and ibuprofen are approved. Because this proceeding to withdraw approval of the Rx PEG 3350 products focuses on whether such products as approved by FDA are meaningfully different than OTC MiraLAX, such arguments regarding unapproved uses of PEG 3350 are irrelevant in this proceeding. Other arguments are relevant to the issue of whether any laxative product should be approved OTC (*e.g.,* constipation may be caused by a serious underlying condition) and not relevant to the issue of whether there is a meaningful difference between the prescription and nonprescription products as approved by FDA.

The ANDA holders' reliance on FDA's decision to allow simultaneous prescription and nonprescription marketing of other active ingredients is misplaced because FDA makes these decisions on a case-by-case basis, based upon the merits of the individual application before the Agency. Nevertheless, the Commissioner will address the examples of simultaneous marketing raised by the ANDA holders. Furthermore, the permitted simultaneous prescription and nonprescription marketing of active ingredients, such as butenafine HCl (Mentax Rx and Lotrimin Ultra), terbinafine HCl (Lamisil), cimetidine, and loperamide are distinguishable from the prescription PEG 3350 products. Unlike MiraLAX, the differences in the cited examples are meaningful for the reasons set forth in this section. Moreover, none of the examples cited below rely upon duration of use alone to support the simultaneous marketing of Rx and OTC products. While some of the Rx and OTC products discussed below do have different durations of use, there is also an additional, more fundamental difference between the Rx and OTC products discussed below, such as different indication, patient population, or dose.

a. Butenafine HCl. The active ingredient, butenafine HCl, is an antifungal agent for which safety and efficacy have been established for the topical treatment of a variety of superficial dermal infections (tinea corporis, tinea cruris (jock itch), interdigital tinea pedis (athlete's foot), and tinea versicolor (a fungal infection of the skin resulting in small, discolored patches)) due to susceptible organisms. FDA considers some of these indications to require the involvement of a practitioner licensed by law and thus to meet the standard for requiring a prescription under section 503(b)(1) of the FD&C Act, while others do not. The active ingredient is marketed with the tradename Mentax as a prescription product, and with the tradename Lotrimin Ultra as a nonprescription product. The indications for the active ingredient butenafine HCl Rx and butenafine HCl OTC are set out in table 4.

TABLE 4—DIFFERENCES BETWEEN THE PRESCRIPTION AND NONPRESCRIPTION VERSIONS OF DRUG PRODUCTS WITH THE ACTIVE INGREDIENT BUTENAFINE HCl AND BUTENAFINE HCl

	Mentax (butenafine HCl) (Rx)	Lotrimin Ultra (butenafine HCl) (OTC)
Indication	Indicated for the topical treatment of the dermatologic fungal infection, tinea (pityriasis) versicolor due to *Malassezia furfur* (formerly *P. orbiculare*).	Indicated for the treatment of athlete's foot (tinea pedis) and jock itch (tinea cruris) in consumers 12 years and older. Consumers less than 12 years old are directed to ask a doctor.

Tinea versicolor, the prescription indication, is usually diagnosed based on a medical history and physical examination. The symptoms may resemble other skin conditions and require the expertise of a physician for diagnosis using an ultraviolet light or other professional diagnostic tools. In contrast, FDA considers the indication for the treatment of athlete's foot and/or jock itch to be conditions that a consumer can self-diagnose and self-treat.

Thus, FDA determined that the prescription indication requires the supervision of a practitioner licensed by law and meets the criteria at section 503(b)(1) of the FD&C Act, while the nonprescription indications did not meet the criteria at section 503(b)(1). Thus, the differences in the indications for the active ingredient, butenafine HCl creams are meaningful in that the conditions for which they are indicated require different levels of expertise to diagnose and treat.

b. Terbinafine HCl. The active ingredient terbinafine HCl is an antifungal agent that is administered either orally or topically. It is marketed as a prescription product under the tradename Lamisil Gel and as a nonprescription product under the tradename Lamisil Cream.[15] Like the last example, the indications for the two products are different as explained in table 5.

TABLE 5—DIFFERENCES BETWEEN PRESCRIPTION TERBINAFINE HCl AND NONPRESCRIPTION TERBINAFINE HCl

	Lamisil DermGel Rx	Lamisil Cream OTC
Indication	For the treatment of tinea (pityriasis) versicolor due to *M. furfur,* tinea pedis (athlete's foot), tinea corporis (ringworm) or tinea cruris (jock itch) due to *Trichophyton rubrum, Trichophyton mentagrophytes,* or *Epidermophyton floccosum*.	For the treatment of athlete's foot (tinea pedis), tinea corporis (ringworm) and jock itch (tinea cruris) in consumers 12 years and older. Consumers less than 12 years old are directed to ask a doctor.

[15] The Rx Gel (NDA 20–846) has been discontinued.

As noted in table 5, the nonprescription version of Lamisil (cream) is used for the treatment of athlete's foot (tinea pedis), ringworm (tinea corporis), and jock itch (tinea cruris)—common conditions a consumer can self-diagnose and self-treat. The prescription version of Lamisil is indicated for the treatment of tinea versicolor, which requires the expertise of a physician to diagnose and treat (as discussed above). Similar to butenafine HCl discussed in section III.D.4.a., the differences in the indication of Rx versus OTC terbinafine HCl are meaningful in that the conditions for which they are indicated require different levels of expertise to diagnose and treat (as discussed above).

c. Loperamide. Loperamide is an oral antidiarrheal agent marketed under the trade name Imodium as a nonprescription product. Loperamide prolongs the transit time of the intestinal contents. It reduces fecal volume, increases the viscosity and bulk density, and diminishes the loss of fluid and electrolytes. Table 6 sets out the differences between the indication, dosage, and duration of use for loperamide Rx versus loperamide OTC.

TABLE 6—DIFFERENCES BETWEEN LOPERAMIDE RX AND LOPERAMIDE OTC

	Loperamide Rx (Imodium) 2 milligram (mg) capsule	Loperamide OTC Loperamide (Imodium) 2 mg caplet
Indication	Indicated for the control and symptomatic relief of acute nonspecific diarrhea and chronic diarrhea associated with inflammatory bowel disease. It is also indicated for reducing the volume of discharge from ileostomies.	Used for the control of symptoms of diarrhea, including travelers' diarrhea.
Dose	The recommended daily dose in adults should not exceed 16 mg (8 capsules). In children, the dosing is based on age and weight range. Following the first treatment day, it is recommended that subsequent doses (1 mg/10 kg body weight) be administered only after a loose stool; total daily dosage should not exceed recommended dosages for the first day.	The recommended daily dose in adults and children over 12 years of age should not exceed 8 mg (4 capsules) in 24 hours. In children, the dosing is based on age and weight range (different from that of the Rx labeling).
Duration of Use	There is no specified limit in the duration of use	Patients are directed to stop use and ask a doctor if symptoms get worse or diarrhea lasts for more than 2 days.

Prescription loperamide is indicated for the control and symptomatic relief of acute nonspecific diarrhea and chronic diarrhea associated with inflammatory bowel disease and for reducing the volume of discharge from ileostomies. These conditions require the diagnostic skills and treatment intervention of a physician. In comparison, OTC loperamide is indicated for the treatment of diarrhea, including traveler's diarrhea, which can be self-diagnosed and treated. In addition, the total daily dose is 8 mg for OTC loperamide and 16 mg for Rx loperamide, and there are differences in dosing for children. Finally, the OTC version has a recommended duration of use of only 2 days, whereas the Rx version is used to treat chronic conditions for an unlimited period of time under the supervision of a physician.

The differences between Rx and OTC loperamide are meaningful in that the conditions for which they are indicated require different levels of expertise to diagnose and treat. In addition, they are dosed at different levels.

d. Cimetidine. Cimetidine is an oral H_2-receptor antagonist used mainly for treating acid-related gastrointestinal disorders. It is marketed as Tagamet. Table 7 sets out the differences between the dosage, indication, and duration of use for cimetidine Rx versus cimetidine OTC.

TABLE 7—DIFFERENCES BETWEEN CIMETIDINE RX AND CIMETIDINE OTC

	Cimetidine Rx	Cimetidine OTC
Indication	Indicated for the treatment of acid-related gastrointestinal disorders such as gastroesophageal reflux disease (GERD) and duodenal ulcers.	Relief of heartburn associated with acid indigestion and sour stomach; prevention of heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages.
Dosage	200 mg–1600 mg as adjusted to individual patient needs	200 mg up to 2 times per day as needed to relieve heartburn.
Duration of Use	2–3 times per day for 4–12 weeks. Indication specific	No longer than 14 days unless directed by a physician.

The conditions for which cimetidine Rx is indicated require a physician for diagnosis and treatment; they cannot be self-diagnosed and are not appropriate for self-treatment. They are also treated at a significantly higher dose (*e.g.,* 400 to 1600 mg per day for 4 to 8 weeks; 800 mg twice a day for 12 weeks) and at a much longer duration (up to 12 weeks) than the OTC drug product with the same active ingredient.

Cimetidine OTC is indicated to relieve or prevent heartburn associated with acid indigestion and sour stomach that occurs after eating or drinking certain food or beverages, a condition that patients can self-diagnose and self-treat. Unlike cimetidine Rx, it is not indicated to be used on a regular dosing regimen to treat a permanent medical condition such as GERD or duodenal ulcers. Rather, the OTC product is used on an ''as needed'' basis to prevent or relieve a symptom, so consumers could take one or two doses (200 to 400 mg) on a day they experience heartburn. The OTC labeling limits use to no more than 2 weeks.

The Rx and OTC versions of cimetidine have meaningful differences in that the conditions for which they are indicated require different levels of expertise to diagnose and treat, and they

have different dosage strengths, durations of use, and indications.

e. Omeprazole. Omeprazole is a proton pump inhibitor used mainly for treating acid-related gastrointestinal disorders. It is marketed as PRILOSEC. Table 8 sets out the differences between the dosage, indication, and duration of use for omeprazole Rx versus omeprazole OTC.

TABLE 8—DIFFERENCES BETWEEN OMEPRAZOLE RX AND OMEPRAZOLE OTC

	Omeprazole Rx	Omeprazole OTC
Indication	Indicated for the treatment of conditions that require profound inhibition of gastric acid secretion, such as treatment of GERD and maintenance of healing of erosive esophagitis in both adult and pediatric patients, and especially the treatment of hypersecretory conditions.	Indicated for the treatment of frequent heartburn occurring 2 or more days a week.
Dosage	20 mg–60 mg. Indication specific	20 mg.
Duration of Use	Ranges from once daily for 4 weeks to an open-ended duration. Indication specific.	No more than 14 days and not more often than every 4 months unless directed by a physician.

The conditions for which Rx omeprazole is indicated require the supervision of a physician for diagnosis and treatment. Depending on the indication, treatment duration could be months and even years. In the particular instance of the treatment of symptomatic GERD, the recommended dose is 20 mg daily for up to 4 weeks and of the treatment of erosive esophagitis due to acid-mediated GERD, the recommended dose is 20 mg once daily for 4 to 8 weeks. The Rx version allows titrating upward to achieve efficacy, especially for pathological hypersecretory conditions.

On the other hand, omeprazole OTC is approved for the treatment of frequent heartburn (defined as occurring 2 or more days per week). This product is to be taken once a day (every 24 hours) every day for 14 days. The product labeling notes that it may take 1 to 4 days for full effect, although some people may get complete relief of symptoms within 24 hours. The consumer is instructed not to take the drug for more than 14 days or use more than one course every 4 months unless otherwise directed by a doctor.

The Rx and OTC versions of omeprazole have meaningful differences in that the conditions for which they are indicated require different levels of expertise to diagnose and treat, and they have different durations of use and indications.

f. Ranitidine HCl 150 mg. Ranitidine HCl is a histamine H_2-receptor antagonist that inhibits stomach acid production. It is marketed as ZANTAC. It comes in a wide variety of strengths, but the 150 mg strength tablet is the only formulation that is marketed as both Rx and OTC. Table 9 sets out the differences between the dosage, indication, and duration of use for 150 mg ranitidine HCl Rx versus ranitidine OTC.

TABLE 9—DIFFERENCES BETWEEN RANITIDINE HCl RX AND RANITIDINE HCl OTC

	150 mg Ranitidine HCl Rx	150 mg Ranitidine HCl OTC
Indication	Pediatric patients (1 month to 16 years): Treatment of duodenal and gastric ulcers, maintenance of healing of duodenal and gastric ulcers, and treatment of GERD and erosive esophagitis. Adult patients: Multiple indications related to duodenal ulcer, gastric ulcer, GERD, erosive esophagitis, and pathological hypersecretory conditions.	Relieves heartburn associated with acid indigestion and sour stomach. Prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages.
Dosage	Pediatric patients: Dose varies based on body weight; dose frequency is one to two times per day, depending on the indication. Adult patients: One to four times per day, depending on the indication.	Adults and children 12 years and over: To relieve symptoms, swallow 1 tablet with a glass of water. To prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn. Can be used up to twice daily (do not take more than 2 tablets in 24 hours). Children under 12 years: Ask a doctor.
Duration of Use	Indication specific. For most indications, duration is open-ended.	Stop use and ask a doctor if your heartburn continues or worsens or if you need to take this product for more than 14 days.

OTC ranitidine HCl is indicated for conditions that the patient may self-diagnose and self-treat and because of the ability to self-diagnose and self-treat, the dosing is on an ''as needed'' basis to prevent or relieve a symptom. For example, a consumer could take one or two doses (150 to 300 mg) on a day they experience heartburn. The OTC product limits time for which a consumer should use the product without consulting a doctor. In addition, the OTC product is only approved for use in adults and children 12 and over.

On the other hand, Rx ranitidine HCl is indicated for the treatment of more serious acid- related gastrointestinal disorders such as GERD and duodenal ulcers, which require a physician to diagnose. These conditions are chronic and require treatment over an extended period of time under the supervision of a physician. Further, the Rx ranitidine HCl is approved for use in children as young as 1 month old. Nexgen acknowledges that Rx ranitidine HCl remains approved because, among other reasons, it is indicated for much more severe medical conditions than the OTC ranitidine HCl (Nexgen Comments at

50). Nevertheless, Nexgen argues that the labeling for prescription PEG 3350 and ranitidine addresses use in elderly patients, which does not appear in the OTC labeling. Such labeling differences result from the differences in the labeling requirements for prescription (§ 201.57) and OTC (§ 201.66) products. Such differences were not set forth in the ANPRM or the NOOH for this proceeding as a factor that FDA would consider in determining that there is a meaningful difference such that the same active ingredient could be marketed in both a prescription and nonprescription product. Unlike OTC MiraLAX and Rx PEG 3350, the Rx and OTC versions of 150 mg ranitidine HCl have meaningful differences in that the conditions for which they are indicated require different levels of expertise to diagnose and treat, and they have different indications, durations of use, dosages, and indicated patient populations.

g. Ibuprofen. Ibuprofen is a nonsteroidal anti-inflammatory drug used as an analgesic for relief of symptoms of, including but not limited to, arthritis, fever, inflammation, and dysmenorrhea. Ibuprofen is marketed under multiple brand names, including ADVIL and MOTRIN, and comes in multiple dosage forms. Tables 10a and 10b set out the differences in indication, dosing, and duration of use of the 100 mg/5 mL suspension for Rx versus OTC use and the meaningful differences in the 400 mg Rx tablet and the 200 mg OTC tablet.

TABLE 10a—DIFFERENCES BETWEEN IBUPROFEN SUSPENSION Rx AND IBUPROFEN SUSPENSION OTC

	Ibuprofen 100 mg/5 mL suspension Rx	Ibuprofen 100 mg/5 mL suspension OTC
Indication	Pediatric Patients: For reduction of fever in patients aged 6 months up to 2 years of age. For relief of mild to moderate pain in patients aged 6 months up to 2 years of age. For relief of signs and symptoms of juvenile arthritis. Adult Patients: For treatment of primary dysmenorrhea. For relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis.	Pediatric Patients (age 2–11): Relieves minor aches and pains due to the common cold, flu, sore throat, headache, and toothache. Reduces fever (stop use and ask a doctor if: Fever or pain gets worse or lasts more than 3 days)
Dosage	Pediatric Patients: Doses vary depending on the condition being treated, but the recommended maximum daily dose in treating any of the conditions is 40mg/kg. Adult Patients: The dose of ibuprofen oral suspension should be tailored to each patient, and may be lowered or raised from the suggested doses depending on the severity of symptoms either at time of initiating drug therapy or as the patient responds or fails to respond.	The dosage depends on the child's age and weight. An attached dosing chart informs the consumer how large of a dose the child should receive.
Duration of use	Ranges from as necessary to an open-ended daily dosage.	No more than 3 days unless directed by a doctor.

TABLE 10b—DIFFERENCES BETWEEN IBUPROFEN TABLET Rx AND IBUPROFEN TABLET OTC

	Ibuprofen 400 mg tablet Rx	Ibuprofen 200 mg tablet OTC
Indication	Indicated for relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis, relief of mild to moderate pain, and treatment of primary dysmenorrhea.	Indicated for the temporary relief of minor aches and pains due to: Headache, minor pain of arthritis, backache, menstrual cramps, muscular aches, toothache, and the common cold. Indicated to temporarily reduce fever.
Dosage	Patients should use the lowest effective dose for the shortest duration consistent with patient treatment goals. After observing the response to initial therapy, the dose and frequency should be adjusted to suit an individual patient's needs. Do not exceed 3200 mg total daily dose. Rheumatoid arthritis and osteoarthritis suggested dosage: 1200 mg–3200 mg daily. Mild to moderate pain suggested dosage: 400 mg every 4 to 6 hours as necessary for relief of pain. Dysmenorrhea suggested dosage: 400 mg every 4 hours as necessary for relief of pain.	Adults and children 12 years and older, take one caplet every 4 to 6 hours while symptoms persist. If pain does not respond to one caplet, two caplets may be used. Do not exceed six caplets in 24 hours, unless directed by a doctor.
Duration of use	Shortest duration consistent with individual patient treatment goals.	Stop and ask a doctor if pain gets worse or lasts more than 10 days, or fever gets worse or lasts more than 3 days.

Both Rx ibuprofen forms allow for high doses to treat rheumatoid arthritis and juvenile arthritis, as well as other chronic conditions. The ibuprofen Rx suspension also allows for titration of doses to treat pain of varying severity in adults who cannot swallow pills and for pediatric patients depending on the severity of the symptoms. Neither Rx ibuprofen form limits the duration of use in patients. The labeled instructions to titrate the dosage and use the product for an unlimited duration support the necessity of physician oversight with both Rx ibuprofen forms.

On the other hand, the ibuprofen OTC suspension product has fixed age and weight range dosing divisions, does not exceed 15 mg/kg per dose, does not allow for dose titration, and limits use to 3 days. The ibuprofen OTC tablet label recommends a maximum daily dose of 1200 mg, whereas the ibuprofen

Rx tablet allowed for up to 3200 mg daily, for certain conditions. The ibuprofen OTC tablet also limits use to 3 or 10 days, for certain conditions. Finally, both OTC ibuprofen forms are indicated for less severe and non-chronic conditions. Because the ibuprofen 100 mg/5 mL suspension Rx and OTC products and the ibuprofen Rx and OTC tablet products differ in the indications, dosage, and durations of use depending upon the indication, they are meaningfully different.

Unlike the meaningful differences in the examples provided in section III.D.4, and for the reasons discussed in other parts of this section, FDA does not consider there to be a meaningful difference between the prescription PEG 3350 products and the nonprescription MiraLAX product. The Commissioner finds that the meaningful differences between the other active ingredients that are marketed in drug products that are both prescription and nonprescription products described in section III.D.4 are distinguishable from the nonmeaningful differences between the prescription PEG 3350 products and the nonprescription MiraLAX product. The examples cited by the PEG 3350 ANDA holders significantly differ in one or more of their indications, dosage, or target population. In addition to these differences, some also have a different duration of therapy. All of these drugs were initially approved as prescription products, and then subsequently the active ingredients were also approved for use in a nonprescription product for different indications, or sometimes a subset of, the prescription indications—unlike MiraLAX where no different prescription indications remain. By definition, prescription products are approved for use for indications for which consumers cannot self-diagnose or self-treat, thus requiring the supervision of a licensed practitioner, *i.e.,* the prescription standard in section 503(b) of the FD&C Act is met. In the case of nonprescription MiraLAX, it is not indicated for any conditions that consumers cannot self-diagnose or self-treat, and thus does not meet the standard in section 503(b) of the FD&C Act.

5. Other Objections

Other objections raised by the PEG 3350 ANDA holders regarding their contention that there is a meaningful difference between the prescription PEG 3350 products and nonprescription MiraLAX include those related to the wording of the indication, the exclusivity granted to Braintree, and the cost of OTC MiraLAX.

Gavis and Nexgen argue that the prescription ANDA PEG 3350 labeling states that the product is for the ''treatment'' of occasional constipation; whereas, nonprescription MiraLAX is for ''reliev[ing]'' occasional constipation. Gavis contends that nonprescription MiraLAX ''relieves'' constipation, rather than treating it, which is a meaningful difference requiring the prescription product to remain on the market (Gavis Comments at 006; Nexgen Objection at 66). Nexgen notes that ''treats'' and ''relieves'' may not be used interchangeably under FDA's regulation for OTC drug products at 21 CFR 330.1(i) (Nexgen Objection at 66). The NOOH explained that the approved OTC MiraLAX labeling uses the word ''relieves'' to ensure consistency with other OTC monograph laxative products. As noted, FDA, in considering whether there is a meaningful difference, compares the active ingredient, dosage form, strength, route of administration, indications, and patient population. In this case, because both the OTC and Rx products are indicated for occasional constipation, the different terms ''relieves'' and ''treats'' do not constitute a meaningful difference.

Paddock also argues that granting Braintree 3 years of exclusivity under section 505(j)(5)(F) of the FD&C Act indicates that there are meaningful differences between the prescription PEG 3350 labeling and the nonprescription MiraLAX labeling because the clinical data submitted to support nonprescription MiraLAX was in different populations (Paddock Comments at 2). In Paddock's opinion, 3-year exclusivity would only be authorized if the data were the result of ''new clinical investigations,'' which would indicate that nonprescription MiraLAX is different from the prescription PEG 3350 products (Paddock Comments at 6). It is true that Braintree conducted new clinical investigations to support its NDA for nonprescription MiraLAX. However, contrary to Paddock's contentions, the basis of approval for the prescription product consisted of two studies, 851–3 and 851–6, which demonstrated that at least one-third of subjects taking 17 g of MiraLAX per day have a bowel movement by Day 1, and at least three-fourths have a first bowel movement by Day 3. The three studies submitted in the nonprescription NDA, studies 851–CR1, 851–ZCC, and 851–CR3, did not show a different efficacy or safety profile in the treated populations when compared with the studies submitted in support of the prescription NDA (851–3 and 851–6). The three studies submitted with the nonprescription NDA simply provided evidence that nonprescription MiraLAX would be safe if used repeatedly over time in an OTC setting. As noted in section III.C.3, Braintree earned 3 years of exclusivity for the new clinical studies it conducted that supported approval of its OTC switch NDA. In the Commissioner's opinion, the fact that clinical data was necessary to provide assurance that nonprescription availability of the product was safe does not, in and of itself, support the contention that the product is meaningfully different from the previously approved prescription product. Sponsors of nonprescription drug products frequently perform additional studies that FDA concludes are essential to support a change from prescription to nonprescription status, such as actual use studies, for which they may receive exclusivity (if the statutory criteria for exclusivity are met).

Paddock also notes that removing the prescription PEG 3350 products from the market will nearly triple the cost of the product for the average insured patient (Paddock Comments at 2). Paddock maintains that this predicted cost increase is because consumers with insurance may pay less out of pocket for prescription drugs than for nonprescription drugs, and the exclusivity granted to Braintree for the nonprescription product would create a monopoly if all competing prescription products were withdrawn from the market (Paddock Comments at 30). Paddock and Nexgen argue that withdrawal of approval for prescription PEG 3350 products will reduce the availability of the products due to the absence of Medicaid and health insurance coverage (Nexgen Comments at 43; Paddock Comments at 30; Nexgen Objection at 41). Nexgen challenges FDA's conclusion in the draft order that cost is not a relevant consideration in this proceeding (Nexgen Objection at 42).

These arguments are irrelevant. In this instance, the prescription PEG 3350 products may no longer be lawfully marketed. In the ANPRM and NOOH, FDA set forth the factors it generally considers in determining whether the same active ingredient may be marketed in a prescription and nonprescription product: Issues related to the cost of drug products are not a relevant consideration.

Nexgen maintains that FDA should stay the withdrawal of the ANDAs pending the finalization of the TFM for OTC laxatives and FDA issuing a response on a pending citizen petition

submitted by Nexgen (Nexgen Objection at 78–82). According to Nexgen, its pending citizen petition requests that FDA find that the prescription MiraLAX NDA was not withdrawn for reasons of safety and efficacy and to declare Nexgen's prescription ANDA as the new RLD drug for prescription PEG 3350 products (Objection at 79). It is not necessary to finalize the TFM for OTC laxatives or to respond to Nexgen's pending citizen petition prior to the withdrawal of the ANDAs. As discussed elsewhere in this order, the OTC MiraLAX labeling is consistent with the TFM for OTC laxatives with respect to the use of the phrase ''relieves'' versus ''treats'' and the instruction to ''use no more than 7 days'' and ''Stop use and ask a doctor if . . . you need to use a laxative for longer than 1 week.'' However, this labeling does not change the factors relevant to determining whether there is a meaningful difference between the prescription and nonprescription PEG 3350 products. If an order is entered withdrawing the approval of the ANDAs, the issues raised in the citizen petition will be moot.

Nexgen complains that FDA largely based its draft proposed order on a January 2013 letter from Merck rather than more carefully reviewing and responding to each argument raised by the ANDA holders, rendering the order suspect (Nexgen Objection at 75–76). In fact, both the Merck letter and the draft proposed order were written in response to the issues and evidence submitted by the ANDA holders. The draft proposed order provided a lengthy analysis addressing the arguments and evidence submitted by the ANDA holders. The fact that the draft proposed order ultimately reached the same conclusion urged by the NDA holder (and the result proposed by CDER in the NOOH) does not render that order ''suspect.''

In sum, the Commissioner believes that the change in prescription to nonprescription status was a complete switch. In addition, the Commissioner concludes that there is not a meaningful difference between the prescription and nonprescription products approved by FDA based on the arguments discussed in this section. The Commissioner finds that the ANDA holders have failed to raise a genuine and substantial issue of fact regarding a meaningful difference between prescription and nonprescription MiraLAX that requires a hearing. The Commissioner does not find the arguments advanced by the PEG 3350 ANDA holders on the topics discussed in this section persuasive and is entering summary judgment against them.

IV. Findings and Order

Based upon the above, the Commissioner finds that the PEG 3350 ANDA holders have failed to raise a genuine and substantial issue of fact requiring a hearing in their responses to the NOOH. A hearing, therefore, is not required under § 12.24(b). The PEG 3350 ANDA holders did not submit any specifically identified reliable evidence demonstrating that a hearing is necessary. Other evidence submitted was not material to the issues in this proceeding. Even if the Commissioner were to accept these factual assertions as having some weight, such evidence does not present a sufficient area of disagreement to require an evidentiary hearing. Rather, the evidence is ''so one-sided that [FDA] must prevail as a matter of law.'' (See *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).)

In addition to finding that the ANDA holders have failed to raise a genuine and substantial issue of fact that requires a hearing, the Commissioner does not find the arguments advanced by the PEG 3350 ANDA holders persuasive and is entering summary judgment against them under § 314.200(g). There is no meaningful difference between the ANDA holders' PEG 3350 products and OTC MiraLAX. The labeling of the ANDA holders' PEG 3350 products is false and misleading because it bears the ''Rx only'' symbol when FDA has determined in approving OTC MiraLAX that the drug can be used safely and effectively in the nonprescription setting and does not meet the criteria for a prescription drug in 503(b)(1) of the FD&C Act. This false and misleading labeling was not corrected within a reasonable time after receipt of written notice from FDA. Therefore, under section 505(e) of the FD&C Act and under authority delegated to the Commissioner, the PEG 3350 ANDA holders' requests for a hearing are denied.

It is ordered, that pursuant to section 505(e) of the FD&C Act (21 U.S.C. 355(e)), that approval of the following ANDAs: ANDA 76–652 held by Kremers Urban Pharmaceuticals, Inc.; ANDA 77–736 held by Breckenridge Pharmaceutical, Inc.; ANDA 77–706 held by Nexgen Pharma, Inc. (formerly known as Anabolic Laboratories, Inc.); ANDA 77–893 held by Paddock Laboratories, LLC.; and ANDA 77–445 held by Teva Pharmaceutical, USA; and all amendments and supplements to them, be and hereby are withdrawn, effective May 2, 2018.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06537 Filed 3–30–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1141]

Mallinckrodt Inc. et al.; Withdrawal of Approval of Five New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of five new drug applications (NDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of May 2, 2018.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 006383	Methadone Hydrochloride (HCl) Powder, 50 grams (g)/bottle, 100 g/bottle, and 500 g/bottle.	Mallinckrodt Inc., 675 McDonnell Blvd., Hazelwood, MO 63042.

Application No.	Drug	Applicant
NDA 020716	Vicoprofen (hydrocodone bitartrate and ibuprofen) Tablets, 7.5 milligrams (mg)/200 mg.	AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064.
NDA 021692	Ultram ER (tramadol HCl) Extended-Release Tablets, 100 mg, 200 mg, and 300 mg.	Valeant Pharmaceuticals North America LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 207621	Troxyca ER (oxycodone HCl and naltrexone HCl) Extended-Release Capsules, 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, and 80 mg/9.6 mg.	Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 207975	Vantrela ER (hydrocodone bitartrate) Extended-Release Tablets, 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg.	Teva Branded Pharmaceutical Products R&D, Inc., 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of May 2, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on May 2, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: March 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06579 Filed 3–30–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services

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

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given that a meeting is scheduled for the National Advisory Committee on Rural Health and Human Services (NACRHHS). This meeting will be open to the public. Information about the NACRHHS and the agenda for this meeting can be obtained by accessing the NACRHHS website at *http://www.hrsa.gov/advisorycommittees/rural/.*

DATES: The meeting will be held on April 16, 2018, from 8:45 a.m.–5:00 p.m. EDT, April 17, 2018, from 8:30 a.m.–5:15 p.m. EDT, and April 18, 2018, from 8:30 a.m.–11:00 a.m. EDT.

ADDRESSES: This meeting will be held at The Saratoga Hilton. The address for the meeting is 534 Broadway Saratoga Springs, NY 12866–2209, (855) 605–0316.

FOR FURTHER INFORMATION CONTACT: Steve Hirsch, MSLS, Administrative Coordinator, NACRHHS, HRSA, 17W29–C, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–0835, Fax (301) 443–2803.

SUPPLEMENTARY INFORMATION: NACRHHS provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas. During the meeting the Committee will examine the issues of Assessing and Mitigating the Effect of Adverse Childhood Experiences and Health Insurance Markets in Rural Areas; conduct site visits to the Adirondack Health Institute in Glens Falls, New York and St. Vincent de Paul Catholic Church in Cobleskill, New York, to visit the Head Start Program; and summarize key findings and develop a work plan for the next quarter. Members of the public will also have the opportunity to provide comments.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–06651 Filed 3–30–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services is hereby giving notice that a meeting is scheduled to be held of the National Vaccine Advisory Committee (NVAC). The meeting will be open to the public via teleconference; a public comment session will be held during the meeting.

DATES: The meeting will be held on May 3, 2018, from 10:30 a.m. to 12:30 p.m. ET. The confirmed meeting times and agenda will be posted on the NVAC website at *http://www.hhs.gov/nvpo/nvac/meetings/index.html* as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted one week prior to the meeting at: *http://www.hhs.gov/nvpo/nvac/meetings/index.html.* Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or participate in the public comment session should register at *http://www.hhs.gov/nvpo/nvac/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: National Vaccine Program Office, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. Phone: (202) 690–5566; email: *nvac@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program. The public meeting will be dedicated to the deliberation of the draft recommendations written by

the HPV Implementation work group. All agenda items are tentative and subject to change. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: *http://www.hhs.gov/nvpo/nvac/index.html.*

Members of the public will have the opportunity to provide comments at the NVAC meeting during the public comment periods designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Individuals are also welcome to submit their written comments. Written comments should not exceed three pages in length. Individuals submitting written comments should email their comments to the National Vaccine Program Office (*nvac@hhs.gov*) at least five business days prior to the meeting.

Dated: March 27, 2018.

Roula Sweis,

Deputy Director, National Vaccine Program Office.

[FR Doc. 2018–06663 Filed 3–30–18; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; The Genetic Testing Registry

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH), Office of the Director (OD) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Dina Paltoo, Director, Division of Scientific Data Sharing Policy, Office of Science Policy, NIH, 6705 Rockledge Dr., Suite 750, Bethesda, MD 20892, or call nontoll—free number (301) 496–9838, or Email your request, including your address to: *SciencePolicy@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function 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.

Proposed Collection Title: The Genetic Testing Registry, 0925–0651, Expiration Date 07/31/2018—EXTENSION, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Clinical laboratory tests are available for more than 10,000 genetic conditions. The Genetic Testing Registry (GTR) provides a centralized, online location for test developers, manufacturers, and researchers to voluntarily submit detailed information about the availability and scientific basis of their genetic tests. The GTR is of value to clinicians by providing information about the accuracy, validity, and usefulness of genetic tests. The GTR also highlights evidence gaps where additional research is needed.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 4,198.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Laboratory Personnel Using Bulk Submission	Minimal Fields	313	25	18/60	2,348
	Optional Fields	313	25	6/60	783
Laboratory Personnel Not Using Bulk Submission	Minimal Fields	64	25	30/60	800
	Optional Fields	64	25	10/60	267
Total		377	18,850		4198

Dated: March 24, 2018.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2018–06572 Filed 3–30–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye 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 Eye Institute Special Emphasis Panel, NEI Loan Repayment Program Applications.

Date: April 26–27, 2018.

Time: 8:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate loan Repayment Program.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Zhihong Shan, MD, PHO, Scientific Review Officer (Contractor), Division of Extramural Activities, National Eye Institute, National Institute of Health, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892, 301–435–1779, *zhihong.shan@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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: *March 27, 2018.*

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–06553 Filed 3–30–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Program Project Application—Zika Vaccine Development.

Date: April 19, 2018.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Dharmendar Rathore, Ph.D., Senior Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G30, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, 240–669–5058, *rathored@mail.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (R13).

Date: April 23–25, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Tracy A. Shahan, Ph.D., MBA, Scientific Review Program, Division of Extramural Activities, Room #3F31, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 79823, Bethesda, MD 20892–9823, (240) 669–5030, *tshahan@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01).

Date: April 24, 2018.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Raymond R. Schleef, Ph.D., Senior Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3E61, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5019, *schleefrr@niaid.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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 27, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–06554 Filed 3–30–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, 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: Biomedical Informatics, Library and Data Sciences Review Committee 01 (Session One).

Date: June 7, 2018.

Time: June 7, 2018, 8:00 a.m. to 6:00 p.m.

Agenda: To review R01, R21 and K01 applications.

Place: Bethesda Hyatt, 1 Bethesda Metro Center, Bethesda, MD 20814.

Name of Committee: Biomedical Informatics, Library and Data Sciences Review Committee 02 (Session Two).

Date: June 8, 2018.

Time: June 8, 2018, 8:00 a.m. to 6:00 p.m.

Agenda: To review R01 applications—PAR–17–159 (Data Science Research: Personal Health Libraries for Consumers and Patients).

Place: Bethesda Hyatt, 1 Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Zoe E. Huang, MD, Acting Chief Scientific Review Officer, Scientific Review Office, Extramural Programs, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892–7968, 301–594–4937, *huangz@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: March 27, 2018.

Michelle D. Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–06555 Filed 3–30–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at *http://www.samhsa.gov/workplace.*

FOR FURTHER INFORMATION CONTACT: Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N03A, Rockville, Maryland 20857; 240–276–2600 (voice).

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines 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 were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The ''Mandatory Guidelines for Federal Workplace Drug Testing Programs,'' as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated January 23, 2017 (82 FR 7920), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

HHS-Certified Instrumented Initial Testing Facilities

Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190 (Formerly: Gamma-Dynacare Medical Laboratories)

HHS-Certified Laboratories:

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 844–486–9226

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.)

Baptist Medical Center—Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7056, 501–202–2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

Dynacare, * 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630 (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on January 23, 2017 (82 FR 7920). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Legacy Laboratory Services—MetroLab, 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

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774 (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Redwood Toxicology Laboratory, 3700 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159

STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800–442–0438

U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only

The following laboratory voluntarily withdrew from the NLCP effective March 16, 2018:

Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 818–737–6370 (Formerly: SmithKline Beecham Clinical Laboratories)

Charles LoDico,

Chemist.

[FR Doc. 2018–06652 Filed 3–30–18; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2018–0004; OMB No. 1660–0085]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Crisis Counseling Assistance and Training Program

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before May 2, 2018.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Information Management Division, 500 C Street SW, Washington, DC 20472, email address *FEMA-Information-Collections-Management@fema.dhs.gov* or Jennifer Voorhies, Lead, Community Services Individual Assistance/Recovery, *jennifer.voorhies@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on January 30, 2018 at 83 FR 4234 with a 60 day public comment period. One comment was received and FEMA modified the collection accordingly. Specifically, FEMA proposed to remove the option A from question 8 on the CCP/ISP Crisis Counseling Assistance and Training Program, Immediate Services Program Application/FEMA Form 003–0–1 and option A from question 12 on the CCP/RSP Crisis Counseling Assistance and Training Program, Regular Services Program Application/FEMA Form 003–0–2. FEMA is now proposing to only remove option A from question 8 on the CCP/ISP Crisis Counseling Assistance and Training Program, Immediate Services Program Application/FEMA Form 003–0–1. The removal of this option from the CCP/ISP Crisis Counseling Assistance and Training Program, Immediate Services Program Application/FEMA Form 003–0–1 will result in a minor hour burden reduction of 1.9 hours.

FEMA is also providing a clarification to both the ISP and RSP applications by modifying the first sentence in option B from question 8 on the CCP/ISP Crisis Counseling Assistance and Training Program, Immediate Services Program Application/FEMA Form 003–0–1 and option B from question 12 on the CCP/RSP Crisis Counseling Assistance and Training Program, Regular Services Program Application/FEMA Form 003–0–2 to include ''local'' service areas. The first sentence will now say: *Use the following table to estimate the impacted population for each requested service area (county, parish, tribal land, local, etc.).* This addition is a minor clarifying change and will result in no additional burden hours.

The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Crisis Counseling Assistance and Training Program.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0085.

FEMA Forms: FEMA Form 003–0–1, Crisis Counseling Assistance and Training Program, Immediate Services Program Application; FEMA Form 003–0–2, Crisis Counseling Assistance and Training Program, Regular Services Program Application; SF–424, Application for Federal Assistance; SF–424A, Budget Information for Non-Construction Programs; SF–425, Federal Financial Report; HHS Checklist/08–2007; HHS Project Performance Site Location Form; ISP report narrative; Quarterly Report Narratives; Final RSP Report Narrative.

Abstract: The CCP consists of two grant programs, the Immediate Services Program (ISP) and the Regular Services

Program (RSP). The ISP and the RSP provide supplemental funding to States, U.S. Territories, and Federally recognized Tribes following a Presidentially-declared disaster. The grant programs provide funding for Training and Services, including community outreach, public education, and counseling techniques. States are required to submit an application that provides information on Needs Assessment, Plan of Service, Program Management, and an accompanying Budget.

Affected Public: State, local or Tribal government.

Estimated Number of Respondents: 150.

Estimated Number of Responses: 165.

Estimated Total Annual Burden Hours: 1513.1.

Estimated Total Annual Respondent Cost: $116,160.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $120,735.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall 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.

Dated: March 27, 2018.

Rachel Frier,

Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2018–06588 Filed 3–30–18; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7008–N–01]

60-Day Notice of Proposed Information Collection: HUD Acquisition Regulation (HUDAR) (48 CFR 24)

AGENCY: Office of the Chief Procurement Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* June 1, 2018.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
HUDAR:						44.28	
2452.204–70	20	1	20	16	320	44.28	14,169.60
2452.209–70	10	1	10	0.5	5	44.28	221.40
2452.209–72	2	1	2	1	2	44.28	88.56
2452.215–70	150	1	150	80	12,000	44.28	531,360.00
2452.215–70, Alt I	25	1	25	40	1,000	44.28	44,280.00
2453.215–72	25	4	100	2	200	44.28	8,856.00
2452.216–72	2	4	8	2	16	44.28	708.48
2452.216–75	2	4	8	40	320	44.28	14,169.60
2452.216–78, Alt II	5	1	5	4	20	44.28	885.60
2452.219–70	50	1	50	0.5	25	44.28	1,107.00
2452.219–74	1	1	1	16	16	44.28	708.48
2452.227–70	5	1	5	40	200	44.28	8,856.00
2452.237–70	150	1	150	1	150	44.28	6,642.00
2452.237–75 (initial)	100	1	100	8	800	44.28	35,424.00
2452.237–75 (report)	100	4	400	8	3,200	44.28	141,696.00
2451.237–81	20	1	20	0.5	10	44.28	442.80
2452.239–70	100	1	100	8	800	44.28	35,424.00
2452.239–70 (report)	100	4	400	8	3,200	44.28	141,696.00
2452.242–71 (plan)	40	4	160	8	320	44.28	14,169.60
2452.242–71 (report)	10	4	40	6	240	44.28	10,627.20
2453.227–70	1	1	1	8	8	44.28	354.24
Contractor Release	150	1	150	1	150	44.28	6,642.00
Contractor Assignment of Rebates, Credits	10	1	5	1	5	44.28	221.40
Total	1,078		1,910		23,007		1,018,749.96

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: HUD Acquisition Regulation (HUDAR) (48 CFR 24).

OMB Approval Number: 2535–0091.

Type of Request: This is an extension of a currently approved collection. The HUDAR supplements the Federal Acquisition Regulation (FAR). Information collection required of the public is solely in connection with the acquisition process.

Form Number: HUD–770.

Description of the need for the information and proposed use: The HUDAR (48 CFR 24) contains the Department's supplement to the Federal Acquisition Regulations (FAR) 48 CFR Chapter 1. The FAR sets forth uniform policies and procedures applicable to Federal agencies in the procurement of personal property and non-personal services (including construction) and the procurement of real property by lease.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: March 12, 2018.

Keith W. Surber,

Chief Procurement Officer.

[FR Doc. 2018–06563 Filed 3–30–18; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R2–ES–2018–N278; FXES11130200000C2–112–FF02ENNM00]

Endangered and Threatened Wildlife and Plants; Draft Recovery Plan for Four Invertebrate Species of the Pecos River Valley

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment.

SUMMARY: We, the Fish and Wildlife Service (Service), announce the availability of our draft recovery plan for four invertebrate species—Noel's Amphipod, Koster's springsnail, Roswell springsnail, and Pecos assiminea—all of which are listed as endangered under the Endangered Species Act of 1973, as amended (Act). These invertebrate species are currently found in southeastern New Mexico and southwest Texas. The draft recovery plan includes specific recovery objectives and criteria to be met in order to enable us to remove these species from the list of endangered and threatened wildlife and plants. We request review and comment on this plan from local, State, and Federal agencies; Tribes; and the public. We will also accept any new information on the status of these species throughout their range to assist in finalizing the recovery plan.

DATES: To ensure consideration, we must receive written comments on or before June 1, 2018. However, we will accept information about any species at any time.

ADDRESSES: If you wish to review the draft recovery plan, you may obtain a copy by any one of the following methods:

- *internet: www.fws.gov/southwest/es/;*
- *U.S. mail:* U.S. Fish and Wildlife Service, NM Ecological Services Field Office, 2105 Osuna NE, Albuquerque, NM 87113; or
- *Telephone:* 505–346–2542.

If you wish to comment on the draft recovery plan, you may submit your comments in writing by any one of the following methods:

- *U.S. mail:* Field Supervisor, at the above address;
- *Hand-delivery:* New Mexico Ecological Services Office, at the above address;
- *Fax:* 505–346–2542; or
- *Email: Debra_Hill@fws.gov.*

For additional information about submitting comments, see the ''Request for Public Comments'' section below.

FOR FURTHER INFORMATION CONTACT: Debra Hill, New Mexico Energy Streamlining Program Coordinator, at the above address and phone number, or by email at *debra_hill@fws.gov.*

SUPPLEMENTARY INFORMATION:

Background

Recovery of endangered or threatened animals and plants to the point where they are again secure, self-sustaining members of their ecosystems is a primary goal of our endangered species program and the Act (16 U.S.C. 1531 *et seq.*). Recovery means improvement of the status of listed species to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the Act. The Act requires the development of recovery plans for listed species, unless such a plan would not promote the conservation of a particular species.

Species History

Noel's amphipod (*Gammarus desperatus*), Koster's springsnail (*Juturnia kosteri*), Roswell springsnail (*Pyrgulopsis roswellensis*), and Pecos assiminea (*Assiminea pecos*) (four invertebrates) are associated with spring systems in desert-grasslands in southeastern New Mexico and southwestern Texas. In 2005, the four invertebrates were federally listed as endangered throughout their range, including the Roswell Basin aquifer system in southeastern New Mexico and the Toyah and Coyanosa Basins in southwest Texas. All four species are found on Bitter Lake National Wildlife Refuge in southern New Mexico. Pecos assiminea (*Assiminea pecos*) is also located at Diamond Y and East Sandia Spring in west Texas. Critical habitat was designated for the four species in 2011.

Water quantity decreases and associated spring flow declines are the primary threats to the four invertebrate species. Groundwater pumping in the

Roswell Basin, New Mexico, and in Pecos and Reeves Counties, Texas, has led to the drying of several springs, many of which are known to have harbored one or more of the four invertebrate species. Droughts and climate change can also affect springs and groundwater recharge through decreased flow, and indirectly through increased groundwater pumping. Threats to water quality are considered to be less significant than threats to water quantity, yet still important due to the species' extremely limited range and specialized tolerances that could be impacted by spills of high magnitude (degree to which the threats are affecting or can affect the species) or scope (how much of the species' range the threats are affecting or can affect). Sources of water quality degradation include, but are not limited to (1) contamination of ground water, (2) limited oil and gas activities, (3) hazardous materials spills from train derailments or other causes, (4) golden algae blooms, and (5) urbanization and stormwater runoff, all of which are expected to increase in the future. All four invertebrate species have a localized range, limited mobility, and fragmented habitat, meaning that any perturbation, either natural or anthropogenic, could eliminate many or all of the existing populations. Having a high number of individuals at a site provides little protection against extinction should their habitat become dry or contaminated. Limited mobility restricts their dispersal abilities and the fragmented (unconnected) habitat restricts gene flow among populations. Additional threats include invasive species, inadequate existing regulatory mechanisms, and climate change.

The overall strategy involves preserving, restoring, and managing their aquatic habitat, along with the water resources necessary to support resilient populations of these species and the ecosystems on which they depend. More specifically, the strategy is to: Ensure adequate water quantity; protect and improve water quality; protect and restore surface habitats; maintain and manage populations throughout each species' range, including conducting monitoring and research and establishing emergency programs necessary to maintain the species in captivity in case of catastrophic events; control invasive and predatory species; collaborate with partners to achieve conservation goals in balance with community water needs; and engage in community outreach to promote the importance of Bitter Lake National Wildlife Refuge and its diverse array of wildlife, including sensitive, rare aquatic invertebrates, worthy of preserving. Employment of this strategy will lead to preservation of the array of habitat types used by the invertebrates, and protection of genetic diversity (representation) of each of the four species.

Recovery Plan Goals

The objective of an agency recovery plan is to provide a framework for the recovery of a species so that protection under the Act is no longer necessary. A recovery plan includes scientific information about the species and provides criteria and actions necessary for us to be able to reclassify the species to threatened status or remove it from the List. Recovery plans help guide our recovery efforts by describing actions we consider necessary for the species' conservation and by estimating time and costs for implementing needed recovery measures. This draft recovery plan identifies the following objectives to achieve the goal of species' recovery:

1. Securing the long-term survival of each species with the appropriate number, size, and distribution of populations;

2. Preserving sites that contain the necessary elements for each species' persistence, such as adequate water quantity and quality;

3. Reducing threats within management units so that the four invertebrate species' populations are capable of enduring stressors;

4. Conducting monitoring and research to understand population patterns, maintain genetic diversity, and identify new sites for species' introductions or repatriation; and

5. Working with others to develop long-term management plans and educational approaches that will protect the four invertebrates and inform the community about their habitat needs and ecological importance.

The draft recovery plan contains recovery criteria based on maintaining and increasing population numbers and habitat quality and quantity and mitigating significant threats to the species. Recovery actions to attain the recovery criteria focus on protecting populations, managing threats, maintaining habitat, monitoring progress, and building partnerships to facilitate recovery. When the recovery of the four species approaches these criteria, we will review the species' status and consider downlisting, and, ultimately, removal from the list of federally threatened and endangered species.

Request for Public Comments

Section 4(f) of the Act requires us to provide public notice and an opportunity for public review and comment during recovery plan development. It is also our policy to request peer review of recovery plans (July 1, 1994; 59 FR 34270). In an appendix to the approved recovery plan, we will summarize and respond to the issues raised by the public and peer reviewers. Substantive comments may or may not result in changes to the recovery plan; comments regarding recovery plan implementation will be forwarded as appropriate to Federal or other entities so that they can be taken into account during the course of implementing recovery actions. Responses to individual commenters will not be provided, but we will provide a summary of how we addressed substantive comments in an appendix to the approved recovery plan.

We invite written comments on the draft recovery plan. In particular, we are interested in additional information regarding the current threats to the species and the implementation of the recommended recovery actions.

Before we approve our final recovery plan, we will consider all comments we receive by the date specified in **DATES**, above. Methods of submitting comments are in the **ADDRESSES** section above.

Public Availability of Comments

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

Comments and materials we receive will be available, by appointment, for public inspection during normal business hours at our office (see **ADDRESSES**).

References Cited

A complete list of all references cited herein is available upon request from the U.S. Fish and Wildlife Service, Branch of Recovery (see **FOR FURTHER INFORMATION CONTACT** section).

Authority

We developed our draft recovery plan under the authority of section 4(f) of the Act, 16 U.S.C. 1533(f). We publish this notice under section 4(f) Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: _February 1, 2018.

Joy E. Nicholopoulos,

Acting Regional Director, Southwest Region, U.S. Fish and Wildlife Service.

[FR Doc. 2018–06614 Filed 3–30–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[18X L1109AF LLUT980300 L12200000. PM0000–24–1A]

Notice of Public Meeting for the Utah Resource Advisory Council/Recreation Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act, the Federal Advisory Committee Act, and the Federal Lands Recreation Enhancement Act, the U.S. Department of the Interior, Bureau of Land Management's (BLM) Utah Resource Advisory Council (RAC)/Recreation Resource Advisory Council (RRAC) will meet as indicated below.

DATES: The Utah RAC/RRAC will hold a public meeting on May 21 and 22, 2018. The group will meet on May 21 from 1 p.m. to 5:00 p.m. and on May 22 from 8 a.m. to 4:00 p.m.

ADDRESSES: The meeting will be held at the BLM Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101. Written comments may be sent to the BLM Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101.

FOR FURTHER INFORMATION CONTACT: Lola Bird, Public Affairs Specialist, BLM Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101; phone (801) 539–4033; or email *lbird@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to leave a message or question for the above individual. The FRS is available 24 hours a day, seven days a week. Replies are provided during normal business hours.

SUPPLEMENTARY INFORMATION: Agenda topics include BLM updates from the State Director, fire dispatch study implementation, 2018 fire season outlook, updates for the planning process of Grand Staircase-Escalante and Bears Ears National Monuments, Watershed Protection Task Force, Mountain Accord, Washington County issues, Lake Powell pipeline project, recreation fee proposals, and other planning updates.

A public comment period will take place on May 22 from 2:15 p.m. to 2:45 p.m., where the public may address the RAC/RRAC. Depending on the number of people who wish to speak, and the time available, the time for individual comments may be limited. Written comments may also be sent to the BLM Utah State Office at the address listed in the **ADDRESSES** section of this Notice.

The meeting is open to the public; however, transportation, lodging, and meals are the responsibility of the participating individuals.

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

Authority: 43 CFR 1784.4–2

Edwin L. Roberson,

State Director.

[FR Doc. 2018–06673 Filed 3–30–18; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–25240; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting comments on the significance of properties nominated before March 10, 2018, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by April 17, 2018.

ADDRESSES: Comments may be sent via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C St. NW, MS 7228, Washington, DC 20240.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before March 10, 2018. Pursuant to Section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

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

Nominations submitted by State Historic Preservation Officers:

CALIFORNIA

Los Angeles County

Torrey, Joseph and Carrie, House, 711 Daisy Ave., Long Beach, SG100002319

San Bernardino County

Integratron, 2477 Belfield Blvd., Landers, SG100002317

CONNECTICUT

Fairfield County

Bridge Street Historic District, Bridge St., Imperial Ave. & Compo Rd. S, Westport, SG100002318

New Haven County

Morris Cove Historic District, Between Dean & Myron Sts., Morris Causeway & Townsend Ave., New Haven, SG100002320

New London County

Stonington Cemetery, SE corner of Main St. & US 1, Stonington, SG100002321

Sound View Historic District, 4–88 Hartford, 4–70 Portland, & 5–86 Swan Aves., 275–287 Shore Rd., Old Lyme, SG100002322

ILLINOIS

Madison County

Glen Carbon Village Hall and Firehouse, 180 Summit Ave., Glen Carbon, SG100002326

McLean County

Bloomington High School, 510 E Washington St., Bloomington, SG100002327

Rock Island County

Best Building, 1701–03 2nd Ave., Rock Island, SG100002328

Wayne County

House at 502 SE 4th St., 502 SE 4th St., Fairfield, SG100002329

IOWA

Lee County

Old Fort Madison and Battlefield (Boundary Increase), Address Restricted, Fort Madison vicinity, BC100002323

Polk County

Hippee Building, 206 6th Ave., Des Moines, SG100002325

MARYLAND

Baltimore Independent city

Commercial Credit Company Building, 300–314 St. Paul Pl., Baltimore, SG100002331

MICHIGAN

Ottawa County

De Zwaan Windmill, Windmill Island Gardens, 1 Lincoln Ave., Holland, SG100002333

MISSOURI

St. Louis County

Tilles, Rosalie, Park, 9551 Litzsinger Rd., Ladue, SG100002336

St. Louis Independent city

Crunden Branch Library, 2008 Cass Ave., St. Louis, SG100002334

St. Luke's Hospital Historic District, 5535 Delmar Blvd., St. Louis, SG100002335

NEVADA

Clark County

Sandstone Ranch (Boundary Increase), Address Restricted, Las Vegas vicinity, BC100002337

PENNSYLVANIA

Delaware County

Sellers Hall, NW corner of Hampden Rd. & Walnut St., Upper Darby Township, SG100002339

Philadelphia County

Franklin Carpet Mill, 2141–2145 E. Huntingdon St., Philadelphia, SG100002340

West Philadelphia Streetcar Suburb Historic District (Boundary Increase), 14–36 S 40th St., 4001 Chestnut St., Philadelphia, BC100002341

Gotham Silk Hosiery Company, (Textile Industry in the Kensington Neighborhood of Philadelphia, Pennsylvania MPS), 2000–2034 N 2nd St., Philadelphia, MP100002342

Waverly Garage, 414–422 S 16th St., Philadelphia, SG100002343

TEXAS

Coleman County

Camp Colorado Replica, (Monuments and Buildings of the Texas Centennial MPS), Coleman City Park, 1700 N Neches, Coleman, MP100002345

Comal County

Riley's Tavern, 8894 FM 1102, New Braunfels vicinity, SG100002346

Denton County

Pioneer Woman Monument, (Monuments and Buildings of the Texas Centennial MPS), Pioneer Cir., Texas Woman's University, Denton, MP100002347

Erath County

Erath Memorial Arch, (Monuments and Buildings of the Texas Centennial MPS), N Erath Ave. & W Washington St., Stephenville, MP100002348

Stephenville Downtown Historic District, Roughly bounded by McNeil, & Tarleton Sts., Barton & Devine Aves., Stephenville, SG100002349

Jackson County

Jackson County Monument, (Monuments and Buildings of the Texas Centennial MPS), 115 W Main St., Edna, MP100002350

Matagorda County

Matagorda County Monument, (Monuments and Buildings of the Texas Centennial MPS), 1700 7th St., Bay City, MP100002351

San Patricio County, San Patricio de Hibernia Monument, (Monuments and Buildings of the Texas Centennial MPS), Main St., Constitution Sq., San Patricio, MP100002352

Sons of San Patricio, Cty. Rd. 1441 (21), Old San Patricio Cemetery, (Monuments and Buildings of the Texas Centennial MPS), San Patricio, MP100002353

VIRGINIA

Amherst County

EL Bethel Methodist Church, 925 Buffalo Springs Tpk., Amherst vicinity, SG100002354

Hanover County

Little River UDC Jefferson Davis Highway Marker, (UDC Commemorative Highway Markers along the Jefferson Davis Highway in Virginia MPS), 15400 Washington Hwy., Doswell vicinity, MP100002355

Richmond Independent city

Lee Medical Building, 1805 Monument Ave., Richmond, SG100002356

Additional documentation has been received for the following resource:

CONNECTICUT

Fairfield County

Hoyt-Barnum House, 1508 High Ridge Rd., Stamford, AD69000199

Nominations submitted by Federal Preservation Officers:

The State Historic Preservation Officer reviewed the following nominations and responded to the Federal Preservation Officer within 45 days of receipt of the nominations) and supports listing the property in the National Register of Historic Places.

MASSACHUSETTS

Essex County

Saugus Iron Works National Historic Site, 244 Central St., Saugus, AD66000047

Authority: Section 60.13 of 36 CFR part 60.

Dated: March 15, 2018.

J. Paul Loether,

Chief, National Register of Historic Places/National Historic Landmarks Program and Keeper, National Register of Historic Places.

[FR Doc. 2018–06608 Filed 3–30–18; 8:45 am]

BILLING CODE 4310–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–584 and 731–TA–1382 (Final)]

Uncoated Groundwood Paper From Canada Scheduling of the Final Phase of Countervailing Duty and Anti-Dumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping and countervailing duty investigation Nos. 701–TA–584 and 731–TA–1382 (Final) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of uncoated groundwood paper from Canada, provided for in subheadings 4801.00.01, 4802.61.10, 4802.61.20, 4802.61.31, 4802.61.60, 4802.62.10, 4802.62.20, 4802.62.30, 4802.62.61, 4802.69.10, 4802.69.20, and 4802.69.30 [1] of the Harmonized Tariff Schedule of the United States, preliminarily determined by the Department of Commerce (''Commerce'') to be subsidized and sold at less-than-fair-value.

DATES: March 19, 2018.

FOR FURTHER INFORMATION CONTACT: Calvin Chang (202–205–3062), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Scope.— For purposes of these investigations, Commerce has defined the subject merchandise as certain paper that has not been coated on either side and with 50 percent or more of the

[1] Subject merchandise may also be imported under subheadings 4805.91.50, 4805.91.70, and 4805.91.90.

cellulose fiber content consisting of groundwood pulp, including groundwood pulp made from recycled paper, weighing not more than 90 grams per square meter. Groundwood pulp includes all forms of pulp produced from a mechanical pulping process, such as thermo-mechanical process (TMP), chemi-thermo mechanical process (CTMP), bleached chemi-thermo mechanical process (BCTMP) or any other mechanical pulping process. The scope includes paper shipped in any form, including but not limited to both rolls and sheets. Certain uncoated groundwood paper includes but is not limited to standard newsprint, high bright newsprint, book publishing, and printing and writing papers. The scope includes paper that is white, off-white, cream, or colored.

Specifically excluded from the scope are imports of certain uncoated groundwood paper printed with final content of printed text or graphic. Also excluded are papers that otherwise meet this definition, but which have undergone a supercalendering process. Additionally, excluded are papers that otherwise meet this definition, but which have undergone a creping process over the entire surface area of the paper.

Also excluded are uncoated groundwood construction paper and uncoated groundwood manila drawing paper in sheet or roll format. Excluded uncoated groundwood construction paper and uncoated groundwood manila drawing paper: (a) Have a weight greater than 61 grams per square meter; (b) have a thickness greater than 6.1 caliper, *i.e.,* greater than .0061'' or 155 microns; (c) are produced using at least 50 percent thermomechanical pulp; and (d) have a shade, as measured by CIELAB, as follows: L* less than or 75.0 or b* greater than or equal to 25.0.

Also excluded is uncoated groundwood directory paper that: (a) Has a basis weight of 34 grams per square meter or less; and (b) has a thickness of 2.6 caliper mils or 66 microns or less.

Background.—The final phase of these investigations is being scheduled pursuant to sections 705(b) and 731(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)), as a result of affirmative preliminary determinations by the Commerce that certain benefits which constitute subsidies within the meaning of section 703 of the Act (19 U.S.C. 1671b) are being provided to manufacturers, producers, or exporters in Canada of uncoated groundwood paper, and that such products are being sold in the United States at less than fair value within the meaning of section 733 of the Act (19 U.S.C. 1673b). The investigations were requested in petitions filed on August 9, 2017, by North Pacific Paper Company, Longview, Washington.

For further information concerning the conduct of this phase of the investigations, hearing procedures, 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 and C (19 CFR part 207).

Participation in the investigations 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 final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on June 22, 2018, and a public version will be issued thereafter, pursuant to section 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on Tuesday, July 17, 2018, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before July 12, 2018. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should participate in a prehearing conference to be held on July 13, 2018, at the U.S. International Trade Commission Building, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.23 of the Commission's rules; the deadline for filing is July 3, 2018. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.25 of the Commission's rules. The deadline for filing posthearing briefs is July 24, 2018. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petition, on or before July 24, 2018. On August 20, 2018, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before August 22, 2018, but such final comments must not contain new factual information and must otherwise comply with section 207.30 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on E-Filing,* available on the Commission's website at *https://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing.

Additional written submissions to the Commission, including requests

pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (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.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: March 27, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–06565 Filed 3–30–18; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0031]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension without Change of a Currently Approved Collection; Records of Acquisition and Disposition, Registered Importers of Arms, Ammunition & Implements of War on the U.S. Munitions Import List

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-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 60 days until June 1, 2018.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any additional information, please contact Desiree Dickinson either by mail at Firearms and Explosives Imports Branch, 244 Needy Road Martinsburg, WV 25405, by email at *desiree.dickinson@atf.gov,* or by telephone at (304) 616–4584.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection (*check justification or form 83): Extension, without change, of a currently approved collection.

2. *The Title of the Form/Collection:* Records of Acquisition and Disposition, Registered Importers of Arms, Ammunition & Implements of War on the U.S. Munitions Import List.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): None.

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: Business or other for profit.

Other (if applicable): None.

Abstract: This information collection involves records of imported items that are on the United States Munitions Import List. The importers must register with ATF, file an intent to import specific items, as well as certify to the Bureau, that the list of imported items were received. The records are maintained at the registrant's business premises where they are available for inspection by ATF officers during compliance inspections or criminal investigations.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 50 respondents will utilize this information collection, and it will take each respondent approximately 5 hours to provide a 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 250 hours, which is equal to 50 (total # of responses) *5 (# of hours to provide 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.

Dated: March 28, 2018.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2018–06593 Filed 3–30–18; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bernard Wilberforce Shelton, M.D.; Decision and Order

On February 16, 2017, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration, issued an Order to Show Cause to Bernard Wilberforce Shelton, M.D. (hereinafter, Registrant), which proposed the revocation of his DEA Certificates of Registration Nos. BS9770961 and FS6457407, as well as the denial of any pending application to renew these registrations or for any other registration. GX 2, at 1. As grounds for the proposed actions, the Government alleged that Registrant's continued registration is ''inconsistent with the public interest'' and that he is without state authority to handle controlled substances in the State of Michigan, the State in which he holds his registrations. *Id.* at 1–2 (citing 21 U.S.C. 824(a)(3) and (4), 823(f)).

With respect to the Agency's jurisdiction, the Show Cause Order alleged that Registrant holds two

registrations, pursuant to which he is authorized to dispense controlled substances in schedules II–V as a practitioner in the State of Michigan: No. BS9770961, at the registered address of 30140 Harper Avenue, Suite #300, Saint Clair Shores, which was due to expire on February 28, 2018, and No. FS6457407, at the registered address of 21700 Greenfield Road, Suite 130, Oak Park, which expires on February 29, 2020. *Id.* at 1.

As to the substantive grounds for the proceeding, the Show Cause Order alleged that the Michigan Department of Licensing and Regulatory Affairs (hereinafter, DLRA) summarily suspended Registrant's Michigan Medical License on January 12, 2017, and that pursuant to Mich. Comp. Laws § 333.7311(6), ''a controlled substance license is automatically void if a licensee's license to practice is suspended or revoked under Article 15 of the Code.'' *Id.* at 2. The Order alleged that as a result of the DLRA's action, Registrant ''is without authority to handle controlled substances in the State of Michigan,'' and ''[c]onsequently, DEA must revoke [his] DEA registration.'' *Id.* (citing 21 U.S.C. 824(a)(3)).

Next, the Show Cause Order alleged that Registrant violated Federal law on numerous occasions when he issued controlled substance prescriptions to four patients outside the usual course of professional practice and for other than a legitimate medical purpose, and that these ''multiple instances of unlawful prescribing in violation of federal law weigh[] in favor of the revocation of [his registration].'' *Id.* at 2 (citing 21 U.S.C. 841(a)(1), 823(f)(2) and 823(f)(4) and 21 CFR 1306.04). The Order also alleged that Registrant's prescribing to the four patients violated Michigan law, *id.* (citing Mich. Comp. Laws §§ 333.7401(1), 333.7333, 333.7405(1)(a)), and the Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain (hereinafter, Michigan Guidelines). *Id.* at 2–3.

The Show Cause Order then alleged that between October 2013 and February 2016, Registrant failed to comply with Federal and State law and the Michigan minimal standards when he issued controlled substance prescriptions to an undercover investigator (hereinafter, UC) and three other patients, D.S., A.L. and R.H. *Id.* at 3–10.

Specifically, the Show Cause Order alleged that on April 1, May 1 and June 15, 2015, Registrant issued prescriptions to the UC for hydrocodone-acetaminophen, a schedule II controlled substance, and alprazolam, a schedule IV controlled substance, which were not for a legitimate medical purpose and outside the scope of professional practice. *Id.* at 3–6 (citing 21 CFR 1306.04(a) and Mich. Comp. Laws §§ 333.7311(1)(e), 333.733, 333.7401(1) and 333.7405(1)(a)). The Order alleged that Registrant issued the controlled substance prescriptions to the UC ''without undertaking actions typical of medical professionals or in accordance with the Michigan Guidelines, such as conducting and documenting a complete medical history, conducting a physical examination, or properly assessing the needs of [the UC] for controlled substances.'' *Id.* at 3. The Order further alleged that Registrant did not make any attempt to address or resolve numerous ''red flags that [the UC] was abusing and/or diverting controlled substances'' before issuing the controlled substance prescriptions to him. *Id.* at 3–6. Further, it alleged that Registrant's medical records for the three visits ''contain multiple false or misleading statements which [are] inconsistent with the Michigan Guidelines standard that medical records are to be ''accurate and complete'''' and gave numerous specific examples. *Id.* at 4–6.

Next, the Show Cause Order alleged that Registrant issued a total of 73 prescriptions to patients D.S., A.L., and R.H., ''despite failing in most instances to conduct an appropriate medical examination and meeting the minimal medical standards required under Michigan law in prescribing controlled substances (or documenting such in the patient's file),'' in violation of Federal and Michigan law. *Id.* at 6–9 (citing 21 CFR 1306.04(a) and Mich. Comp. Laws §§ 333.7311(1)(e), 333.733, 333.7401(1) and 333.7405(1)(a)).

Specifically, the Show Cause Order alleged that ''[f]rom on or about January 12, 2015, through on or about February 29, 2016,'' Registrant issued to D.S. 14 prescriptions for oxycodone 30 mg, a schedule II controlled substance; two prescriptions for phendimetrazine tartrate 105 mg, a schedule III controlled substance; four prescriptions for phentermine 37.5 mg and five prescriptions for Ultram (tramadol) 50 mg, both schedule IV controlled substances. *Id.* at 7. The Order also alleged that Registrant ''issued these orders despite the presence of . . . red flags that D.S. was abusing and/or diverting controlled substances, '' including a Michigan Automated Prescriptions Report (MAPS) which showed ''that D.S. had been prescribed combinations of opioids, benzoids and stimulants'' between February and June 2011, by up to three different medical providers; that his ''medical records indicate that D.S. was likely suffering from drug dependence''; and that ''D.S.'s urine drug tests showed signs of dangerous drug use or dependency,'' including positive results for methadone, cocaine and amphetamines when none of these drugs had been prescribed in the previous month. *Id.* at 7. The Order further alleged ''there is no documentation in D.S.'s medical records demonstrating that [Registrant] conducted any appropriate medical examination or review to address or resolve these indicators of possible abuse and/or diversion.'' *Id.* at 8.

With respect to A.L., the Show Cause Order alleged that between October 17, 2013 and May 6, 2014, Registrant issued to her three prescriptions for Norco (hydrocodone/acetaminophen), then a schedule III controlled substance; three prescriptions for Adipex (phentermine) 37.5 mg, two prescriptions for Xanax (alprazolam) 2 mg, and three prescriptions for Soma (carisoprodol) 350 mg, and authorized two refills for each prescription. *Id.* at 8. The Order alleged that the combination of hydrocodone, alprazolam and carisoprodol is a drug ''cocktail'' known as the ''Holy Trinity'' and ''is widely known to be abused and/or diverted.'' *Id.* The Order also alleged that on three occasions in 2011, Registrant prescribed to A.L. ''another variation of the Holy Trinity cocktail,'' substituting Roxicodone (oxycodone) for hydrocodone and that ''[t]here is no documentation in A.L's medical records demonstrating any legitimate medical need for prescribing her that cocktail.'' *Id.*

The Show Cause Order further alleged A.L.'s medical records show that she presented various red flags and that ''there is no documentation in [her] medical records demonstrating that [Registrant] conducted any appropriate medical examination or review to address or resolve these indicators of possible abuse and/or diversion.'' *Id.* at 8–9. The Order alleged that these included a MAPS report dated January 24, 2011 showing that A.L. ''had been prescribed combinations of opioids, benzoids, and stimulants by up to eight different medical providers'' between January 2010 and January 2011, and that this combination of stimulants with opioids or benzoids or both is known to drug users as ''speed-balling.'' *Id.* at 8–9.

The Order also alleged that on a ''Health History Questionnaire'' which A.L. completed when she first became Registrant's patient, she listed the drugs she was currently taking as including Roxicodone, Xanax and Soma, and that

this combination ''also constitutes the 'Holy Trinity' drug cocktail.'' *Id.* at 9. The Order further alleged that a Feb. 25, 2013 chart entry showed that A.L. was possibly engaged in diversion as it states: ''She says she cannot get her pain medications and has to be buying it off the streets to satisfy her pain. The last time she was given pain medication from this office was in September of last year.'' *Id.*

With respect to patient R.H., the Show Cause Order alleged that from June 2015 through February 24, 2016, Registrant issued to him 10 prescriptions for Norco (hydrocodone-acetaminophen [1]) 10/325 mg, 10 prescriptions for morphine sulfate 30 mg tablets, and 10 prescriptions for morphine sulfate 100 mg tablets, each of these being a schedule II controlled substance; five prescriptions for alprazolam 1 mg; and two prescriptions for Soma (carisoprodol) 350 mg tablets. *Id.* The Order again alleged that ''there [was] no documentation in R.H.'s medical records demonstrating any legitimate medical need for prescribing him the [combination of Hydrocodone, Alprazolam and Carisoprodol drugs known as the] Holy Trinity cocktail,'' ''which is widely known to be abused and/or diverted.'' *Id.*

The Show Cause Order also alleged that on six other occasions in 2011, Registrant prescribed other variations of this cocktail to R.H. despite the presence of red flags in his medical records. *Id.* at 10. Specifically, the Order alleged that Registrant's ''medical records indicated that R.H. was possibly suffering from drug dependency'' because the ''medical chart dated December 21, 2011 states 'he [sic] is taking the valium three times ad [sic] although he is given it twice daily so he runs out early [sic].''' *Id.*

The Show Cause Order further alleged that R.H.'s urine drug test results showed signs of dangerous drug use or drug dependency. The Order alleged that on seven occasions during 2015 through 2016, R.H. tested positive for amphetamines and that on three occasions during 2015, he tested positive for benzodiazepines and that Registrant ''had not prescribed'' either class of drugs to him in the months preceding the positive results. *Id.* Finally, the Order alleged that ''[t]here is no documentation in R.H.'s medical records demonstrating that [Registrant] conducted any appropriate medical examination or review to address or resolve these indicators of possible abuse and/or diversion.'' *Id.*

The Show Cause Order then asserted that Registrant ''fail[ed] in most instances to conduct an appropriate medical examination'' and failed to meet ''the minimal medical standards required under Michigan law in prescribing controlled substances (or documenting such in the patient's file).'' *Id.* at 9 (citing 21 CFR 1306.04(a) and Mich. Comp. Laws §§ 333.7311(1)(e), 333.733, 333.7401(1) and 333.7405(1)(a)). The Order further asserted that Registrant's conduct ''completely betrayed any semblance of legitimate medical treatment'' in that he ''failed to take reasonable steps, like conduct medical examinations, to guard against diversion of controlled substances.'' *Id.* at 10 (citing *Jack A. Danton* 76 FR 60,900 (2011); *Hatem M. Ataya* 81 FR 8221 (2016) (other citations omitted)).

The Show Cause Order notified Registrant of his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence for failing to elect either option. *Id.* at 11 (citing 21 CFR 1301.43). The Show Cause Order also notified Registrant of his opportunity to submit a Corrective Action Plan in accordance with 21 U.S.C. 824(c)(2)(C). *Id.* at 11–12.

On February 23, 2017, a DEA Special Agent and a Diversion Investigator (DI) personally served Registrant with the Order to Show Cause at his office located at 30140 Harper Avenue, Suite #300, Saint Clair Shores, Michigan. GX 31 (Declaration of Special Agent), at 4. According to the Agent, Registrant signed a DEA Receipt for the Show Cause Order. *Id., see also* GX 29.

On May 8, 2017, the Government filed its Request for Final Agency Action (RFAA) with my Office and forwarded the evidentiary record, stating that more than 30 days have passed since Registrant was personally served, and DEA has not received a request for a hearing or any other reply from Registrant. RFAA, at 1.

Based on the Government's representations that more than 30 days have now passed since the date of service of the Show Cause Order and that Registrant has not submitted a request for a hearing or any other reply including a Corrective Action Plan, I find that Registrant has waived his right to a hearing or to submit a written statement in lieu of a hearing. 21 CFR 1301.43(d). I therefore issue this Decision and Final Order based on relevant evidence contained in the record submitted by the Government. 21 CFR 1301.43(d) & (e). I make the following findings of fact.

Findings of Fact

Registrant is the holder of DEA Certificate of Registration No. FS6457407, pursuant to which he is authorized to dispense controlled substances in schedules II—V, at the registered location of 21700 Greenfield Road, Oak Park, Michigan. GX 1 (Copy of Registrations). This registration does not expire until February 29, 2020. *Id.* Registrant also held DEA Certification of Registration No. BS9770961, pursuant to which he was authorized to dispensed controlled substances at the registered location of 30140 Harper Avenue, Suite #300, in Saint Clair Shores. *Id.* He was also authorized, under DATA-Waiver Identification Number XO9770961, to dispense Suboxone and Subutex to up to 100 opiate-addicted patients pursuant to the Drug Addiction Treatment Act of 2000 (DATA). *Id.; see* 21 U.S.C. 823(g)(2). However, Registration No. BS9770961 and DATA-Waiver Identification No. XO9770961 expired on February 28, 2018, when Registrant failed to renew this registration.

Registrant holds a license to practice medicine in the State of Michigan, as well as several controlled substance and drug control licenses issued by the Michigan Board of Pharmacy. GX 30, at 1–2. However, on January 12, 2017, the Director of the Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs (DLRA), ordered the summary suspension of Registrant's medical license based on the Department's ''find[ing] that the public health, safety, and welfare requires emergency action.'' *See* GX 30, at 1. The Order also stated that ''[Public Health] Code § 7311(6) provides that a controlled substance license is automatically void if a licensee's license to practice is suspended or revoked.''[2]

According to the online records of the DLRA, of which I take official notice, *see* 5 U.S.C. 556(e),[3] on July 12, 2017,

[1] Effective October 6, 2014, combination hydrocodone drugs were moved from schedule III to schedule II. *See* DEA, *Schedules of Controlled Substances: Rescheduling of Hydrocodone Combinations Products from Schedule III to Schedule II,* 79 FR 49661 (2014).

[2] According to the website of the Michigan Department of Licensing and Regulatory Affairs, Registrant held: a Pharmacy CS–3 license 5315079480, which was issued on November 23, 2016 but is currently in a ''lapsed'' status; a Pharmacy Drug Treatment Program Prescriber license 5304001334, which was issued November 3, 2016 but is currently in ''lapsed'' status; and a Pharmacy Drug Control Location license 5315079209, which was issued November 14, 2016 but is also currently in ''lapsed'' status. *See https://w2.lara.state.mi.us.*

[3] In the RFAA, the Government noted that it had been notified by the DLRA that a settlement had been reached with Registrant subject to Board approval; however, the Consent Order had not been issued at the time the RFAA was submitted to my

Registrant entered into a consent order with the Board of Medicine pursuant to which the summary suspension was dissolved but his medical license was suspended for 15 months to include the period ''during which the order of summary suspension was in effect.'' *See In re Bernard Wilberforce Shelton, M.D.,* No. 43–16–140510, Consent Order at 2 (Mich. Bd. of Med., July 12, 2017). The Consent Order further ordered that ''[r]einstatement of [Registrant's] license shall not be automatic'' and he must petition for reinstatement. *Id.* Under the consent order, to obtain reinstatement, ''Respondent must demonstrate . . . by clear and convincing evidence: (1) Good moral character; (2) the ability to practice the profession with reasonable skill and safety; (3) satisfaction of the guidelines on reinstatement adopted by the Department; and (4) that it is in the public interest for the license to be reinstated.'' Consent Order, at 2.

The DLRA also required that Registrant pay a $10,000 fine. *Id.* I also take official notice that Respondent's medical license remains suspended as of the date of this Decision and Order. *See also https://w2.state.mi.us.*

The Investigation

In January 2015, DEA began its investigation of Registrant after receiving information from the St. Clair Shores Police Department and Michigan Blue Cross/Blue Shield (MBCBS) about the investigation they were conducting of Registrant. GX 31, at 1 (Declaration of Special Agent). DEA then initiated this investigation, which included supervising three undercover visits by an MBC/BS investigator (hereinafter, also referred to as UC) to Registrant at his office in St. Clair Shores. *Id.* at 1–2; *see also* GX 8. As part of the investigation, on September 29, 2015, a Special Agent (SA) and a Diversion Investigator (DI) interviewed Registrant. GX 31, at 2–3.

During the interview, Registrant informed the SA and DI about ''his [patient] protocols . . . including how his office conducts drug screens and his new patient procedures, how he conducts physical exams on his patients, and how he determines what controlled substances to prescribe over time.'' *Id.* at 2. According to the SA, in the interview he ''also discussed with [Registrant] his patient 'James Howard' (the MBC/BS investigator), specifically discuss[ing] the three visits and how Mr. Howard's diagnoses were determined, . . . reviewed the associated patient records, discussed his urine drug screen results and how those were evaluated, and . . . discussed the controlled substances [Registrant] had prescribed to'' the investigator. *Id.*

The same day, the St. Clair Shores Police Department executed a state search warrant at Registrant's office and a second warrant at his residence. *Id.* at 2–3. During the execution of the warrant, the SA and another SA conducted a second interview with Registrant, who ''stated that he conducts physical exams on his patients and that he can do an exam by looking at the patient.'' *Id.* at 3.

On approximately February 22, 2016, the SA subpoenaed various patient records, and Registrant provided copies of the electronic patient records that were requested. *Id.* The SA also subpoenaed Registrant's records for specific patients, including those of D.S., A.L., and R.H., from Network Technology Inc., d/b/a RXNT, a firm which develops and implements products related to electronic health records and electronic prescribing. *Id.* at 2–3. On June 22, 2016, after reviewing MAPS and RxNT's records to identify specific prescriptions, the SA also subpoenaed from various pharmacies copies of the prescriptions issued by Registrant to various patients, including D.S., A.L., and R.H. *Id.* Subsequently, the SA also subpoenaed and obtained from Registrant the patient records of the MBC/BS Investigator. *Id.*

The Undercover Visits

On April 1, 2015, the MBC/BS Investigator (UC) conducted the first of three undercover visits to Registrant at his St. Claire Shores Medical office. GX 12, at 5. During each visit, he posed as patient D.H., whose occupation was driving. *Id.* The investigative record includes video recordings of each of his visits, transcripts of the recorded visits, his medical file, and photographs of the vials containing the filled controlled substance prescriptions issued by Registrant. GXs 3–12.

At the visit, the UC filled out new patient paperwork which included a registration form, a health history questionnaire, a pain questionnaire, and signed a narcotics contract. GX 12, at 5, 6–9, 11–12, 13–14. On the Health History Questionnaire, the UC wrote the name of a referring doctor and stated that his last exam had been in the ''summer 2014,'' and that ''Nerves'' and ''Back'' were ''medical problems that other doctors have diagnosed.'' *Id.* at 6. Under ''prescribed drugs,'' he wrote ''Zanax [sic] Strength 1 Frequency Taken 2.'' *Id.* at 7. He left the ''Health Habits and Personal Safety'' section mostly blank, including questions about his alcohol intake and recreational or street drug use. *Id.* at 7–8. In the Mental Health section, he circled ''no'' as his answer to the questions: ''Is stress a major problem for you?''; ''Do you feel depressed?''; ''Do you feel panic when stressed?''; and ''Have you ever been to a counselor?'' *Id.* at 9. He circled ''yes'' to the question ''Do you have trouble sleeping?'' *Id.*

The UC also filled out a Pain Questionnaire. *Id.* at 11. This consisted of a body diagram where he circled the lower back portion, and a section where he was to circle words describing his pain, such as ''Aching, Stabbing, Gnawing, Sharp, Burning, Exhausting, Tiring, Nagging, Numb, Miserable or Unbearable.'' UC did not, however, circle any of these descriptors, and instead, wrote ''Stiff.'' *Id.* He indicated that his pain was ''worst'' in the morning, but left blank four questions which asked him to rate his pain level at its worst, least, average for the month, as well as ''right now,'' on a scale of one to ten. *Id.* He wrote that ''Meds'' made his pain better, and left blank what made it worse. *Id.* at 12. He circled ''None'' in answer to ''what treatment or medication are you receiving for your pain?'' *Id.* He also left blank a series of questions asking him to rate the level of interference of pain on his general activity, mood, normal work, sleep, enjoyment of life, ability to concentrate, and relationships with other people. *Id.* He signed and dated this form ''7–9–70.'' *Id.* A section at the bottom of the form for Notes, Action Plan details and the Clinician's Signature are blank. *Id.*

UC also signed a narcotic contract, stating that he would use a Walgreens pharmacy. *Id.* at 13–14.

The video recording and transcript of the visit show that after he filled out the paperwork, he saw a nurse in an exam room, who asked a series of questions from a form while taking notes, including: ''Have anxiety? I noticed that you take uh . . . .'' GX 4, at 3. UC stated ''I don't know what you call it. . . uh . . . you know my nerves get jacked up and what not. I don't know what you call it.'' *Id.* UC added that he took Xanax and Norco, and that he had previously seen a physician in Flint, but it was ''too far and I travel a lot.'' *Id.;* GX 3, Video Recording (VR) 2, at 15:45:20–15:46:41.

office. RFAA, at 2 n.1. Under the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). While under DEA's regulations, ''any party, on timely request, shall be afforded [an] opportunity to controvert such fact,'' 21 CFR 1316.59(e), Registrant waived his right to a hearing or to submit a written statement and is therefore not entitled to refute my findings with respect to the Consent Order.

The nurse asked: ''As far as your medical history goes you want me just . . . to put anxiety down?'' GX4, at 3. UC stated: ''Whatever you call that, I don't know what the word,'' which prompted the nurse to ask: ''What brings you here?'' *Id.* UC answered: ''Just to get Xanax refills.'' *Id.* The nurse then asked UC if he ''had pain anywhere?'' and UC answered: ''Ah . . . like my back is stiff. But I don't know . . . Pretty much a stiff back. I drive a lot and what not, know what I'm saying.'' *Id.* at 3–4; GX 3, VR 2, at 15:46:41–15:47:11.

Following a discussion of Registrant's background, the Nurse then told UC that Registrant ''drug test[s] everybody.'' GX 4, at 4. As the Nurse proceeded with obtaining his weight, UC said that he was ''cool,'' that he did not ''want to cause any problems for anybody'' including Registrant, and that he was ''[m]ore or less healthy. You know what I'm saying?'' *Id.* at 4–5; GX 3, VR 2, at 15:47:11–15:48:48.

After determining UC's marital status, the nurse said: ''So, basically, you don't even—you don't have any problems besides the little bit of anxiety and your back gets stiff because of driving.'' GX 4, at 5. UC replied: ''Yeah, yeah. You got it.'' *Id.; see also* GX 3, VR 2, at 15:48:48–15:49:22.

The nurse continued to take UC's vitals as the two discussed his work as a driver, after which UC mentioned a patient in the lobby who, in UC's words, was ''yip-yapping and jaw-jacking.'' GX 4, at 6–7. The nurse denied that patients could easily get their prescriptions and stated that patients were tested and ''if they have other stuff in their system they cannot get their script . . . because they could drop dead if they mix.'' *Id.* at 7–8. Continuing, the nurse stated that Registrant is ''really strict about that'' and UC said: ''The worst thing I do is drink moonshine here and there. Little liquor on the weekends you know. But when I take that Xanax, I'm pretty chilled, so I don't really need to drink too much. You know it keeps me from getting stupid.'' *Id.* at 8; GX 3, VR 2, at 15:49:22–15:53:59.

As the nurse continued to review UC's medical history and discussed various subjects with him, UC noted that a sign on the wall ''says our office is no longer writing prescriptions for . . . ah . . . oxycodone or [R]oxicodone. Is that what that says?'' GX 4, at 11. The nurse replied: ''I don't think it says that. He writes that.'' *Id.* UC pointed out where he read the statement, and the nurse replied that ''it's for people that come in here just one time . . . [T]hey can't come in here (unintelligible).[4] *Id.* at 11–12; *see also* GX 3, VR 2 at 15:53:59–16:01:44.

Registrant eventually entered the exam room, greeted UC while donning a headphone set connected to the computer, resolved an issue with another patient, and appeared to dictate and record into the computer while he spoke to UC. GX 4, at 14. The nurse informed Registrant that UC was a new patient, and Registrant read aloud UC's height, weight, age and occupation from the computer screen. *Id.* at 16; *see also* GX3, VR3, at 16:16:23–16:19:39.

Registrant confirmed with UC that he drove for a living, and asked: ''And you have pain or what?'' ''What is your problem mostly?'' GX 4, at 17. UC stated: ''My back gets stiff because I drive a lot so sitting down too much. My back, you know, so it's stiff pretty much.'' *Id.* Registrant determined that UC did not have a CDL (commercial driver's license) and asked, ''You don't use methadone?'' UC responded: ''Absolutely not. I use moonshine. You know what that is?'' *Id.* Registrant asked: ''Too much?'' UC answered: ''No'' and ''You know if I take that Xanax it keeps me from drinking too much so it works out good.'' *Id.* at 17–18; GX 3, VR 3, at 16:19:40–16:21:22.

Registrant then asked: ''So what can I give you today to help you out?'' *Id.* UC answered: ''Usually Xanax helps me out. And Norco helps my back. That's all I really need. I don't have any—I'm pretty healthy.'' GX 4, at 18; GX 3, VR 3, 16:21:27–16:21:41.

Thereafter, Registrant resolved a problem with accessing the dictation software on his computer and began dictating into it, stating that UC ''is here for his first visit. . . . He is suffering also from anxiety and back spasms due to his long sitting. He currently does not have a CDL.'' GX 4, at 18. After UC told Registrant that he drove eight to 12 hours a day, Registrant stated: ''He denies drinking or using any stimulants such as methadone.'' *Id.* Registrant then asked whether UC was diabetic, and after UC said that he was not, Registrant dictated: ''He only uses Xanax occasionally for his anxiety. . . . Today, he is complaining mostly of some level of anxiety.'' *Id.* Registrant then asked UC if had ever seen a psychiatrist and UC answered: ''No, if I did, it was a long, long time ago.'' *Id.;* GX 3, VR 3, at 16:21:41–16:24:16.

Registrant then asked UC if he ''suffered from any childhood mental disorder'' such as ''attention deficit'' disorder. GX 4, at 18. UC said: ''Well . . . yeah. I don't know what they called it, but I didn't do very good in school.'' *Id.* Registrant asked: ''But not diagnosed? Not medicated?'' *Id.* UC replied: ''I use to take ADD—Ritalin.'' *Id.* Registrant asked: ''Ritalin as a child?'' *Id.* at 19. UC replied: ''Yeah. You know sometimes I do lose focus so I mean it might help me focus.'' *Id.* Registrant then resumed dictating and stated: ''After questioning the patient, admits to having had some childhood diagnosis of attention deficit disorder and was on Ritalin occasionally as a child. Sometime he complains of losing some focus but other than that he is doing well.'' *Id.* After dictating several additional comments, Registrant told UC to ''[l]ook at me'' and said ''ok.'' *Id.;* GX 3, VR 3, at 16:24:16–16:25:18.

UC told Registrant that he was ''[p]retty much a healthy guy'' and ''I try to take care of myself.'' GX 4, at 19. Continuing, UC said: ''Drink a little too much on the weekends sometimes, but you know.'' *Id.;* GX 3, VR 3, at 16:25:18–16:25:29.

Registrant then told UC: ''You know in this business of what I do, I don't know who is who. I have to be very careful when patients come in here.'' GX 4, at 19. UC replied: ''Oh you don't want trouble makers coming in here'' and Registrant said:

> Not the trouble makers. You know people come in here in all different shapes and forms. Sometimes they are investigators. Sometimes they are undercover cops.
>
> Sometimes they're anything and when I miss something it's just the right time for them to jump on me for something. So don't be worried that I'm paying attention to almost everything, you know. Did they give you a urine screen and test?

Id. UC said ''[n]o.'' *Id.* Registrant again asked UC if he gave a urine; UC again said ''no.'' *Id.;* GX 3, VR 3, at 16:25:30–16:26:20.

Again looking at his computer screen, Registrant stated: ''Your last physician recorded here was Dr. Vora Kandarp. He gave you Norco. He also gave you Xanax 0.5mg. He also gave you Naproxen. You saw a Dr. Miky in September.'' GX 4, at 19. UC said, ''I did,'' after which Registrant named three other doctors who he believed UC had seen in July and May of the previous year, noted that one of doctors had prescribed Adderall, and named the drug store which had filled this prescription. *Id.* Registrant then asked UC if he had high blood pressure because ''somebody gave you blood pressure medication.'' *Id.* UC denied having high blood pressure, stating that it was ''low actually'' and ''I never took that.'' *Id.* at 19–20; GX 3, VR 3, at 16:26:20–16:27:15.

UC then asked Registrant: ''How do you see that on there? You guys on the

[4] The sign is not, however, visible on the video. GX 3, VR 2, at 16:00:52–16:01:44.

same computer system?'' GX 4, at 20. Registrant replied: ''Everything. Everything shows up.'' UC then noted that the nurse had said that Registrant had ''a lot of problems with idiots coming in here trying to get drugs'' but ''that's not me.'' *Id.* Registrant discussed with UC his use of amphetamines, with UC noting that he ''didn't take it all the time'' and it ''[t]ook [him] a while to use it.'' *Id.* Registrant stated that he ''shouldn't take it all the time'' and did not prescribe the drug. *Id.;* GX 3, VR 3, at 16:27:15–16:27:46; see *also* GXs 5 & 12.

Registrant then moved on to UC's use of Xanax, noting that ''it seems like you started with .25 Xanax. You're up to .5 now, double it, to 60, that's in December. Is that sufficient for you?'' GX 4, at 20. UC said ''Yeah . . . Probably,'' and Registrant said: ''Okay. I will do that for you, sir.'' *Id.;* GX 3, VR 3, at 16:27:45–16:28:11.

Registrant further noted, ''And . . . you did get a few pain medication'' and asked: ''You want that too?'' GX 4, at 20. UC said ''[y]es'' and Registrant said ''[a]lright.'' *Id.;* GX 3, VR 3, at 16:28:11–16:28:18.

Registrant then stated: ''It's just the good thing is nothing is hidden anymore, you know. You can't come and hide anything.'' GX 4, at 20. Continuing, Registrant said: ''And these medications are good medications.'' Registrant then discussed the dosing of two non-controlled medications he was prescribing (Baclofen and Naproxen). *Id.* at 20–22; GX 3, VR 3, at 16:28:18–16:28:48.

Registrant proceeded to dictate dosing instructions for the prescriptions and asked UC which pharmacy he used. GX 4, at 22. UC asked if there was ''a good pharmacy around here'' or if he could ''take them on paper and go wherever I want?'' *Id.* Registrant suggested a pharmacy that was ''right up the street.'' *Id.* UC asked: ''They won't give me a hard time?'' and Registrant said ''no.'' *Id.* at 23. Registrant then wrote electronic prescriptions which he sent to the pharmacy that he and UC had agreed upon. *Id.;* GX 3, VR 3, at 16:28:48–16:31:56.

As the visit was about to end, Registrant noted that ''we need to get a urine from him'' and added: ''All the new patients—did they draw blood from you? You'll give a urine on the way out.'' GX 4, at 23. UC said he wasn't ''too good with needles'' and avoided the blood test but provided a urine sample. *Id.* at 26. *See also* GX 3, VR 3, at 16:31:56–16:44:32.

In the subjective section of the visit note, Registrant documented UC's chief complaint as: ''I drive for a living my back gets very stiff anxiety as well.'' GX 12, at 16. Under ''History of Present Illness,'' Registrant wrote that UC:

> is here for his first visit . . . he is suffering also from anxiety and back spasms due to his long sitting . . . he denies drinking or using any stimulants such as methadone or is a diabetic nor . . . on insulin. On the only use is Xanax occasionally for his anxiety. Today he is complaining mostly of [] some level of anxiety. . . . [P]atient admits to having had . . . a diagnosis of attention deficit disorder. . . . Sometimes he complains of losing some focus but other than that he's doing well.

Id.

The visit note's Review of Systems section contained fourteen different areas. *Id.* at 16–17. With the exception of ''BJE/Muscoskeltal,'' next to which Registrant noted ''Back Pain'' but ''Negative for Arhitis [sic], Joint Pain, Joint Swelling, Muscle Cramps, Muscle Weakness, Stiffness and Leg Cramps,'' all the areas contained negative findings, including the entry for Psychiatric, next to which Registrant documented: ''Negative for Anxiety, Depression, Hallucinations, Memory Loss, Mental Disturbance, Paranoia, Suicidal Ideation, Panic Attacks.'' *Id.*

In the ''Physical Examination'' section, Registrant noted UC's ''General Appearance'' as: ''Patient appears to be appropriate for age dressed appropriate for work responded to questions and no acute distress at this time.'' *Id.* at 17. Registrant noted that there were ''[n]o abnormal findings'' with respect to the ''exam'' of UC's ''[m]uscoskeletal'' and ''[n]eurologic'' systems. *Id.* at 18.

Yet Registrant then noted diagnoses of ''Spasm of Muscle,'' ''Anxiety State not Otherwise Specified,'' as well as ''Attention or Concentration Deficit.''[5] *Id.* For each diagnosis, he documented that ''7/22/2015,'' a date more than three months into the future, was both the date of onset and the date of diagnosis; he also noted that each diagnosis was active. *Id.* at 18.

As for Registrant's treatment plan, he listed only medications, which included ''naproxen 500 mg,'' ''hydrocodone 7.5 mg-acetaminophen 325 mg,''[6] and ''alprazolam 0.5 mg,'' and a follow-up visit ''after [one] month.'' *Id.* at 19. Consistent with other evidence, the record includes two photographs of a pharmacy bottle with the label for 90 tablets of hydrocodone APAP'' 7.5/325 mg prescribed to D.H. (UC's alias) by Registrant, to be taken three times daily as needed for back pain and stiffness, which was filled by a pharmacy in Mt. Clemens, Michigan on April 1, 2015. GX 5, at 1–2. Two other photos show the label attached to a vial which indicates that it was a prescription for 60 Alprazolam 0.5 mg, to be taken twice daily for anxiety, which was also prescribed by Registrant to UC and was filled at the same pharmacy. *Id.* at 5–6.

UC's medical file includes the report of the urine drug screen obtained at his April 1 visit, as well as a report run on the same date from the Michigan Automated Prescription System (MAPS). GX 12, at 20 (UDS report); *id.* at 3 (MAPS report). As for the drug screen results, which were reported back to Registrant on April 9, 2015, the results were negative for all controlled substances listed, including alprazolam, hydrocodone, and hydromorphone, the latter being a metabolite of hydrocodone. *Id.* at 20. As found above, UC had represented to Registrant (and his nurse) that he took both hydrocodone and Xanax, and the visit note listed hydrocodone as a current medication. GX 4, at 18 (transcript of visit); GX 12, at 7 (questionnaire), 17 (visit note), and 20 (UDS report noting UC was prescribed hydrocodone and Xanax).

As for the MAPS report, it showed that on December 15, 2014, UC had last filled prescriptions which were issued by Dr. Vora of Gladwin, Michigan for 90 tablets of hydrocodone/apap 7.5/325 mg and 60 tablets of alprazolam .5 mg. *Id.* at 3. The report also showed that the UC had obtained four prescriptions for various quantities and dosages of alprazolam from four different providers, two of whom were located in Flint, the others in Marquette and Detroit. *Id.*

The Government also submitted a declaration by the UC. GX 32. With respect to the April 1 visit, UC stated that Registrant reviewed his alias's purported medical history and saw that he had seen at least three other doctors in the months prior to his first visit, but did not conduct any further inquiry or follow up with him on that issue. *Id.* at 2. UC also stated that during the April 1 visit, Registrant conducted virtually no physical examination, and that the portion of his visit with Registrant lasted only a few minutes and consisted mainly of answering questions. *Id.* He also stated that during the visit, Registrant was repeatedly distracted by issues he was having with the dictation software for his electronic patient records. *Id.* My review of the video evidence corroborates each of these statements. GX 3, VR 3, 16:15:22–16:33:22.

UC further stated that he reviewed Registrant's patient records for him and determined that portions of it either

[5] He also documented a diagnosis of ''Body Mass Index Between 29.0–29.9 Adult.'' GX 12, at 18.

[6] Hereinafter, referred to as hydrocodone/apap.

misstate his statements during the visit or falsely indicate the extent to which he received or did not receive a medical examination. GX 32, at 2. UC explained:

> For instance, the patient record lists ''spasm of muscle'' as one diagnosis, even though I did not complain of spasms during the visit. And the record states that I ''den[ied] drinking'' even though I indicated that I do drink. The record also documents findings from a physical exam in categories such as ''Eyes,'' ''ENT,'' ''Cardiovascular,'' ''Muscoskeletal'' and ''Neurologic'' even though other than the taking of my vitals no physical exam was performed during the visit.

Id.

Second Undercover Visit

On May 1, 2015, UC again saw Registrant at the St. Claire Shores clinic. GX 12, at 22; GX 6 (video recording of visit). After UC provided a urine sample, a medical assistant (MA) took his vitals and UC asked if he could get paper prescriptions. GX 7, at 12 (transcript of recording). The MA asked what medications he was taking, UC said ''Norco and Xanax'' and that he had gotten them last month. *Id.* As the MA continued to take his vitals, she asked UC if he had a ''pharmacy problem'' and UC said: ''They take forever.'' *Id.;* GX 6, VR 5, at 11:19:58–11:22:31.

The MA then asked: ''[W]hat's bothering you actually?'' GX 7, at 12. UC replied: ''Just refills. I'm just here for refills. I'm just here for my back pills and my nerves.'' *Id.* The MA asked, ''Your lower back?'' and UC replied ''Yeah.'' *Id.;* GX 6, VR 5, at 11:22:31–11:23:03.

After she confirmed that ''just your back is [the] problem,'' the MA asked UC if he ''had a back injury before?'' GX 7, at 13. UC said that he didn't know and didn't ''know what it was.'' *Id.* The MA went through a list of symptoms including headaches and anxiety and asked if he had none of them; UC answered: ''I get headaches when I drink too much liquor'' and ''I do it big sometimes.'' *Id.* After a discussion of her shoes, MA asked UC: ''just back right?'' *Id.* UC said ''Uh-Huh,'' after which MA asked if he ''sometimes'' took medicine for headaches; UC answered: ''No, I just take the Xanax and Norco.'' *Id.; see also* GX 6, VR5, at 11:23:03–11:24:23.

The MA then asked if he had an ''anxiety problem?'' GX 7, at 13. *Id.* UC replied: ''Yeah. No—I don't know what you call it. But my nerves,'' prompting the MA to interject ''Anxiety'' and UC said ''I call it nerves.'' *Id.* The MA then asked UC if he took Xanax, and after UC confirmed this and that he took the one milligram dosage form, UC added: ''7.5 Norcos. That's all I need. I'm easy. What do you need?'' after which the MA asked UC to fill out a questionnaire. *Id.;* GX 6, VR 5, at 11:24:20–11:25:44.

UC filled out the questionnaire, and after the MA asked him if he had undergone various tests and had his blood drawn, UC was escorted to Registrant's office where the visit took place. Notably, the video shows that Registrant sat behind his desk for the duration of the visit, which lasted approximately three and a half minutes. *See* GX 6, VR 5, at 11:46:33–11:49:46; VR 6, at 11:49:47–11:50:01.

Registrant greeted the UC, confirmed his name, checked his computer screen, and discussed his lunch order with an unidentified employee, after which he asked UC about his insurance, and finally inquired if ''the medication [he] had last time went well?'' GX 7, at 16–17; UC replied ''Yep.'' After commenting about UC's blood pressure and height, Registrant asked: ''So you're okay with what we have?'' *Id.* at 18. UC said ''Yes'' and asked: ''Can I get it on paper this time?'' *Id.* Registrant asked ''why'' and if he went to a particular pharmacy, to which UC replied that ''it took forever,'' that he ''waited in line behind eight people,'' and he was ''going the other way this time too . . . to Detroit.'' *Id.* Registrant then agreed to give UC a paper prescription. *Id.;* GX 6, VR 5, at 11:46:3–11:48:05.

Registrant and UC proceeded to discuss the latter's job as a driver for a car transporter and cars in general, and were interrupted by the MA. GX 7, at 18–20. While Registrant discussed another patient with the MA, she handed several paper prescriptions to Registrant. Registrant signed the prescriptions and handed them to UC, saying, ''Here, sir'' and ''Alright, Take care.'' *Id.* at 19–20. UC thanked Registrant and said he would see Registrant ''in a month,'' and the visit ended. *Id.* 20; GX 6, VR 5, at 11:49:23–11:49:46; VR 6, at 11:49:50–11:50:01.

The evidence includes a visit note dated May 1, 2015, which lists UC's Chief Complaint as: ''I am having lower back pain with anxiety problem[.]'' GX 12, at 22. In the note's Review of Systems section, Registrant documented: ''BJE/Musculoskeletal: ''Back Pain:—.Negative for Arhitis [sic], Joint Pain, Joint Swelling, Muscle Cramps, Muscle Weakness, Stiffness, Leg Cramps.'' *Id.* Registrant noted UC's psychiatric condition as ''Anxiety:—.Negative for, Depression, Hallucinations, Memory Loss, Mental Disturbance, Paranoia, Suicidal ideation, Panic Attacks.'' *Id.* With respect to all other systems, including ''neurological,'' Registrant noted: ''No symptoms at this time.'' *Id.*

In the Physical Examination section, Registrant noted under ''General Appearance,'' that ''patient doesn't seems [sic] to be in any distress, appropriate to respond to questions alert,'' and under ''Muscoskeletal,'' he noted ''Limited Motion:—Arthritis.'' *Id.* at 23. Registrant again listed his diagnoses as ''Attention or Concentration Deficit,'' ''Spasm of Muscle,'' and ''Anxiety State Not Otherwise Specified.'' *Id.* at 23–24. For each diagnosis, he again listed ''7/22/2015'' as both the date of diagnosis and the date of onset and noted that the diagnosis was ''[a]ctive.'' *Id.*

In the Plan section of the note, Registrant did not list any prescriptions. *See id.* The evidence, however, includes copies of the prescriptions he issued at this visit; these include a prescription for 90 hydrocodone/apap 7.5/325 mg, 60 alprazolam 0.5 mg, as well as naproxen and baclofen. GX 8, at 1–4. As part of his plan Registrant ordered a ''urine drug screen'' and noted a follow-up visit ''after one month.'' GX 12, at 24.

A result sheet for the urine drug screen which was done on this date and apparently tested by Registrant's clinic [7] states that UC's test results were ''normal'' for amphetamines, benzodiazepines, opiates and oxycodone, as well as other controlled substances. *Id.* at 25. A second report shows the results of a test which was done by a lab (which were reported on May 6, 2015). *Id.* at 26. Notably, the lab reported ''Not Detected'' for both alprazolam and hydrocodone as well as each drug's metabolites [8] even though Registrant had prescribed the drugs at UC's previous visit. *Id.*

In his declaration, UC stated that Registrant ''did not conduct any physical examination'' and ''sat behind his [office] desk the entire time we talked'' which ''lasted only a few minutes.'' GX 32, at 3. He also stated that he had reviewed Registrant's patient records for the May 1, 2015 visit and determined that ''portions of them either misstate my statements during the visit or falsely indicate the extent to which I received (or did not receive) a medical examination.'' *Id.* These included the diagnosis of ''spasm of muscle'' even though ''I did not complain of and was not found to have muscle spasms during the visit,'' as well as that the medical ''record quotes me as saying 'I am having lower back pain'

[7] The result sheet indicates that these results were obtained within 20 minutes of the time of the test.

[8] These include hydroxyalprazolam, a metabolite of alprazolam, and norhydrocodone and hydromorphone, which are metabolites of hydrocodone. GX 12, at 26.

even though I made no such statement.'' *Id.*

Third Undercover Visit

On June 15, 2015, UC again saw Registrant. GX 9 (Video Record), GX 10 (transcript), GX 32 (UC's Declaration); *see also* GX 12, at 28 (Pt. file). According to the visit transcript, UC paid a co-pay and provided a urine sample. GX 10, at 1–3. Next, UC met with a nurse, who took his blood pressure and heart rate and asked him his weight and height. *Id.* at 4; GX 9, VR 3, at 13:32:58–13:35:43.

After UC noted that the last visit had taken place in Registrant's office and that he had ''sat across from the doctor who wrote me up,'' the nurse asked: ''you just needed your refills?'' GX 10, at 5. UC said: ''Yeah. That's all I need. I'm easy. Easy for sure.'' *Id.;* GX 9, VR 3, at 13:35:43–13:36:08.

The nurse accessed UC's electronic medical record and asked: ''So you're here for meds?'' *Id.* at 6. UC said: ''That's it. I'm pretty healthy.'' *Id.* The nurse then asked: ''Any new pain or anything? Pain is about the same?''; UC said: ''It's the same. Everything is the same.'' *Id.* The nurse replied: ''Unfortunately we still have to do all this charting, you know . . . [f]or DEA . . . It's just really crazy . . . those controlled things are really . . . it's like impossible to find meds . . . . It's being purposely done. People don't realize that, but DEA is behind it . . . .'' *Id.* UC remarked ''[c]lamping down?'' to which she replied ''Yep.'' *Id.;* GX 9, VR 3, at 13:36:08–13:37:59.

The nurse had UC fill out some paperwork, after which she proceeded to question UC as to whether he had experienced various symptoms including appetite problems, chills, fatigue, fevers, night sweats, weight gain or loss, ringing ears (which prompted UC to say that ''[m]y ears only ring after I drink a jug of moonshine''), blurry or double vision, coughing, difficulty breathing, wheezing, snoring, chest pain, or heart skippings; UC answered ''no'' to each of these. GX 10, at 9–10; GX 9, VR 3, at 13:39:26–13:43:52.

Continuing, the nurse asked UC if he had ''[a]ny muscular skeletal problems? Pain? Back pain, joint pain, and arthritis? No? No back pain?'' GX 10, at 10. UC stated: ''I got like, you know, the normal,'' to which the nurse said, ''No, I don't'' and asked again: ''You got back pain?'' *Id.* UC responded ''I got stiffness.'' Tr. at 10. UC then denied having joint pain. *Id.;* GX 9, VR 3, at 13:43:52–13:44:54.

The nurse then asked: ''Any anxiety, depression?'' GX 10, at 10. UC replied: ''No. Just my nerves get jacked up a little bit, but,'' prompting the nurse to ask: ''Panic attacks?'' *Id.* UC replied: ''I don't know what you would call it. Like I drink a couple cocktails on the weekend and I'm cool or that Xanax pretty much chills me down, so . . . Basically I take that Xanax, I don't need to drink too much. Everything is smooth. Makes sense?'' *Id.;* GX 9, VR 3, at 13:44:54–13:45:16.

The nurse stated: ''Makes perfect sense'' and asked if UC had ''[a]ny memory loss?'' *Id.* UC denied memory loss. GX 10, at 10. The nurse asked UC ''[w]hen was the last time'' he had visited; UC stated ''a month and a half ago'' and added that the ''last time they just let me go in his office.'' *Id.* at 11; GX 9, VR 3, at 13:45:15–13:46:16.

The nurse then asked what medications UC was taking; he answered ''Norco, Xanax, Baclofen'' and ''sometimes'' Naproxen. GX 10, at 11. The Nurse asked UC about his daily dosing for each drug, before asking if he had ''been out of some of these meds?'' *Id.* at 12. UC admitted that he had been out, and after the Nurse noted that his visit had been on May 1, asked: ''So what have you been doing?'' *Id.* UC replied: ''I have to get them from my neighbor. Well, I tried to get in here. They cancelled my appointment. The doctor was sick one day.'' *Id.;* GX 9, VR 3, at 13:46:40–13:48:48.

The nurse and UC discussed what pharmacy he used, stating that Registrant wanted to have one in case UC needed to have something called in, and that it was easier for e-scripting. GX 10, at 12. The nurse then encountered some difficulty with the electronic records and stated she was ''just putting no symptoms, because I'm not going through all that again. We already went through it.'' *Id.* at 14; GX 9, VR 3, at 13:48:50–13:52:00.

After a discussion of the use of suboxone, the nurse asked: ''Did you say you have joint pain, back pain?'' GX 10, at 15. UC replied: ''My back's stiff, but when I take that Norco, I'm cool'' and asked if ''[t]that make[s] sense?'' *Id.* The nurse replied: ''that's a reason to have it . . . for insurance purposes. You know what I mean?'' and UC said: ''As long as I take that, I'm smooth.'' *Id.;* GX 9, VR 3, at 13:54:36–13:54:47.

UC and the nurse then went to Registrant's office, where the latter was seated behind his desk and an MA was seated facing him. During this period, the nurse and MA remained in the office, and Registrant asked UC if he was a new patient. GX 9, at 16. After UC said ''No,'' Registrant asked: ''You a regular? How many times?'' *Id.* UC said: ''It's the third time I've been here . . . you cancelled me last time.'' *Id.;* GX 9, VR 3, at 13:55:02–13:55:40.

After several minutes of discussing whether Registrant remembered UC, the nurse told Registrant, ''he just needs these four,'' and that ''he needs them printed.'' GX 10, at 17. Apparently referring to the pharmacy UC wanted to use, Registrant asked UC if he didn't know which pharmacy he normally went to and whether he went ''to different people?'' *Id.* UC said he ''was going to Walgreens,'' but ''last time they didn't have some of my stuff. I had to come back two days later. So I'll just take them on paper if I can.'' *Id.* Registrant said ''ok.'' *Id.;* GX 9, VR 3, at 13:55:40–13:57:37.

Registrant and UC then discussed where the latter worked as well as Registrant's car and its gas mileage, after which Registrant demonstrated the versatility of a Bluetooth speaker system in his office, followed by the MA, Registrant and UC discussing their musical tastes and sharing stories about Registrant's daughter. GX 10, at 17–20. As the video shows, during the course of this conversation, Registrant checked his computer screen, signed the prescriptions which he handed to the nurse, who in turn handed them to the UC saying ''[y]ou're all set,'' UC asked ''Am I good, ok?'' and Nurse said ''yep.'' *Id.* at 22. Registrant told the UC to ''take care''; UC thanked Registrant and left his office. *Id.;* GX 9, VR 3, at 13:57:37–14:03:06.

The visit note lists UC's chief complaint as ''I am having lower back pains and anxiety.'' GX 12, at 28. In the Review of Systems section, Registrant again noted ''Stiffness'' under BJE/Muscoskeletal; however, he also noted ''negative'' for each of the symptoms that were listed including ''back pain'' and ''muscle cramps.'' *Id.* Under Psychiatric, he noted ''Anxiety'' and ''Panic Attacks.'' *Id.*

In the Physical Exam section, Registrant noted under ''General Appearance'' that ''patient states hes [sic] very anxious appears to be in mild pain alert to question and appropriate with his response.'' *Id.* at 29. As for his purported ''Muscoskeletal'' findings, Registrant noted: ''Limited Motion:—Muscle Spasm:—Tenderness:—Arthritis.'' And as for his purported ''Neurologic'' findings, Registrant noted: ''Abnormal reflexes:—Abnormal Gait:—Weakness Atrophy.'' *Id.*

As for his diagnoses, Registrant again listed ''Attention or Concentration Deficit,'' ''Spasm of Muscle'' and ''Anxiety State Not Otherwise Specified,'' and noted ''7/22/2015'' as the date of both diagnosis and onset for

each diagnosis. He further noted that each diagnosis was ''Active.'' *Id.*

As for his plan, Registrant listed hydrocodone/apap 7.5/325 mg, Xanax 0.5 mg, as well as Baclofen 10 mg and Naproxen 500 mg. *Id.* at 30. He also noted a follow-up in one month. *Id.* The Government's evidence includes copies of the prescriptions issued by Registrant to UC at this visit; the prescriptions include 60 tablets of alprazolam .5 mg and 90 tablets hydrocodone 7.5/325 mg, as well as baclofen and naproxen. GX 11.

UC's patient file includes a report for a urine drug sample collected from him at the June 15, 2015 visit which was tested at Registrant's clinic the same day. The report noted that neither benzodiazepines or opiates were detected and listed the results as ''normal.'' *Id.* at 31. While these results were available the same day, UC's visit occurred approximately two weeks after the medication from his previous visit would have run out.[9]

In his declaration, UC stated that he told Registrant's staff that when he ran out of medication, he obtained controlled substances from a neighbor to fill the gap between visits and that neither Registrant nor his staff conducted any further inquiry on this issue. GX 32, at 3. UC also stated that Registrant did not conduct any physical examination and that the portion of his visit with Registrant occurred in Registrant's office, where Registrant ''sat behind his desk the entire time.'' *Id.* UC further stated that his patient record quotes him ''as saying 'I am having lower back pains' even though I explicitly stated that I had 'stiffness.' '' *Id.* at 4 (*Compare* GX 12, at 28 *with* GX 10, at 10 (Nurse asks ''You got back pain?'' and UC responds: ''I got stiffness.''). Finally, UC stated that the visit note lists the results of a muscoskeletal exam, but other than the taking of his vital signs, no physical exam was performed during this visit and none of the conditions listed were discussed or found. GX 32, at 4.

The Government's Expert

The Government retained Dr. R. Andrew Chambers, M.D., to review the videos, transcripts and prescriptions related to the undercover visits made by the UC investigator, as well as the medical files for three patients, D.S., A.L. and R.H., which were obtained during the investigation. Dr. Chambers is an addiction psychiatrist in Indiana. GX 33 (Expert's Declaration). He is also an Associate Professor of Psychiatry at the Indiana University (IU) School of Medicine in the IU Neuroscience Center where he trains psychiatrists and physicians on the diagnosis and treatment of mental illness and drug addiction. *Id.* at 1. He also runs a university-affiliated mental health center and addiction treatment clinic where he treats patients. *Id.* He has been board certified in addiction medicine since 2008 and addiction psychiatry since 2012, and has published over 40 peer-reviewed journal articles and approximately nine textbook sections. *Id.* In addition, Dr. Chambers has provided expert testimony which was found credible in a previous DEA proceeding. *See Lon F. Alexander,* 82 FR 49704, 49714, 49725–26 (2017).

Dr. Chambers stated that he reviewed various materials to familiarize himself with the standard of care for the prescribing of controlled substances in Michigan, including the Michigan Board of Medicine's Guidelines for the Use of Controlled Substances for the Treatment of Pain, (hereinafter, ''Michigan Guidelines''), as well as various state laws, a document of the Michigan Board of Pharmacy entitled ''Pharmacy—Controlled Substances,'' and information posted by the Michigan Advisory Committee on Pain and Symptom Management. *Id.* at 2.

Dr. Chambers stated that ''as a professor and practicing psychiatrist, I have an understanding of how to prescribe controlled substances and the risks associated with doing so. I am also familiar with how doctors and practitioners should conduct themselves when prescribing controlled substances for a legitimate medical purpose in the usual c[o]urse of their profession.'' *Id.* Based on his ''professional experience and review'' of the Michigan Guidelines and state law, he opined that ''the standard of care for prescribing controlled substances in Michigan is similar to and consistent with that in Indiana . . . and that the standards in Michigan are similar to and consistent with the national norms in the medical profession for prescribing controlled substances.'' *Id.* He then discussed the standards for prescribing controlled substances in Michigan:

> First, in accordance with Michigan state law, any controlled substance must be prescribed for a legitimate or professionally recognized therapeutic purpose. To determine that, the practitioner must take a complete medical history of the patient and conduct an adequate physical examination to determine if there is a legitimate medical basis for so prescribing. Second, as explained in the Michigan Guidelines, ''when evaluating the use of controlled substances for pain control, . . . [a] complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse.'' The guidelines also instruct on providing a written treatment plan, obtaining informed consent and agreement for treatment, conducting a periodic review at ''reasonable intervals based on the individual circumstances of the pain,'' and ''referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.'' Third, practitioners must keep accurate and complete records of the forgoing and other aspects of medical care. Although that requirement is explicitly stated in the Michigan Guidelines, I can also [] attest based on my knowledge and experience that keeping accurate and complete patient records is required to meet the standard of care for the prescribing of any controlled substance, not just that which relate to pain control.

Id. at 3.

Dr. Chambers also stated that he was ''aware of red flags, or possible indicators of potential abuse, addiction or diversion, and the need for red flags to be addressed and resolved by a practitioner.'' *Id.* According to Dr. Chambers, these include ''patients seeking to have medications refilled early, patients asking for specific medications, and indications that the patient is addicted to or is diverting medications.'' *Id.* He further stated that ''under the standard of care, practitioners' records should identify any potential red flags and steps taken to resolve them.'' *Id.*

I find that Dr. Chambers is qualified to provide an expert opinion on the standards of professional practice for prescribing controlled substances under the Michigan Board's Guidelines and Michigan law, as well as the standard of care generally with respect to the treatment of both pain and anxiety. I also find that Dr. Chambers is qualified to provide expert testimony as to the risks associated with prescribing controlled substances.

Dr. Chambers provided a written report regarding Registrant's prescribing of controlled substances to UC and three other patients (D.S., R.H., and A.L.). With respect to UC, Dr. Chambers stated that he ''reviewed the undercover videos, transcripts, and prescriptions,'' as well as the medical records related to each of the three visits.

Dr. Chambers opined that Registrant prescribed both hydrocodone, an opioid, and alprazolam, a

[9] UC file's also includes the results of the UDS which was tested by an outside laboratory on June 18, 2015. GX 12, at 32. The report noted that the results were inconsistent with the drugs prescribed in that neither alprazolam nor hydrocodone were detected. *Id.*

benzodiazepine, and that this combination of drugs raises a serious overdose risk. *Id.* He further opined that ''[t]here are three clinical contexts in which the risks associated with opioid and benzodiazepine combination therapies are considered acceptable, these being for hospice care, for ''critical-care or closely monitored inpatient settings,'' and ''for short-term, closely monitored detoxification protocols for patients with addictions,'' none of which are relevant in assessing Registrant's prescribing to UC. *Id.* at 3–4.

Dr. Chambers opined that at UC's first visit, Registrant failed to do a ''proper evaluation of current substance use symptoms or substance disorder history.'' GX 33, Attachment B, at 19. As Dr. Chambers explained, UC had admitted to significant alcohol use at this visit yet Registrant did not further question UC about his alcohol use. *Id.* While UC had represented that he was taking Xanax and Registrant reviewed his MAPS report which showed that he had obtained the drug from multiple providers, some of whom were hundreds of miles apart, Registrant did not do a ''proper evaluation of current psychiatric symptoms or psychiatric history of present illness.'' *Id.* Dr. Chambers also noted that while a nurse obtained UC's vital signs and weight, ''a physical exam was never performed'' and yet the medical records include ''normal physical examination findings.'' *Id.* at 20. Moreover, the patient record ''falsely states that the patient denies drinking.'' *Id.*

With respect to Registrant's diagnoses, Dr. Chambers opined that none of them was properly supported. As for the diagnosis of muscle spasm, Dr. Chambers noted that ''there was no physical exam . . . to confirm muscle spasm or any other somatic source of pain or muscular-skeletal disorder.'' *Id.* at 21. He further observed that Registrant prescribed opioids but there was no diagnosis of pain and ''opioids are not indicated for muscle spasm.'' *Id.*

As for the diagnosis of anxiety, Dr. Chamber reiterated that Registrant did not perform an ''adequate psychiatric evaluation.'' *Id.* Dr. Chambers also observed that the diagnosis of an attention or concentration deficit ''was not evaluated[,] or measured in any current way.'' *Id* at 20.

Dr. Chambers observed that while Registrant went over the dosing instructions, he did not caution UC about the risks of combining opioids and benzodiazepines, which ''may produce serious hazards for driving''' even though UC said he was professional driver. *Id.* at 19.

Addressing UC's second visit, Dr. Chambers noted that ''there [was] no physical examination.'' *Id.* at 19. Dr. Chambers further observed that ''[t]he actual clinical encounter and evaluation with [Registrant] last[ed] three minutes'' and that ''[t]he most substantial evaluative questions'' which Registrant asked the UC were: ''Doing OK?'' and ''Med went well?'' *Id.*

With respect to UC's third visit, Dr. Chambers noted that UC had ''again ma[de] comments that he engage[d] in significant drinking.'' *Id.* Dr. Chambers then observed that ''[t]his information was ignored and/or falsified in the Medical Record by'' Registrant. *Id.* at 22.

Dr. Chambers also noted that UC stated that because his third appointment was two weeks late, he had run out of medications and had obtained controlled substances from his neighbor. *Id.* at 20. Dr. Chambers observed that ''this activity was never addressed by'' Registrant. *Id.*

As for UC's interaction with Registrant, Dr. Chambers noted that this occurred in Registrant's office, that the entire encounter lasted eight minutes, during which ''there [was] essentially no clinical evaluation of the patient to assess symptoms, illness course or treatment response,'' and ''the only questions'' asked by Registrant were ''where the patient work[ed] and what pharmacy he use[d].'' *Id.* Dr. Chambers also observed that most of the encounter was spent discussing matters that had nothing to do with the UC's medical condition and a physical exam was not performed. *Id.*

In addition, Dr. Chambers noted that Registrant falsified the visit note in various respects. These include: (1) The statement that UC ''appears to be in mild pain,'' which Dr. Chambers opined was inconsistent with the UC's ''voice, affect and thought content,'' notwithstanding that the video does not show how UC appeared; (2) the statement that ''patient states he is very anxious,'' which UC ''never stated''; and (3) the exam findings of ''limited motion, spasm, tenderness,'' as well as ''abnormal reflexes'' and ''weakness/atrophy,'' as Registrant ''never performed a physical exam or touched the patient.'' *Id.* at 21.

Dr. Chambers thus concluded that ''the controlled substances prescriptions that [Registrant] issued to the investigator during the undercover visits were not issued for any legitimate medical basis and were issued outside of the standard of care in . . . Michigan.'' GX 33, at 4.

The Expert's Chart Review of Registrant's Patients D.S., A.L. and R.H.D.S.

Dr. Chambers reviewed the patient file for D.S., whose ''typical chief complaints were back and neck pain, and sometimes knee pain'' during the five years she was treated by Registrant. GX 33, at 4. According to the patient file, D.S.'s initial appointment with Registrant was on August 31, 2011. GX 14, at 5.

Dr. Chambers found that documented prescription records from Registrant's electronic patient file showed a prescribing pattern which rapidly escalated from D.S.'s initial visit. GX 33, Attachment B, at 7. Dr. Chambers specifically expert found that on August 31, 2011, Registrant prescribed 90 mg/day morphine, yet only two weeks later (September 14, 2011), Registrant doubled the dosage to 180 mg/day. *Id.* Only one month later (October 14, 2011), Registrant increased D.S.'s dosing to 320 mg/day morphine and added 700 mg/day carisoprodol. *Id.* at 8.

Dr. Chambers also found that in two years of appointments between January 2014 and February 2016, Registrant's records show diagnoses of pain and depression. *Id.* The Expert found, however, that over this period, D.S.'s patient file contained no evidence that Registrant did physical exams other than to take vital signs; he also found that Registrant's treatment plans were essentially non-existent. *Id.* Yet during this period, Registrant prescribed to D.S. such narcotics as hydrocodone 10/325 mg. and oxycodone 30 mg. which included repeated prescriptions for 120 dosage units of the latter drug; he also repeatedly prescribed carisoprodol, a schedule IV muscle relaxant during this period. GX 13, at 1–48. Dr. Chambers noted, however, that the D.S.'s ''records do not typically document evidence of improvement in pain symptoms.'' GX 33, at 6.

Registrant also repeatedly prescribed other controlled substances including stimulants such as Adipex-P (phentermine) and Bontril (phendimetrazine), which are schedule III and IV controlled substances. GX 13, at 6. Dr. Chambers further found that Registrant's introduction of these stimulants into D.S.'s medication regimen was ''not accompanied by a diagnosis or clinical indication in the charting.'' GX 33, Attachment B, at 8.[10]

[10] He also found that Registrant made a diagnosis of depression on January 15, 2014, but there was no attempt to treat it. *Id., see also* GX 15, at 1–3. In fact, the record shows that under Review of Systems, Registrant noted ''no [psychiatric]

Continued

Dr. Chambers identified multiple instances in which D.S.'s medical records indicated that she was suffering from addiction. These include notes on April 11 and May 9, 2012 documenting ''dependence,'' a note on June 8, 2012 that ''she constantly needs more [pain medications],'' a note on September 28, 2012 of ''medication dependence,'' a note on October 26, 2012 of ''[m]edication dependence illness,'' and a note on November 20, 2012 of ''patient continues to display dependence.'' GX 33, at 6.

Dr. Chambers also identified multiple instances in which D.S. provided aberrant urine drug screens. These included tests which showed the presence of methadone on February 14, 2014 and buprenorphine on November 10, 2014, neither of which were prescribed to D.S.; the presence of cocaine on March 14, 2014; the presence of psychostimulants (amphetamines) on March 14, April 14, and May 12, 2014 which were not prescribed by Registrant; instances in which the tests were negative for drugs prescribed by Registrant (Nov. 10, 2014 negative test for oxycodone and morphine and June 22, 2015 negative test for oxycodone); and four tests which found levels of oxycodone which were above the recommended therapeutic range of those drugs.[11] GX 33, Attachment B, at 8–9.

Dr. Chambers explained that the drug test results show ''a number of different problems that represent serious warning signs of dangerous drug use and or addiction.'' *Id.* at 8. He further observed that Registrant's records contain no acknowledgment of D.S.'s aberrational drug tests results and reflect that he did not change the treatment plan or any clinical actions to address the results. *Id.* at 9.

Dr. Chambers concluded that ''D.S. was very likely suffering from drug addiction that was not adequately diagnosed or treated, and [Registrant] failed to act on an overall lack of treatment response to the controlled substance combinations he was prescribing.'' GX 33, at 6. He further opined that Registrant ''was prescribing dangerous combinations of controlled substances without documenting a medical need for so doing, and he failed to adequately document ongoing examinations and treatment planning . . . and/or he failed to perform these professional functions altogether.'' *Id.* Dr. Chambers thus concluded that Registrant issued numerous prescriptions without ''any legitimate medical basis'' and acted ''outside of the standard of care in the state of Michigan.'' *Id.*

A.L.

Registrant treated patient A.L. from January 17, 2011 through April 30, 2014. *Id.* at 14–16. *See also* GX 18 (patient medical file), GX 19 and 20 (electronic patient files). Regarding Registrant's patient records for A.L., Dr. Chambers reported that they contain notes for various medical issues including anxiety, depression, and pain, the latter including knee, lower back, ankle and neck pain. GX 33, at 6–7.

Dr. Chambers reviewed 11 controlled substance prescriptions Registrant issued to A.L. between October 17, 2013 and May 6, 2014. *Id.* at 7. The prescriptions included three prescriptions for 120 du of hydrocodone/apap 10/325 mg with two refills, three prescriptions for 30 du of phentermine 37.5 mg with two refills, three prescriptions for 150 du of carisoprodol 350 mg with two refills, and three prescriptions for 120 du of alprazolam 2 mg. GX 17, at 2–23 (copies of prescriptions obtained from filling pharmacy, and pharmacy patient profile report).

Dr. Chambers observed that ''[f]or the most part there are no physical examinations documented in the medical records.'' GX 33, at 7. Dr. Chambers also noted that ''the combination of Hydrocodone, Alprazolam and Carisoprodol drugs . . . is a prescription 'cocktail' known among users and law enforcement as the 'Trinity,''' and that it ''is widely known to be used non-therapeutically as part of a substance disorder and/or diverted.'' *Id.* He further noted that on four occasions in 2011, Registrant had also prescribed another variation of this cocktail, which substituted Roxicodone (oxycodone) for hydrocodone. *Id.* He then opined that ''there is no documentation in A.L.'s medical records demonstrating a legitimate medical justification or clinical context for prescribing this dangerous combination of controlled substances.'' *Id.*

Dr. Chambers also found that ''[t]here are numerous signs of addiction'' in A.L.'s patient file, beginning with her initial visit with Registrant on January 17, 2011. *Id.* Dr. Chambers noted that the MAPS report showed that A.L. ''had seen up to eight prior prescribers over the prior year for various controlled substances, including combinations of opioids, benzodiazepines, and stimulants,'' resulting in 50 dispensings of drugs which included hydrocodone, oxymorphone, oxycodone, morphine, diazepam, alprazolam and amphetamine. GX, 33 at 7–8; *see also* GX 18, at 32–40. He also observed that on her ''Health History Questionnaire,'' which was completed in January 2011, she reported taking Roxicodone, Xanax, and Soma, which as Dr. Chambers previously explained, comprises the highly abused '''Trinity' drug cocktail.'' *Id.* at 8; *see also* GX 18, at 14.[12]

Dr. Chambers further noted that A.L.'s medical records documented that she ''was possibly engag[ed] in diversion.'' *Id.* at 8. As support for this observation, Dr. Chambers pointed to a chart entry of February 25, 2013 which states: ''She says she cannot get her pain medications and has to be buying it off the streets to satisfy her pain. The last time she was given pain medication from this office was in September of last year.'' *Id.* at 8; *see also* GX 19, at 8. Dr. Chambers found that there was no evidence in the patient record that Registrant ''addressed or resolved these red flags.'' GX 33, at 8. Moreover, Dr. Chambers found that Registrant's ''charting is devoid of UDS data collection or tracking.'' GX 33, Attachment B, at 18.

Based on his review of A.L.'s record and the prescriptions, Dr. Chambers concluded that that she ''was suffering from a drug addiction that was not adequately diagnosed or treated; [that Registrant] was prescribing extremely dangerous combinations of controlled substances without documenting an appropriate medical context or justification for so doing, and [that he] failed to adequately document ongoing examinations and treatment planning . . . and/or he failed to perform these professional functions altogether.'' GX 33, at 8. Dr. Chambers thus opined that ''the prescriptions [Registrant] issued to A.L. were not issued for any legitimate medical basis and were issued outside of the standard of care in the state of Michigan.'' *Id.*

R.H.

Dr. Chambers also reviewed the controlled substances Registrant issued to R.H. from June 2, 2015 through February 24, 2016. According to Dr. Chambers, during this time period, R.H. presented a variety of chief complaints which ''included complaints of lower back and hand joint pain, anxiety,

symptoms at this time: Negative for anxiety, depression . . . mental disturbance . . . panic attacks.'' *Id.* at 1. There were also ''no [psychiatric] symptoms at this time'' noted at D.S.'s following visit. *Id.* at 4.

[11] Two tests also found amphetamines at levels above the recommended therapeutic range. GX 33, Attachment B, at 9.

[12] The same Health History Questionnaire also lists Opana, Vickodin [sic], and MS Contin as ''prescribed drugs.'' GX 18, at 14.

numbness, a rash on face/head, fractured left toes, sciatica, and arms and shoulder pain.'' *Id.*

During this period, Registrant issued to R.H. 10 prescriptions for 90 du of hydrocodone/apap 10/325 mg; 10 prescriptions for 60 du of morphine sulfate 100 mg; 10 prescriptions for 120 du of morphine sulfate 30 mg; five prescriptions for 60 du of alprazolam 1 mg, including one which provided for two refills; and two prescriptions for 60 du of carisoprodol 350 mg, each of which provided for two refills. *Id.* at 8–10. Dr. Chambers again noted that the combination of hydrocodone, alprazolam, and carisoprodol comprise the Trinity cocktail. *Id.* at 10. He also found that on six occasions between March 11, 2011 and September 26, 2011, Registrant prescribed hydrocodone, carisoprodol and Valium (diazepam), another version of the Trinity cocktail. *Id.*

Dr. Chambers found that ''[f]or the most part there are no physical exams documented in the medical records.'' *Id.* He also found that ''[t]here is no documentation in R.H.'s medical records demonstrating a legitimate medical justification or clinical context for prescribing this dangerous combination of controlled substances.'' *Id.*

Dr. Chambers noted that R.H.'s records contain ''numerous signs of possible addiction or abuse.'' *Id.* at 11. These include a note (Dec. 21, 2011) in which Registrant documented that ''R.H. is taking the valium three times a [day] although he is given it twice daily so he runs out eary'' [sic]. *Id.* Dr. Chambers also found that ''R.H.'s urine drug screens also show[] a number of different problems that represent serious warnings signs of dangerous drug use and or addiction, including the presence of amphetamines and benzodiazepine[s] that [were] not prescribed by'' Registrant. *Id.* Dr. Chambers further found that ''[t]here are no indications in the patient records that [Registrant] addressed or resolved these red flags.'' *Id.*

Based upon his review of R.H.'s patient file and prescriptions, Dr. Chambers concluded that he ''was suffering from drug addiction that was not adequately diagnosed or treated.'' *Id.* Dr. Chambers further concluded that Registrant ''was prescribing extremely dangerous combinations of controlled substances without documenting a medical need for so doing, and [that Registrant] failed to adequately document ongoing examinations and treatment planning . . . and/or he failed to perform these professional functions altogether.'' *Id.* Dr. Chambers thus opined that the prescriptions Registrant issued to R.H. ''were not issued for any legitimate medical basis and were issued outside of the standard of care in . . . Michigan.'' *Id.*

Summary of the Expert's Findings

With respect to the UC and the three other patients, Dr. Chambers opined that:

> The evidence reveals that [Registrant] has been engaged in prescribing dangerous levels and combinations of opioid and benzoid drugs to multiple patients in chronic patterns that have no legitimate medical purpose, and are not supported by the evidence base. Moreover, it is precisely these types of controlled substance patterns that are shown by a wealth of biomedical, clinical and epidemiological evidence to produce diversion and to contribute to addiction, worsening mental illness, and premature death. The case evidence suggests to various degrees that all of these outcomes have happened as a result of [Registrant's] prescribing and clinical practices.
>
> This prescribing was also occurring in the absence of minimally adequate practice standards of care by [Registrant], including failures to appropriately evaluate, diagnose and monitor disease processes, and treatment outcomes or treatment side effects. All 4 cases presented strong evidence that patients were suffering with mental illness and addiction of some kind when initially presenting for treatment. In 3 cases, these conditions did not change and/or worsened over time even as they were not appropriately treated, or referred elsewhere for treatment, and even as these conditions were adversely contributed to by the benzoid-opioid combination of drugs [Registrant] was prescribing.

Id. at Attachment B, at 5.

Dr. Chambers further opined that Registrant was not practicing in ''good faith'' as defined by Michigan Code § 333.7333(1). *Id.* This provision defines ''good faith'' as:

> The prescribing or dispensing of a controlled substance by a practitioner licensed under section 7303 in the regular course of professional treatment to or for an individual who is under treatment by the practitioner for a pathology or condition other than that individual's physical or psychological dependence upon or addiction to a controlled substance, except as provided in this article.

Mich. Code § 333.7333(1). Dr. Chambers thus concluded that ''rather than providing legitimate medical care, [Registrant] was actually using the guise of medical practice . . . to deal addictive drugs to patients with untreated addictions and mental illness.'' GX 33, Attachment B, at 5.

Dr. Chambers also evaluated the evidence in light of the Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain. Dr. Chambers explained that the Guidelines ''set forth six key components of legitimate medical practice that should be observed in the use of controlled substance for the treatment of pain,'' to ''include appropriate:

> (1) Evaluation (history taking and physical examination, psychiatric screening);
> (2) Treatment Planning;
> (3) Informed consent (discussion of risks and benefits of medications . . .);
> (4) Periodic Review (evaluate and monitoring of treatment progress);
> (5) Consultation; and
> (6) Medical record keeping.''

Id. at 5–6.

Dr. Chambers opined that ''there are 2 other key aspects of the evidence that highlight the particularly malignant nature of [Registrant's] practices and prescribing pattern.'' *Id.* at 6. First, Dr. Chambers concluded that the ''evidence suggest[s] that Registrant deliberately acted to obscure, in the medical record, the dangerousness of his practice, to cover-up the degree to which it was a drug dealing operation, instead of a legitimate medical practice.'' *Id.* As he further explained, the evidence ''show[s] that [Registrant] is padding the medical record with initial PDMP evaluations and UDS testing that he never acts on regardless of what these data show, as if the point is to create the appearances of maintaining standards and adequate monitoring in the medical record without actually doing so.'' *Id.* Second, Dr. Chambers explained that the evidence shows that ''[h]e not only engages in little history taking and no physical examination of the patient, but he falsely documents examination findings that do not exist, in an examination that was never performed, in order to justify the continuing prescription of controlled drugs.'' *Id.*

Dr. Chambers thus concluded that ''this evidence shows that [Registrant] is performing well below the standard of care, and is a danger to []his patients and the public at large with respect to his prescribing of controlled substances. The evidence is highly suggestive that he is providing prescriptions for addictive substances, not in 'good faith' consistent with medical norms, but as a distribution business, *i.e.* as a drug dealing operation under the guise of legitimate health care.'' *Id.* I agree.

Discussion

In its Request for Final Agency Action, the Government seeks revocation on two independent grounds. First, it argues that revocation is warranted because Registrant lacks authority under state law to dispense controlled substances. RFAA, at 6 (citing 21 U.S.C. 824(a)(3)). Second, it

argues that Registrant has committed acts which render his registration inconsistent with the public interest because he unlawfully distributed controlled substances in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04(a). *Id.* at 9. I agree that the Government is entitled to an order of revocation on both grounds.

Lack of State Authority

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823, ''upon a finding that the registrant . . . has had his State license . . . suspended [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' Moreover, DEA has held repeatedly that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton,* 43 FR 27616 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined ''the term 'practitioner' [to] mean[] a . . . physician . . . or other person licensed, registered or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the Act, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the State in which he practices medicine. *See, e.g., Calvin Ramsey,* 76 FR 20034, 20036 (2011); *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci,* 58 FR 51104, 51105 (1993); *Bobby Watts,* 53 FR 11919, 11920 (1988). *See also Frederick Marsh Blanton,* 43 FR 27616 (1978).

Here, while the Michigan Board's Consent Order suspended Registrant's medical license for 15 months, the Board's Order further provides that ''reinstatement shall not be automatic,'' and that Registrant must petition for reinstatement by demonstrating, ''by clear and convincing evidence,'' that he: (1) Is of ''good moral character''; (2) has ''the ability to practice the profession with reasonable skill and safety''; (3) has satisfied ''the guidelines on reinstatement adopted by the Department''; and (4) ''that it is in the public interest for the license to be reinstated.'' Consent Order, at 2. Thus, it is far from certain that Registrant will be able to satisfy these conditions and be reinstated to the practice of medicine.

More importantly, this Agency has held that even where a State has imposed a suspension of finite duration of a practitioner's medical license, revocation is nonetheless warranted because the controlling question is not whether a practitioner's license to practice medicine in the State is suspended or revoked; rather, it is whether the Registrant is currently authorized to handle controlled substances in the State. *Hooper,* 76 FR at 71371 (citing *Anne Lazar Thorn,* 62 FR 12847, 12848 (1997)). Because one cannot obtain a practitioner's registration unless one holds authority under state law to dispense controlled substances, and because where a registered practitioner's state authority has been revoked or suspended, the practitioner no longer meets the statutory definition of a practitioner, DEA has held repeatedly that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for both obtaining and maintaining a practitioner's registration. *See Blanton,* 43 FR 27616 (1978) (revoking registration based on one-year suspension of medical license); *Hooper,* 76 FR at 71371 (same).

Thus, because Registrant is no longer currently authorized to dispense controlled substances in Michigan, the State in which he is registered with the Agency, I find that he is not entitled to maintain a DEA registration in the State. Accordingly, I will order the revocation of his existing registration on this ground. *See* 21 U.S.C. 824(a)(3) .

The Public Interest Analysis

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to ''dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). With respect to a practitioner, the Act requires the consideration of the following factors in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing * * * controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id. § 823(f)

''These factors are * * * considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[ ] appropriate in determining whether a registration should be revoked.'' *Id.; see also Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009). While I must consider each factor, I am ''not required to make findings as to all of the factors.'' *Volkman,* 567 F.3d at 222; *see also Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct. *Jayam Krishna—Iyer, M.D.,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay* v. *DEA,* 664 F.3d. 808, 821 (10th Cir. 2011).

Even in a non-contested proceeding, the Government has the burden of producing substantial evidence to support the allegations and its proposed sanction. *See Gabriel Sanchez,* 78 FR 59060, 59063 (2013); 21 CFR 1301.44(e). In this case, I find that the Government's evidence with respect to Factors Two and Four [13] establishes that Registrant

[13] In its Request for Final Agency Action, the Government states that Factors I, III and V do not weigh in favor of or against revoking Registrant's registration. RFAA at 8, fn. 4 (citing 21 U.S.C §§ 823(f)(1), (3) and (5)). As explained above, with

''has committed such acts as would render his registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

Factors Two and Four—Registrant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

Under a longstanding DEA regulation, a prescription for a controlled substance is not ''effective'' unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). *See also* Mich. Comp. Laws § 333.7333(1) (''As used in this section, 'good faith' means the prescribing of a controlled substance by a practitioner licensed under section 7303 in the regular course of professional treatment to or for an individual who is under treatment by the practitioner for a pathology or condition other than that individual's physical or psychological dependence upon or addiction to a controlled substance, except as provided in this article.''); *id.* § 333.7401 (''A practitioner licensed by the administrator under this article shall not dispense, prescribe, or administer a controlled substance for other than a legitimate and professionally recognized therapeutic or scientific purposes or outside the scope of practice of the practitioner . . . .'').

Under the CSA, it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *See United States* v. *Moore,* 423 U.S. 122, 142–43 (1975); *United States* v. *Lovern,* 590 F.3d 1095, 1100–01 (10th Cir. 2009); *United States* v. *Smith,* 573 F.3d 639, 657 (8th Cir. 2009); *see also* 21 CFR 1306.04(a) (''An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'').

As the Supreme Court has explained, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *Moore,* 423 U.S. 122, 135, 143 (1975)).

Both this Agency and the federal courts have held that establishing a violation of the prescription requirement ''requires proof that the practitioner's conduct went 'beyond the bounds of any legitimate medical practice, including that which would constitute civil negligence.' '' *Laurence T. McKinney,* 73 FR 43260, 43266 (2008) (quoting *United States* v. *McIver,* 470 F.3d 550, 559 (4th Cir. 2006)). However, as the Sixth Circuit (and other federal circuits have noted), '' '[t]here are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice. Rather, the courts must engage in a case-by-case analysis of the evidence to determine whether a reasonable inference of guilt may be drawn from specific facts.' '' *United States* v. *August,* 984 F.2d 705, 713 (6th Cir. 1992) (citations omitted) (quoted in *United States* v. *Singh,* 54 F.3d 1182, 1187 (4th Cir. 1995)).

Thus, in *Moore,* the Supreme Court held the evidence in a criminal trial was sufficient to find that a physician's ''conduct exceeded the bounds of 'professional practice,' '' where the physician ''gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' ''took no precautions against . . . misuse and diversion,'' ''did not regulate the dosage at all'' and ''graduated his fee according to the number of tablets desired.'' 423 U.S. at 142–43.

However, as the Sixth Circuit has explained, ''[o]ne or more of the foregoing factors, or a combination of them, but usually not all of them, may be found in reported decisions of prosecutions of physicians for issuing prescriptions for controlled substances exceeding the usual course of professional practice.'' *United States* v. *Kirk,* 584 F.2d 773, 785 (6th Cir. 1978). *See also United States* v. *Hooker,* 541 F.2d 300, 305 (1st Cir. 1976) (affirming conviction under section 841 where physician ''carried out little more than cursory physical examinations, if any, frequently neglected to inquire as to past medical history and made little to no exploration of the type of problem a patient allegedly'' had, and that ''[i]n light of the conversations with the agents, the jury could reasonably infer that the minimal 'professional' procedures followed were designed only to give an appearance of propriety to [the] unlawful distributions''); *United States* v. *Tran Trong Cuong,* 18 F.3d 1132, 1139 (4th Cir. 1994) (holding evidence sufficient to find physician prescribed outside of professional practice, in that ''in most cases the patients complained of such nebulous things as headaches, neckaches, backaches and nervousness, conditions that normally do not require . . . controlled substances,'' physician was ''aware that some of the[] patients were obtaining the same drugs from other doctors,'' ''[m]ost of the patients were given very superficial physical examinations,'' and patients were not ''referred to specialists''); *United States* v. *Bek,* 493 F.3d 790, 799 (7th Cir. 2007) (upholding convictions; noting that the evidence included ''uniform, superficial, and careless examinations,'' ''exceedingly poor record-keeping,'' ''a disregard of blatant signs of drug abuse,'' ''prescrib[ing] multiple medications having the same effects . . . and drugs that are dangerous when taken in combination''); *United States* v. *Feingold,* 454 F.3d 1001, 1010 (9th Cir. 2006) (''[T]he *Moore* Court based its decision not merely on the fact that the doctor had committed malpractice, or even intentional malpractice, but rather on the fact that his actions completely betrayed any semblance of legitimate medical treatment.''); *United States* v. *Joseph,* 709 F.3d 1082, 1104 (11th Cir. 2013) (upholding conviction of physician where ''record establishe[d] that [physician] prescribed an inordinate amount of certain controlled substances, that he did so after conducting no physical examinations or only a cursory physical examination, that [physician] knew or should have known that his patients were misusing their prescriptions, and that many of the combinations of prescriptions drugs were not medically necessary'').[14]

respect to Factor One—the Recommendation of the State Board—the Board made no recommendation to the Agency in this matter. More importantly, as discussed above, the Board has suspended his medical license thus rendering him ineligible to maintain his registration.

With respect to Factor Three, I acknowledge that there is no evidence that Respondent has been convicted of an offense under either Federal or Michigan law ''relating to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d at 822. The Agency has therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

The Government makes no argument that Factor Five is implicated in this matter.

[14] However, as the Agency has held in multiple cases, ''the Agency's authority to deny an application [and] to revoke an existing registration . . . is not limited to those instances in which a practitioner intentionally diverts a controlled substance.'' *Bienvenido Tan,* 76 FR 17673, 17689

Continued

The evidence shows that Registrant unlawfully distributed controlled substances by issuing prescriptions to the UC on multiple occasions outside the usual course of professional practice and for other than a legitimate medical purpose, in violation of 21 U.S.C. 841(a)(1) and 21 CFR 1306.04(a). *See also* Mich. Comp. Laws § 333.7401(1) (''A practitioner . . . shall not . . . prescribe . . . a controlled substance for other than legitimate and professionally recognized therapeutic or scientific purposes or outside the scope of practice of the practitioner.''); *id.* § 333.7405(1)(a) (a licensed practitioner shall not ''distribute, prescribe, or dispense a controlled substance in violation of section 7333'').

The Michigan Guidelines set forth the applicable standards of professional practice for the prescribing of controlled substances in the State. GX 28. The Guidelines provide that:

> when evaluating the use of controlled substances for pain control . . . [a] complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse.

GX 28. The Guidelines also state that the physician is to keep ''accurate and complete records'' of the forgoing and other aspects of medical care. *Id.*

The Government's evidence shows that Registrant dispensed controlled substances to the UC on multiple occasions, notwithstanding his failure to conduct an adequate evaluation, including any physical examination to support a finding that the prescribing of both hydrocodone and the Xanax was medical necessary to treat the UC. GX 3–4, 6–7, 9–10. Dr. Chambers explained that Registrant failed to do a proper evaluation of the UC's substance use even though he admitted to significant alcohol use, did not properly evaluate his psychiatric symptoms even though he said he was using Xanax and the PMP report showed that he had obtained this drug from multiple providers, failed to perform a physical examination of the [UC] at any point, and failed to perform adequate treatment planning. Dr. Chambers further explained that Registrant falsified the medical record by fraudulently documenting in it that the UC denied drinking, as well as by making physical exam findings such as ''[l]imited motion, spasm, tenderness, weakness, atrophy, abnormal reflexes,'' when he did not perform the tests necessary to make these findings. GX 33, Attachment B, at 22.

Moreover, on the pain questionnaire, the UC did not circle any of the descriptors, did not rate his pain, nor indicate whether his pain interfered with various life activities listed on the form. Yet Registrant made no inquiry as to why the UC left most of the form blank.

Most significantly, during his visit with Registrant, the UC never complained of anything more than back stiffness, made no complaint that he suffered from anxiety and stated that he took Xanax because it kept him from drinking too much on the weekends. Here again, Registrant falsified the medical record by documenting: ''Today [the UC] is complaining mostly of [ ] some level of anxiety.'' Dr. Chambers further concluded that there was no basis for the various diagnoses which Registrant documented in the UC's record, including anxiety and muscle spasms; he also noted that Registrant made no diagnosis of pain and that opioids are not indicated for muscle spasms.

The UC's second visit with Registrant lasted all of three and a half minutes. As Dr. Chambers explained, the most substantial questions Registrant asked the UC for evaluating his need for the (hydrocodone and alprazolam, were: ''Doing OK?'' and ''Med went well?'' Moreover, Registrant did not perform a physical exam during the visit and yet, he again falsified the medical record by noting various exam findings.

As for the third visit, Dr. Chambers noted that Registrant did not address the UC's statements regarding his drinking and statements that he had run out of medication and obtained controlled substances from his neighbor. Dr. Chambers further opined that there was essentially no clinical evaluation of the UC's symptoms, illness course or treatment response. Registrant again falsified the visit note by indicating that the UC ''appears to be in mild pain'' and ''states he is very anxious,'' as well as by making physical exam findings of ''limited motion, spasm, tenderness,'' ''abnormal reflexes'' and ''weakness/atrophy,'' when he did not perform the tests necessary to make these findings.

I thus conclude that Registrant acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he issued the prescriptions for hydrocodone and alprazolam at each of the UC's visits. 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1); *see also* Mich. Comp. Laws § 333.7401(1). With respect to the UC, I conclude, based on Dr. Chambers' testimony, that Registrant failed to comply with the Michigan Guidelines in that he failed to take a complete medical history, conduct a physical examination, and document in the medical record ''the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse.'' *Michigan Guidelines,* Section II.1. Based on Dr. Chambers' testimony, I also conclude that Registrant ''essentially'' failed to comply with each of the standards of the Michigan Guidelines, including developing a treatment plan which sets forth objectives for determining treatment success and considering other treatment modalities, obtaining informed consent, conducting periodic reviews, and maintaining accurate and complete records. GX 33, Attachment B, at 5–6. (Expert Declaration), at 6. I further conclude that Registrant violated Michigan Law and the CSA in that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to the UC. 21 CFR 1306.04(a); *see also* Mich. Comp. Laws §§ 333.7401(1).

I also find that Registrant failed to comply with the Michigan Guidelines, and violated both Michigan Law and the CSA in that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to patients D.S., A.L. and R.H. 21 CFR 1306.04(a); *see also* Mich. Comp. Laws § 333.7401(1). As discussed above, Dr. Chambers found that there was evidence that all three patients were suffering from drug addiction which Registrant did not adequately diagnose or treat, and that Registrant's prescribing practices contributed to their addiction. With respect to each of the chart review patients, Dr. Chambers also found that Registrant ''was prescribing extremely dangerous combinations of controlled substances without documenting an appropriate medical context or justification for so

(2011) (citing *Paul J. Caragine, Jr.,* 63 FR 51592, 51601 (1998)); *see also Dewey C. MacKay,* 75 FR at 49974. As *Caragine* explained: ''[j]ust because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify'' the revocation of an existing registration or the denial of an application for a registration. 63 FR at 51601.

''Accordingly, under the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion.'' *MacKay,* 75 FR at 49974; *see also Patrick K. Chau,* 77 FR 36003, 36007 (2012).

doing, and [that he] failed to adequately document ongoing examinations and treatment planning . . . and/or he failed to perform these professional functions altogether.'' GX 33, at 6 (D.S.), 8 (A.L.), 11 (R.H.).

With respect to D.S., Dr. Chambers found that over the two-year period between January 2014 and February 2016, there was no evidence in the patient file that Registrant performed physical exams other than to take vital signs and that his treatment plan was essentially non-existent. He also found that D.S.'s chart contained multiples notations that she was suffering from addiction but no evidence that Registrant addressed this with her. Most significantly, as Dr. Chambers observed, D.S. provided multiple aberrational drug tests which included: (1) The presence of controlled substances which he did not prescribe on six occasions, including methadone, buprenorphine, cocaine, and amphetamines; (2) the non-presence of controlled substances (oxycodone and morphine) which he had prescribed on two occasions; and (3) the presence of oxycodone above the recommended therapeutic range on four occasions. Yet there is no evidence that Registrant addressed any of these aberrational test results with D.S.

As for A.L., Dr. Chambers found that ''for the most part,'' Registrant did not document the performance of a physical exam and there is no documentation in the patient file to support Registrant's prescribing of the combinations of narcotics, benzodiazepines, and carisoprodol that he did. GX 33, at 7. Moreover, A.L.'s MAPS report showed that she had seen eight other providers in the year prior to her first visit with Registrant and that she had obtained controlled substances on 50 occasions [15] which included hydrocodone, oxymorphone, oxycodone, morphine, diazepam, alprazolam and amphetamine based on prescriptions issued by these providers. Moreover, at her first visit with Registrant, A.L. reported that she was taking the Trinity of oxycodone, Xanax, and Soma, and while at one point, Registrant even documented that A.L. stated that she was buying drugs off the street, Registrant did not address this aberrant behavior. Moreover, as Dr. Chambers observed, her chart is devoid of evidence that she was monitored through the use of urine drug screens. *See* GXs 18–20.

With respect to R.H., Dr. Chambers found that ''[f]or the most part there are no physical exams documented in the medical records'' and ''[t]here is no documentation in R.H.'s medical records demonstrating a legitimate medical justification . . . for [Registrant's] prescribing'' the ''dangerous combination[s]'' of narcotics, benzodiazepines, and carisoprodol to R.H. GX 33, at 10. Dr. Chambers also found that R.H.'s urine drug screens showed the presence of controlled substances including amphetamines and benzodiazepines that Registrant did not prescribe to him and that Registrant had also documented that R.H. was overmedicating with respect to Valium. However, R.H.'s medical record contains no indication that Registrant resolved these red flags.

Accordingly, I agree with Dr. Chambers that Registrant lacked a legitimate medical purpose and acted outside of the usual course of professional practice when he issued the various controlled substance prescriptions identified above to D.S., A.L., and R.H. 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1). I also agree with Dr. Chambers that Registrant's prescribing to D.S., A.L. and R.H. violated Mich. Comp. Laws § 333.7401(1) and did not comply with the Michigan Guidelines.

I thus conclude that Registrant's multiple violations of 21 CFR 1306.04 (a), 21 U.S.C. 841(a)(1), and Mich. Comp. Laws § 333.7401(1) are egregious and support the conclusion that he ''has committed such acts as would render his registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).[16] I therefore conclude that the Government's evidence with respect to Factors Two and Four makes out a *prima facie* case for revoking his existing registration and denying any applications for a new registration. As Registrant has waived his right to a hearing or to submit a written statement of position, there is no evidence to refute the conclusion that his registration is inconsistent with the public interest. I will therefore order that Registrant's remaining registration be revoked and that any pending application be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No. FS6457407 issued to Bernard Wilberforce Shelton, M.D., be, and it hereby is, revoked. I further order that any pending application of Bernard Wilberforce Shelton to renew or modify the above registration, as well as any other pending application for registration be, and it hereby is, denied. This Order is effective immediately.[17]

Dated: March 24, 2018.

Robert W. Patterson,

Acting Administrator.

[FR Doc. 2018–06617 Filed 3–30–18; 8:45 am]

BILLING CODE 4410–09–P

[15] In some instances, she obtained the controlled substances through a refill of a previously issued prescription. *See, e.g.,* GX 18, at 32 (alprazolam refill); *id.* at 33–34 (refills of hydrocodone).

[16] This provides a separate and independent ground from the finding that he does not currently possess state authority for revoking his registration and denying his application.

[17] Based on the egregious nature of Respondent's prescribing violations, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Angela L. Lorenzo, P.A.: Decision and Order

On December 18, 2017, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Angela L. Lorenzo, P.A. (Registrant), of Las Vegas, Nevada. The Show Cause Order proposed the revocation of Registrant's Certificate of Registration No. ML0901985 on the ground that she lacks ''authority to handle controlled substances in the State of Nevada, the State in which [she is] registered with the DEA.'' Order to Show Cause, Government Exhibit (GX) A–3, at 1 (citing 21 U.S.C. 824(a)(3)).[1] For the same reason, the Order also proposed the denial of any of Registrant's ''pending applications for a new registration or for renewal.'' *Id.*

With respect to the Agency's jurisdiction, the Show Cause Order alleged that Registrant is registered as a practitioner in schedules II through V, pursuant to DEA Certificate of Registration No. ML0901985, at the address of 811 N Buffalo Road, Suite 113, Las Vegas, Nevada. *Id.* at 1–2. The Order also alleged that this registration

[1] The Show Cause Order also proposed that Registrant's DEA registration should be revoked because she ''committed acts which render [her] registration inconsistent with the public interest.'' GX 3, at 1 (citing 21 U.S.C. 823(f), 824(a)(4)). However, the Government did not include evidence to support this allegation with its Request for Final Agency Action (RFFA). Instead, the Government requested ''leave to supplement its [R]equest to include the grounds for revocation under 21 U.S.C. 823(f), 824(a)(4)'' should Registrant ''regain her Nevada state license during the pendency of this Request for Final Agency Action.'' RFFA at 1 n.1. The Government has not filed a request to supplement its RFFA, apparently because Registrant has not regained her Nevada state medical license. Accordingly, I do not consider the Government's public interest allegation.

does not expire until March 31, 2018. *Id.*at 2.

As substantive grounds for the proceeding, the Show Cause Order alleged that on September 29, 2017, the Nevada State Board of Medical Examiners (hereinafter NSBME) ''issued an Order of Summary Suspension immediately and indefinitely suspending [her] license to practice medicine in the State of Nevada.'' *Id.* The Order alleged that, ''[a]s a result, [she is] currently without authority to practice medicine or handle controlled substances in the State of Nevada, the [S]tate in which [she is] registered with the DEA.'' *Id.* Based on her ''lack of authority to handle controlled substances in the State of Nevada,'' the Order asserted that ''DEA must revoke'' her registration. *Id.* (citing 21 U.S.C. 823(f), 824(a)(3)).

The Show Cause Order notified Registrant of her right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence for failing to elect either option. *Id.* at 4 (citing 21 CFR 1301.43). The Show Cause Order also notified Registrant of her right to submit a corrective action plan. *Id.* at 4–5 (citing 21 U.S.C. 824(c)(2)(C)).

The Government states that on December 19, 2017, a Data Analyst in DEA's Office of Chief Counsel sent a copy of the Show Cause Order by first-class mail to (1) the post office box address provided by Registrant as the ''mail to'' address on her DEA registration, P.O. Box 36190, Las Vegas, Nevada, and (2) her registered address of 911 N Buffalo Road, Suite 113, Las Vegas, Nevada. Government's ''Request for Final Agency Action'' (RFFA), at 2 n.2, 3; GX B (Declaration of Data Analyst) at 1–2. The Government also states that only the mailing to the registered address was returned as undeliverable. *See id.* Also, on December 19, 2017, a Diversion Investigator (DI) ''emailed a copy of the [Show Cause Order] to'' the ''contact email'' address that Registrant had provided to the Agency on her DEA registration without receiving ''any error messages indicating that the email was not successfully sent'' or ''any notifications that the email was undeliverable.'' RFFA, at 3; GX A (Declaration of the Diversion Investigator), at 2.[2] Based on these facts, I find that the Government's attempts to serve Registrant with the Show Cause Order satisfied its obligation under the Due Process Clause ''to provide 'notice reasonably calculated, under all circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections.' '' *Emilio Luna, M.D.,* 77 FR 4829, 4829 (2012) (quoting *Jones* v. *Flowers,* 547 U.S. 220, 226 (2006) (quoting *Mullane* v. *Central Hanover Bank & Trust Co.,* 339 U.S. 306, 314 (1950))).

On February 1, 2018, the Government forwarded its Request for Final Agency Action and an evidentiary record to my Office. Therein, the Government represents that it has received neither a hearing request nor a written statement from Registrant regarding the Show Cause Order. RFFA, at 2. Based on the Government's representation and the record, I find that more than 30 days have passed since the Order to Show Cause was served on Registrant, and she has neither requested a hearing nor submitted a written statement in lieu of a hearing. *See* 21 CFR 1301.43(d). Accordingly, I find that Registrant has waived her right to a hearing or to submit a written statement and issue this Decision and Order based on relevant evidence submitted by the Government. I make the following findings.

Findings of Fact

Registrant is a physician's assistant who is registered as a practitioner in schedules II–V pursuant to Certificate of Registration No. ML0901985,[3] at the address of 911 N Buffalo Rd., Ste. 113, Las Vegas, Nevada.[4] Her registration does not expire until March 31, 2018. *See supra* footnote 3.

On September 28, 2017, the Investigative Committee (IC) of the NSBME issued an ''Order of Summary Suspension'' to Registrant that ''IMMEDIATELY SUSPENDS [her] license to practice medicine.'' GX A–1, at 1. Specifically, the IC suspended Registrant's license to practice medicine in the State of Nevada because ''the health, safety and welfare of the public is at imminent risk of harm by [Registrant's] continued performance of medical services without supervision, including the prescription of controlled substances, . . . her dishonest conduct, and . . . her continued refusal to comply with the lawful Orders of the [NSBME].'' *Id.* at 2.[5] In light of the passage of time since the effective date of the Order, I have queried the NSBME website regarding the status of Registrant's medical license, and I take official notice that Registrant's Nevada medical license remains suspended as of the date of this decision.[6]

Thus, I find that that the IC's Order suspending Registrant from practicing medical services, which it stated includes dispensing controlled substances, independently bars Registrant from dispensing controlled substances in Nevada. *Accord* Nev. Rev. Stat. §§ 630.160 (2015) (''Every person desiring to practice medicine must, before beginning to practice, procure from the [NSBME] a license authorizing the person to practice.''); 630.020 (defining ''[p]ractice of medicine'' to include prescribing). Based on the above, I find that Registrant does not currently have authority under the laws

[2] On December 19, 2017, Government counsel represents that he ''provided'' a copy of the Show Cause Order to the attorney representing Registrant in the underlying NSBME proceeding. RFFA, at 2 n.3. On January 4, 2018, that attorney emailed Government counsel ''to advise [him] that, as of today, I no longer represent Ms. Lorenzo . . . but she is advised of her obligation to respond to the Order to Show Cause.'' RFFA, at 2 n.3; GX C (copy of email from Registrant's former attorney to Government counsel).

[3] The RFFA did not attach a copy of Registrant's DEA Certificate of Registration. However, I take official notice that the Agency's registration records show that Registrant obtained a registration as a mid-level practitioner-physician assistant on December 19, 2002, in schedules II through V, and last renewed her registration on April 15, 2015. According to the Agency's records, she has not submitted an application for renewal of her registration.

Under the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Registrant is ''entitled on timely request to an opportunity to show to the contrary.'' 5 U.S.C. 556(e); see also 21 CFR 1316.59(e).

[4] The Show Cause Order states that the registered address is at 811 N Buffalo Road, Suite 113, Las Vegas, Nevada, even though the DEA registration shows a registrant address at 911 N Buffalo Road. In addition, the top of the Show Cause Order was addressed to Registrant at 911 N Buffalo Road, consistent with the registration. Accordingly, I find that Registrant's address is 911 N Buffalo Road, Suite 113, Las Vegas, Nevada, and I deem the Show Cause Order's reference to 811 N Buffalo Road a scrivener's error.

[5] In its Order, the IC found, *inter alia,* that on September 6, 2017, ''IC staff personally notified [Registrant] at her offices located at 911 N Buffalo Drive, Suite 113, Las Vegas, NV'' that she was prohibited under Nevada law ''from performing medical services until she obtained a supervising physician licensed and approved'' by the NSBME. *Id.* at 2. Although Registrant advised the IC on September 6, 2017 ''verbally and in writing that she would cease practicing,'' on September 11, 2017, she nevertheless wrote a prescription for Phentermine, a [s]chedule IV controlled substance.'' *Id.* The IC found that this conduct demonstrated that Registrant ''perform[ed] medical services, including the prescription of controlled substances,'' (1) in violation of Nevada law's requirement of physician supervision and (2) in ''direct contradiction to her prior written statement . . . on September 6, 2017.'' *Id.*

[6] I take official notice under the authority set forth *supra* in footnote 3.

of Nevada to dispense controlled substances.[7]

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of Title 21, ''upon a finding that the registrant . . . has had his State license . . . suspended [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, DEA has long held that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a registration. *See, e.g., James L. Hooper,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *see also Frederick Marsh Blanton,* 43 FR 27616 (1978) (''State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.'').

This rule derives from the text of two provisions of the CSA. First, Congress defined ''the term 'practitioner' [to] mean[] a . . . physician . . . or other person licensed, registered or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which [s]he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the Act, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever she is no longer authorized to dispense controlled substances under the laws of the State in which she engages in professional practice. *See, e.g., Calvin Ramsey,* 76 FR 20034, 20036 (2011); *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci,* 58 FR 51104, 51105 (1993); *Bobby Watts,* 53 FR 11919, 11920 (1988); *Blanton,* 43 FR 27616 (1978).

Thus, ''the controlling question'' in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a practitioner's registration ''is currently authorized to handle controlled substances in the [S]tate,'' *Hooper,* 76 FR at 71371 (quoting *Anne Lazar Thorn,* 62 FR 12847, 12848 (1997)). Here, Registrant is no longer currently authorized to dispense controlled substances in Nevada, the State in which she is registered with the Agency. I will therefore revoke her DEA registration, deny any pending application to modify her registration, or any pending application for any other registration in Nevada.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No. ML0901985, issued to Angela L. Lorenzo, P.A., be, and it hereby is, revoked. I further order that any pending application of Angela L. Lorenzo to renew or modify the above registration, or any pending application of Angela L. Lorenzo for any other registration in the State of Nevada, be, and it hereby is, denied. This Order is effective immediately.[8]

Dated: March 24, 2018.

Robert W. Patterson,

Acting Administrator.

[FR Doc. 2018–06618 Filed 3–30–18; 8:45 am]

BILLING CODE 4410–09–P

[7] Registrant's DEA registration information states that Registrant had a Nevada Controlled Substance License No. CS12166, but that it expired on October 31, 2016. I have queried the NSBME website regarding the status of Registrant's controlled substance license, and I take official notice (*see supra* footnote 3) that Nevada's online list of holders of active controlled substance licenses does not include Registrant by name or by her Nevada controlled substance registration number.

[8] For the same reasons that led the NSBME to suspend Registrant's license, I find that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Mine Safety and Health Administration Grant Performance Reports Office of the Secretary

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Mine Safety and Health Administration sponsored information collection request (ICR) proposal titled, ''Mine Safety and Health Administration Grant Performance Reports,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995. Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before May 2, 2018.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* website at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201711-1219-001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–MSHA Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW, Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks PRA authority for the Performance Reports for Mine Safety and Health Administration Grants information collection. Mine Safety and Health Administration grantees are required by DOL regulations to submit project and final reports.

A grantee submits a technical project report to the MSHA no later than 30 days after quarterly deadlines. A technical project report provides both quantitative and qualitative information and a narrative assessment of performance for the preceding three-month period. This includes the current grant progress against the overall grant goals. Between reporting dates, the grantee informs MSHA of significant developments or problems affecting the organization's ability to accomplish the work.

A grantee provides (1) a final report that summarizes the technical project reports, (2) an evaluation report, and (3) a closeout financial report at the end of the grant period project. These final reports are due no later than 90 days after the end of the 12-month performance period. Federal Mine Safety and Health Act of 1977 section 103(h) authorizes this information collection. *See* 30 U.S.C. 813(h).

This proposed information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. For additional information, see the related notice published in the **Federal Register** on June 12, 2017 (82 FR 26951).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB ICR Reference Number 201711–1219–001. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–MSHA.

Title of Collection: Mine Safety and Health Administration Grant Performance Reports.

OMB ICR Reference Number: 201711–1219–001.

Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 60.

Total Estimated Number of Responses: 300.

Total Estimated Annual Time Burden: 750 hours.

Total Estimated Annual Other Costs Burden: $53.

Dated: March 27, 2018.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2018–06549 Filed 3–30–18; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Division of Coal Mine Workers' Compensation; Proposed Collection; Comment Request: Request To Be Selected as Payee (CM–910)

ACTION: Notice.

AGENCY: Division of Coal Mine Workers' Compensation, Office of Workers' Compensation Programs, DOL.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, the Office of Workers' Compensation Programs is soliciting comments concerning the proposed collection: Request to be Selected as Payee (CM–910). A copy of the proposed information collection request can be obtained by contacting the office listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before April 2, 2018.

ADDRESSES: You may submit comments by mail, delivery service or by hand to Ms. Yoon Ferguson, U.S. Department of Labor, 200 Constitution Ave. NW, Room S–3323, Washington, DC 20210; by fax to (202) 354–9647; or by Email to *ferguson.yoon@dol.gov.* Please use only one method of transmission for comments (mail/delivery, fax, or Email). Please note that comments submitted after the comment period will not be considered.

SUPPLEMENTARY INFORMATION:

I. Background: The Black Lung Benefits Act (BLBA), 30 U.S.C. 901 *et seq.,* provides for the payment of benefits to coal miners who are totally disabled due to pneumoconiosis and to certain survivors of the miner. If a beneficiary is incapable of handling his or her affairs, the person or institution responsible for their care is required to apply to receive the benefit payments on the beneficiary's behalf. The CM–910 is the form completed by representative payee applicants. The payee applicant completes the form and either mails it or files it electronically through a web portal for evaluation by the district office that has jurisdiction over the beneficiary's claim file. Regulations 20 CFR 725.505–513 require the collection of this information. This information collection is currently approved for use through June 30, 2018.

II. Review Focus: The Department of Labor is particularly interested in comments which:

* Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

* evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

* enhance the quality, utility and clarity of the information to be collected; and

* minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions: The Department of Labor seeks approval for the extension of this currently-approved information collection in order to carry out its responsibility to evaluate an applicant's ability to be a representative payee. If the Program were not able to screen representative payee applicants, the beneficiaries' best interests would not be served.

Agency: Office of Workers' Compensation Programs.

Type of Review: Extension.
Title: Request to be Selected as Payee.
OMB Number: 1240–0010.
Agency Number: CM–910.
Affected Public: Individuals or households; Business or other for profit; Not-for-profit institutions.
Total Respondents: 250.
Total Annual Responses: 250.
Average Time per Response: 15 minutes.
Estimated Total Burden Hours: 63 hours.
Frequency: On occasion.
Total Burden Cost (capital/startup): $0.
Total Burden Cost (operating/maintenance): $132.50.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: March 13, 2018.

Yoon Ferguson,

Agency Clearance Officer, Office of Workers' Compensation Programs, U.S. Department of Labor.

[FR Doc. 2018–05624 Filed 3–30–18; 8:45 am]

BILLING CODE 4510–CK–P

LEGAL SERVICES CORPORATION

Notice of Revisions to Performance Area Four of LSC's Performance Criteria

AGENCY: Legal Services Corporation.

ACTION: Notice of revisions to guidelines.

SUMMARY: To provide grantees with the most effective guidance, in 2018 the Legal Services Corporation revised Performance Area Four to refine and expand the areas of inquiry to focus on those criteria for which LSC has found the most deficiencies, particularly Criteria 1 (Board Governance), 4 (Financial Administration), and 7 (General Resource Development). The 2018 revisions codify the work of LSC staff with numerous grantees and provide evidence-based guidance to recipients on how to run a high-performing nonprofit organization.

FOR FURTHER INFORMATION CONTACT: Lynn Jennings, Vice President for Grants Management, Legal Services Corporation, 3333 K Street NW, Washington, DC 20007, (202) 295–1645, *performancearea4@lsc.gov.*

SUPPLEMENTARY INFORMATION: LSC's Performance Criteria indicate that legal services programs should be led and managed effectively with high-quality governance, administrative systems, procedures, and policies. Good leadership and strong internal operations increase the likelihood of effective program services for clients.

Over the past several years, LSC has observed some areas of weakness in grantee governance through performance quality visits, compliance reviews, and Office of Inspector General (OIG) visits. The 2018 revisions codify the work of LSC staff with numerous grantees and provide evidence-based guidance to recipients on how to run a high-performing nonprofit organization.

Since 2010, LSC's Office of Program Performance has conducted 133 Program Quality Visits of 124 grantees. LSC issued 1,901 Tier One [1] recommendations across the reports summarizing those visits. Of the 1,901 Tier One recommendations, 695 recommendations—36.5%, the most of any performance area—pertained to Performance Area 4. From 2011 to 2016, LSC's Office of Compliance and Enforcement conducted 111 Compliance Reviews of 106 grantees. LSC issued more than 1,200 Required Corrective Actions (RCAs) related to both regulatory and fiscal issues. Approximately 25% of the RCAs identified deficiencies in the grantees' financial administration. Additionally, OIG conducted 41 A–50 reviews between June 2012 and September 2017. As a result of those reviews, the OIG made 160 referrals to OCE. The referrals covered issues related to timekeeping, deficiencies in policies and procedures, cost allocation, and internal controls.

This is the background against which LSC evaluated the existing criteria for Performance Area 4. The statistics above gave LSC valuable information about which areas of grantee administration, leadership, and governance needed more rigorous evaluation.

These Performance Criteria are guidelines for ensuring high program quality. They are not requirements. They reflect best practices to which programs should aspire and which they should, to the extent possible and consistent with program resources, attempt to achieve. These revisions do not reflect a change in the purposes of the Performance Criteria stated in the Introduction to the 2007 revised version. The purposes of the Performance Criteria are twofold. First, the Performance Criteria ''guide LSC's assessments of program performance generally and in the competitive grants process.'' Second, the Performance Criteria serve as a ''useful framework for internal program self-evaluations, planning, and program development, as well as external peer reviews and expert assessments by other funding sources.''

LSC will begin using the revised Performance Area 4 on June 1, 2018. LSC management recognizes that it may take time, guidance, and experience for all grantees to adjust to the revisions. LSC will, therefore, provide training and forums to discuss the implementation of the changes. When conducting program assessments, LSC staff will take the scope of the revisions and each program's capacity into consideration when making recommendations.

As the table below indicates, LSC reorganized the order of the Performance Criteria. The current Criterion 3—Overall Management and Administration—includes a limited review of a grantee's technology infrastructure and administration. To more accurately reflect the role technology plays in the daily operations of an organization and in providing efficient and effective client services, LSC proposed creating a separate, new technology criterion, Criterion 3: Technology Infrastructure and Administration. The criterion for Overall Administration and Management would now be Criterion 6, with Internal Communication being folded into the proposed Criterion 6.

[1] According to LSC's Office of Program Performance Procedure Manual:

- Tier One Recommendations are those recommendations that are determined to be significant and will be included in the next Request for Proposal to the grantee.
- Tier One Recommendations are those that *if addressed,* have the potential for significantly improving program quality and/or program performance within the short term, *i.e., two years.*

A Tier One Recommendation must:

- be stated in simple straightforward terms such that there is no doubt by the program that a response is required; and
- have an objective, the value of which equals or outweighs any additional burden that the recommendation imposes on the program (does not apply to statutory or regulatory requirements).

PERFORMANCE AREA 4: CRITERION ORDERING

Current ordering of Performance Area 4 Criteria	2018 Revised ordering of Performance Area 4 Criteria
Criterion 1: Board Governance	Criterion 1: Board Governance
Criterion 2: Leadership	Criterion 2: Leadership
Criterion 3: Overall Management and Administration	Criterion 3: Technology Infrastructure and Administration
Criterion 4: Financial Administration	Criterion 4: Financial Administration
Criterion 5: Human Resources Administration	Criterion 5: Human Resources Administration
Criterion 6: Internal Communication	Criterion 6: Overall Management and Administration
Criterion 7: General Resource Development and Maintenance	Criterion 7: General Resource Development and Maintenance

Criterion 1. Board Governance. The program articulates a clear mission for the organization. Each board member demonstrates commitment to the program and its mission through consistent engagement in Board activities that involve all other board members. The board effectively engages in strategic organizational planning with program leadership and staff. It is responsible for major policy decisions, while holding organizational management accountable for effective performance of their responsibilities. The board assists with or oversees, as appropriate, the organization's efforts to develop and maintain resources. The board also promotes public awareness of the program in the community in a manner that aims to enhance the program's overall effectiveness and influence.

Indicators	Areas of inquiry
Board Composition, Size and Tenure	
As a whole, the board is appropriately diverse and representative of the various geographical areas and low-income populations served by the program.	• Is the board membership diverse and representative of the service area? • Is the board either composed of an appropriate mix of members that are sufficiently expert in areas applicable to the program's operations and achievement of overall goals related to the mission—e.g. non-profit management, financial oversight, fundraising, community engagement—or has it taken steps to ensure that such expertise is available to the board on a consistent basis? • Does the board adhere to LSC regulations regarding board composition?
The size of the board is conducive to effective oversight	• Is there evidence that the board's size facilitates the effectiveness of its operation?
When determining board tenure, the board struck a balance between longevity and board experience and the need for new ideas and insights.	• What is the tenure of each of the board members, including the board chair(s)? • Does the organization impose term limits on board membership? • If so, what are the term limits? • Does the board have a policy or practice regarding length of service on the board and on its Executive Committee? • If the board imposes term limits, how does the organization avoid the loss of the experience and expertise of valued directors? • Is there a process for removing board members?
The board has processes and procedures for recruiting and orienting new board members.	• Does the board have and follow established policies and practices regarding recruitment, qualification and retention and engagement of new members? • Is there a job description for board members explaining their role and duties? • Is the job description provided to board members? • Is there an onboarding process for new members? • Are board members given appropriate orientation and continuing training, including: training on the role of the board, potential conflicts of interest, and on fiscal, fiduciary, and other responsibilities? • Is there training on the LSC Act, LSC regulations, LSC performance criteria, and other best practices?
Board Committees	
The board's committees structure promotes effective oversight of the organization.	• What is the board's committee structure? • What is the composition of each committee? • Does each committee have clearly defined responsibilities that are documented in written form? • If so, is there periodic review and updating of the documents? • Is there a committee responsible for assessing the performance of the board? • Is there an executive committee, and, if so, what is its composition? • How often does the executive committee meet? • What is the scope of business usually conducted? • Is there a separate Finance or Audit Committee? • Does a member of the audit or finance committee have a financial background? • If not, does the committee engage sufficient assistance from non-board sources to provide consistent and competent guidance on financial matters? • Is there a separate fundraising committee?

Indicators	Areas of inquiry
Board Meetings and Deliberations	
The board fulfills the meeting requirements of LSC regulations.	• The board of directors meets at least four times a year. • There is public notice of meeting and meetings are public.
The board has quorum requirements that are adhered to	• Is the board required to reach a membership attendance quorum before it can take formal action? • What is the percentage or number requirement for a quorum? • How many times within the past two years has the board tried to meet but has not had a quorum? • If there is no quorum, what percentage of the board attended each meeting? • Does the organization permit its board to act through virtual meetings such as email voting, in addition to remote participation by teleconferences or video-conference? • Are there guidelines or a protocol for virtual meetings?
The board and committee meetings are well planned and focused to ensure that the board and its committees can carry out their oversight function.	• Are there pre-circulated agendas for all board and committee meetings? • If so, who sets the agenda? • Do the board chair or committee chair and the executive officer contribute to the agenda?
Meeting materials	• Do individual members feel that the board packets distributed in the board and committee meetings provide them with useful information about the program and equip them to participate meaningfully in the board or committee meeting? • What is the quality of the materials? • How far in advance is board information circulated? • Do board materials contain updated financial information?
Executive session	• Do board meetings include an executive session without any staff (including the executive director)?
The board members are engaged and regularly attend and participate in board and committee meetings.	• What is the level of attendance at board and committee meetings? • Do individual members prepare for and participate in meetings? • Are client board members actively engaged in board meetings and decisions?
Board and committee decisions are appropriately documented.	• Are board decisions appropriately documented in board minutes? • Minutes of full board and committee meetings are prepared, reviewed and approved by the board at least by the next scheduled meeting. • Who prepares the meeting minutes? • Apart from minutes of board meetings, does the board maintain a separately indexed chronological record of resolutions that reference their initial date of adoption and subsequent actions?
Board Transparency and Accountability	
The board and members individually, are committed to the program and its mission. The board properly discloses and manages any organizational or personal conflicts.	• Is the board supportive of the program? • Does the board have a policy or practice that effectively deals with conflicts of interest or potential conflicts of interest? • Is the policy or practice in writing? • Are organizational or individual conflicts addressed quickly and effectively?
Board Engagement with Strategic Planning	
The board ensures that the program establishes and adheres to effective strategic planning.	• Does the board adopt a mission statement, that has been collaboratively developed with management? • Does the board establish a vision for the future? • Does the board approve strategic goals? • Does the board articulate core values/principles? • What is the board's role in developing the strategic plan? • Does the board work in close partnership with the management to ensure a successful planning process? • Does the board regularly review progress in accomplishing the goals of the strategic plan and take appropriate action to ensure implementation? • Does it periodically discuss progress toward strategic goals with program management?
Board Oversight of the Organization—Programmatic	
The board is involved in major policy decisions, aware of issues in and performance of the program, while leaving day-to-day management of program operations to program management personnel.	• How are major policy decisions made? • Do board members understand and adhere to clear distinctions between board governance and program management? • Do board members understand the major issues at stake for the program? • How does the board exercise its oversight of program operations? • Does the board receive regular reports providing objective data on program performance? • Monitoring: Does the board receive periodic information on the work of the program? • Evaluating: Does the board seek information to evaluate the effectiveness of the program's services?

Indicators	Areas of inquiry
Board Oversight of the Organization—Financial	
The board exercises effective financial oversight	• Are board members aware of and accurate in their perception have a general understanding of the requirements of the program's funding sources. • What systems and procedures does the board have to ensure effective financial oversight?
Ensure funds are used for intended charitable purposes, and funds are appropriately accounted for.	• How often does the board review financial statements and do they understand what the financial statements say? • Do they have experience in or guidance from board members or other advisors in interpreting the financial statements? • Is there a finance and/or audit committee to select the independent auditor? • Is the Form 990 presented to the board and management team prior to or after it is filed with the IRS? • Are there opportunities for the CFO/Controller or highest ranking financial officer to confer with the board, or members of the board? • Has the board established budget guidelines?
The board safeguards investments	• Are policies in place to evaluate the organization's investment decisions and performance? • Are policies in place to safeguard the organization's assets and tax-exempt status?
Evaluation of the Executive Director	
The board effectively evaluates the chief executive officer or executive director.	• What is the process for evaluating the Executive Director and other top officers in the organization? • Do they employ a 360 evaluation? • Who is involved in the evaluation process? • How frequently does the board evaluate the chief executive officer or executive director? • What, if any, are the criteria used for evaluating the Executive Director?
The boards practices appropriate oversight over the Executive Director's Compensation plan.	• Is there a process for reviewing and setting executive compensation? • If so, what is the process? • Who is involved in this process? • Are all board members aware of the Executive Director's entire compensation package? • Is the Executive Director's compensation based on market data? • Is there contemporaneous substantiation of the board's deliberation and decision on the Executive Director's compensation?
Board's Role as Ambassador for the Organization	
The board effectively promotes and expands the reach and influence of the program in the communities it serves.	• Do individual members, including client members, speak on behalf of the organization to external audiences at appropriate opportunities? • Is there a protocol for who speaks on behalf of the board and the organization? • Does everyone know the "elevator speech?" • Do individual members represent the community to the organization by bringing back concerns, ideas, suggestions and compliments when they have merit or possibility?
Board's Role in Resource Development	
The board effectively promotes and expands the reach and influence of the program in the communities it serves, and develops additional resources for the program.	• Do board members assist effectively in fundraising and development activity? • Does the board consult and communicate with the Executive Director to identify and, where appropriate, pursue all types of needed resources? • Determines how board members will participate in fundraising from sources where they have knowledge or influence, such as the private bar? • Does the board receive regular reports on staff fundraising activity?
The board ensures that the program is in compliance with state and local laws related to solicitation.	• Has the organization adopted policies to ensure compliance with federal/state laws on solicitation of funds? • Are solicitation materials accurate?
The board ensures donations comply with LSC Requirements	• Donations are properly recorded pursuant to LSC regulations
Continuous Learning and Assessment	
The board is committed to continuous improvement	• Does the organization maintain and provide its board members with an up-to-date board handbook or on-line resources? • Do members keep up with issues that affect the functioning and future of the organization? • Does the board engage in periodic formal or informal self-assessment processes?

Indicators	Areas of inquiry
General Good Governance Practices	
The board ensures legal and ethical integrity and maintains accountability.	• Does the board adopt and regularly evaluate a code of ethics that describes behaviors it wants to encourage and behavior it wants to discourage? • Did the board adopt a policy for handling employee and client complaints? • Are there established procedures for employees to report financial impropriety or misuse of the organization's resources? • Does the organization have a whistleblower policy? • Does the board periodically review the bylaws to ensure that the organization is in compliance with its governing documents and relevant laws? • Does the board have policies establishing standards for document retention and destruction? • Does the organization keep books and records relevant to its tax-exempt status and IRS filings for appropriate time periods?
The board ensures transparency and accountability by making information available to the public on the program's mission, activities, finance and governance.	• Are the program's Form 990 and annual report reported on its public website? Are these documents available to the public upon request?
The members of the board exercise independent judgment in general board decision-making.	Is there evidence that board members engage in independent analysis of materials and information provided to them?

Criterion 2. Leadership. The program has effective leadership that establishes and maintains a shared sense of vision and mission. Program leadership means a commitment to and achievement of the program's goals and objectives according to a model that emphasizes teamwork, transparency, excellence, effectiveness, efficiency, and innovation.

Indicators	Areas of inquiry
General Leadership	
Key program staff, starting with the executive director or chief executive officer, are respected and recognized as the program leaders.	• Starting with the chief executive officer, are there recognized, positive, and effective leaders in the program? • Do board members, community leaders, clients and the legal community express confidence in the program's leadership?
Program leaders hold themselves accountable for motivating staff, and for promoting an environment that embraces mentoring and the professional development of all staff, helping them to achieve their fullest potential.	• What specific leadership and professional development training and activities has the program provided? • What are the outcomes of these efforts? • What opportunities are afforded staff to develop and exercise leadership skills? • Do staff see themselves as valued members of the program's team? • Do program leaders model and encourage teamwork? • Do program leaders delegate effectively?
Key staff are appropriately involved in decision-making processes.	• Does the program's leadership seek the opinions and input of staff and other stakeholders in its decision-making processes?
The program's leadership demonstrates strong, effective communication skills and the capacity to engage in positive conflict resolution.	• Beginning with the executive director or chief executive officer, is there evidence that the leadership of the program communicates effectively with the board, staff and community stakeholders? • Do program leaders effectively address challenges and issues that impede the program's progress in accomplishing its mission? • Starting with the executive director or chief executive officer, is there evidence that program leadership effectively models, motivates and inspires creativity, innovation, excellence, and achievement?
Mission and Vision	
Program leaders frame a vision and mission	• Is there a shared sense of vision and mission? • Is it expressed in written form? • Are staff aware of it?
Program leaders model a high level of energy, commitment and integrity in carrying out the program's mission.	• What mechanisms does the program's leadership use to measure program effectiveness and adherence to the mission and vision? • In what ways does the program's stated mission and vision guide the program's planning and decision-making?
Diversity	
Starting with the executive director or chief executive officer, the program values and embraces diversity and provides opportunities for the development of a diverse group of leaders.	• In what ways does the program and its leadership demonstrate inclusion and an appreciation for diversity? • Is the program's leadership and management diverse, and, is there evidence that diversity and inclusion are valued by the program?

Indicators	Areas of inquiry
Succession Plan	
The program has a leadership succession plan that addresses preserving institutional knowledge and strong leadership across all levels of program management.	• Does the program have a clear and reasonable succession plan? • Is it written?

Criterion 3. *Technology infrastructure and administration.* The program provides a stable and secure technology infrastructure sufficient for staff to work efficiently and effectively in the delivery of legal services and to support the operations of the organization. It devotes appropriate resources to provide the capacities outlined in LSC's ''Technologies That Should Be in Place in a Legal Aid Office Today.''

Indicators	Areas of inquiry
Technology planning is ongoing and integrated into the overall strategic plan of the program, includes staff input, and is reviewed and updated at least annually.	• Who is involved in technology planning? • Does the program get input from staff on technology needs? • Has the program ever had an outside technology audit? • How often is the technology plan reviewed and updated? • Does the plan include deadlines for implementation?
The program has competent IT staff and/or consultants with appropriate training and certifications to properly maintain and support its technology systems.	• What type of network does the program have? • Are there appropriate firewalls? • Are servers hosted on-site, off-site, cloud-based? • If on-site, where are they and how are they secured (locked office, server room, appropriate A/C)? • What is the program's IT security program, its policies, user security training and are the servers, computers and devices patched and kept up to on a regular schedule? Is the network scanned for IT vulnerabilities regularly?
The grantee informs employees of their rights when using grantee-owned computers.	• Does the grantee have a warning banner that appears while employees are logging on and notifies employees of their rights when using their grantee-owned computer?
The program devotes appropriate resources to establish and maintain its technological infrastructure, including planning and budgeting appropriately for ongoing replacement/upgrades of its technology systems.	• What is the internet bandwidth in each office (any redundant connection available)? • Do offices have Wi-Fi available (is it password protected)?
The program has a proper written IT security program to include robust IT security policies and procedures regarding protecting client and case data, ensuring the security and integrity of passwords, use of the Internet and social media, policies for the use of mobile devices, and if staff can bring their own devices (BYOD) to access work documents. Staff are familiar with and follow such policies and procedures.	• Is server equipment kept in a secure environment with appropriate ventilation and cooling? Are IT systems currently patched and updated? • Is there a disaster recovery plan (that includes periodic testing) for mission critical technology systems? • Are there security policies and procedures for protecting client and case data, sensitive personal and personnel data, and all communications from loss or unauthorized intrusion? • Are there security policies and procedures for use of the Internet and social media, content security on all devices, and integrity of passwords, retention and deletion of data? • Are employees given notice concerning prohibited uses of their computer equipment including a warning banner that notifies employees of their rights (including no expectation of privacy) when using their grantee-owned computer? • Is there routine IT security training for staff? • Is the user's system access granted based on roles and responsibilities?
The program has sufficient procedures to back up its data and has testing protocols to demonstrate that data recovery/protection policies work in practice.	• What are the backup procedures? • Are test restores done periodically from the backups?
The program stays informed of new technology developments and how it can make better use of technology to meet its mission.	• What is the replacement cycle for technology equipment (desktops/laptops, servers, printers, scanners, copiers, telephones, etc.)? • What type of phone system does the program use? • How old is it? • When was the last upgrade? • What reports can it provide? • Who maintains it?
Extent to Which Technology Enhances Program Operations and Service Delivery	
Maximum use of technology is made to facilitate and enhance internal communication.	• Does the program use technology effectively to enhance the efficiency of program operations and service delivery? • How does the program use technology to facilitate and enhance communication? • Does the program's website effectively follow the Ernst and Young Best Practices (*http://webassessment.lsc.gov/report/*)?

Indicators	Areas of inquiry
Staff Training	
Program staff are provided with appropriate training on the use of technology.	• Does the program have a policy for the secure use of its technology, including protecting data (including Personally Identifiable Information), use of the Internet and social media, password policies and if/when staff can bring their own devices? • Do staff understand and follow the policy? • What software does the program use, including case management system manufacturer and version? • Are staff provided with ongoing training in its use?

Criterion 4. Financial administration. The program has and follows financial policies, procedures, and practices that comport with Generally Accepted Accounting Principles (GAAP), requirements of the program's funding sources, and comply with federal, state and local government regulations. The program has established sound internal controls and conducts effective budget planning and oversight.

Indicators	Areas of inquiry
Fiscal Policies and Staff	
The program has detailed written policies and procedures describing its financial operations which comply with all applicable requirements. The program follows such policies and procedures.	• Is the program's accounting manual current and updated as appropriate?
The program has sufficient, capable, trained and effective staff dedicated to financial administration.	• How many financial staff does the program have? • Does the program have competent financial personnel? • What is the training and background of the financial staff? • The job descriptions of personnel are clear and lay out the roles and responsibilities of each position. • Is periodic training given to program staff, management, and the governing body regarding LSC regulations and accounting guide, as applicable?
Top management and the governing body are actively involved in the budgeting process. The budget is updated periodically and changes/variances are reviewed. The program engages in financial planning beyond the current year.	• Is the budget consistent with the program's mission, goals, and objectives? • Does the program effectively adhere to its budget? • Is the budget updated monthly (or at least quarterly), based on changes in revenues or expenditures? • Does the program engage in financial planning beyond the current year?
The program maintains LSC funds held for immediate operating expenses in federally-insured bank accounts.	• Does the recipient adhere to LSC Investment Guidelines?
Board of Directors	
The recipient's governing body has fulfilled its fiduciary responsibility to the program through the establishment of a financial oversight committee or committees. The financial oversight committee(s) has at least one member who is a financial expert or the board has access to a financial expert.	• Has the board established a financial oversight committee or committees that perform the roles of a finance committee and an audit committee? • Does the financial oversight committee collectively possess the knowledge to set the strategic, financial course for the recipient and oversee management in execution of the strategy? • Does the financial oversight committee have the leadership of individual well-versed in non-profit GAAP, COSO Internal Control Framework, and other relevant standards and guidelines? • Does the financial oversight committee meet on a regular basis? • Does the committee have a charter or governing document and fulfill the responsibilities outlined therein? • Does the financial oversight committee set the strategic direction of the recipient for financial and audit related matters?
The governing body regularly determines the compensation of the program's Executive Director.	• Does a governing body set and review the compensation of the Executive Director using an independent compensation consultant, comparable pay studies from other nonprofit organizations, and/or a compensation survey?
The Executive Director's expenses are approved by a member of the board.	• Are there procedures in place that require approval of the Executive Director's expenses by a member of the governing body?
Audited Financial Statements	
The program issues accurate financial statements on a timely basis.	• Are the audited financial statements submitted to LSC in accordance with the LSC Audit Guide for Recipients and Auditors? • Has the program submitted their audited financial statements in a timely manner over the last 3 years?
Executed one-time grants, such as TIG and PBIF awards, are reported separately in the program's audited financial statements in accordance with 45 CFR 1628.3(e).	• Are executed one-time grants, such as TIG and PBIF awards, reported either as a supplemental schedule of related revenue and expense or a separate column within the financial statement?

Indicators	Areas of inquiry
Annual program audits do not reveal any significant problems or issues; where such items have been identified, the program addresses them effectively and promptly.	• Do past audits or outside reports and evaluations reflect problems? • Have any such problems been addressed? • Is there any evidence of failure to comply with applicable funder or governmental requirements? • What type of auditor's report did the IPA issue regarding the financial statements? Unmodified or modified? If modified, why? • What type of auditor's report did the IPA issue regarding Federal Awards? Unqualified or Qualified? If qualified, why? • Did the IPA issue findings in the audited financial statements? What were the findings? Have they been addressed? • Did the IPA issue a management letter? What did it contain? Has the recipient addressed the issues? • Are audit findings repeated from one fiscal year end to the next in the audited financial statements? • Does the recipient adequately address audit findings by performing the corrective actions outlined in the audited financial statements?
Internal Controls	
The recipient has established and maintains adequate accounting records and internal control procedures. which is designed to provide reasonable assurance of achieving the following objectives: (1) Safeguarding of assets against unauthorized use or disposition; (2) reliability of financial information and reporting; and (3) compliance with regulations and laws that have a direct and material effect on the program.	• There is sufficient segregation of duties. • Do the accounting policies and procedures require an appropriate level of supervisory review and adequate checks and balances to ensure the accuracy, completeness and timeliness of transaction processing? • The recipient has established and adheres to an adequate system of internal control following the principles of the COSO Integrated Internal Control Framework.
Contracting	
The program has a contracting policy to prevent abuse, limit waste of scarce funds, and prevent possible questioned cost proceeding.	• Does the program have a contracting policy? • Does the policy identify the contracting procedures for the various types of contracts, dollar thresholds, and competition requirements? • Is the process used for each contract action fully documented and is the documentation maintained in a central file? • Is the required approval level (including items that need to be approved by LSC) established for each contract type and dollar threshold, including when the board of directors should be notified and/or give approval? • Do policies include procedures for documenting and deviating from the approved contracting process, such as when sole-source contracts are executed? • Is each contract or agreement executed with a price, time-period, and services to be performed?
Fraud Prevention	
The program has robust policies and safeguards in place to prevent fraud.	• Assess the organization's segregation of duties. • Who has access to the program's bank accounts? • How are permissions and authorizations assigned? • Does the program have Whistleblower and Conflict of Interest Policies? • Is the program's IT infrastructure adequately secure? • Is the physical and logical access to the program's computer network adequately secure? • Does the program's governance and management of IT resources promote effective operations and provide a robust system of internal control? • Do the program's computer applications incorporate and facilitate a robust system of internal control? • Have thorough and well documented hiring practices and procedures? • Are staff periodically trained or reminded of the Whistleblower and Conflict of Interest Policies? • Does the program employ computer banners on all servers, computers and devices to inform employees of prohibited use activities and no right to privacy of grantee equipment?
Cash Disbursements	
The program's disbursements are approved in writing by an authorized individual.	• Are procedures adequate to provide that salary and wage rates are approved by an authorized individual and employees are paid in accordance with approved wage and salary plans? • Were invoices properly approved, with dates, before disbursement checks were processed? • Do policies and procedures for disbursements address unallowable expenses, purchase approvals, securing and approving new vendors, segregation of purchasing duties, and duplicate payment controls?

Indicators	Areas of inquiry
The program's criteria and procedures for purchases are documented.	• Is there a procedure for proper payment and approval of expenditures at an appropriate level of management?
Cash Receipts	
The program has established internal control procedures related to cash receipts.	• Is initial accountability for cash established as soon as a cash item is received? • Do the accounting records adequately identify all cash receipts as to source and purpose? • Is an effective chain of custody in place for cash receipts?
The program maintains a client trust fund and accounting system to account for funds held on the client's behalf.	• Has the program established a method to determine the balance for each client trust account? • Does the program have a process to ensure that dormant funds are escheated to the state in compliance with state requirements?
Asset and Property Records	
A physical inventory of property purchased with LSC funds is conducted at least once every two (2) years and the results are reconciled with property records.	• Is a physical inventory conducted at least once every two (2) years? • Are any differences between the physical inventory and the accounting records reconciled?
The program has established adequate internal controls to safeguard its petty cash funds.	• Is there a surprise count of petty cash conducted periodically? • Are the petty cash and client trust funds secured in locked location? • Are all petty cash disbursements supported by an original receipt or appropriate supporting documentation?
Subgrants	
The program has established adequate procedures related to the subgranting of LSC funds to ensure compliance and proper fiscal oversight.	• Does the subgrant agreement or contract with the sub recipient specify financial reporting responsibility? • Where a relationship with a sub recipient exists, do the notes to the financial statements of the recipient and subrecipient fully disclose the nature of that relationship?
Bonding of Recipients	
The program maintains fidelity bond coverage at a minimum level of at least ten (10) percent of the program's annualized LSC funding level for the previous fiscal year, or of the initial grant or contract.	• Does the program carry at least the minimum level of fidelity bond coverage for fraud and employee dishonesty as described in 45 CFR Part 1629?
The program carries adequate fidelity bond coverage for all staff required to be bonded.	• Does the program carry fidelity bond coverage for all staff required to be bonded: Every director, officer, employee and agent of a program who handles funds?
Accounting Software	
The program's accounting software is appropriate to support the operations and financial oversight of the organization.	• Does the program use up-to-date technology to enhance efficient financial operation? • Is the software appropriate to support the operations of the organization? • Does the accounting software incorporate adequate internal controls? • Is the recipient effectively using the software to ensure internal controls are in place?
The program limits access to its accounting software	• Does the program limit access to its accounting software? • Does each user have his/her own password security based on their fiscal functions and are accounting software passwords changed periodically? • Is a user's system access granted based on roles and responsibilities?

Criterion 5. Human resources administration. The program promotes organizational excellence through the recruitment, management, and retention of a high-performing, diverse workforce consistent with its mission and goals. The program develops and communicates sound policies and procedures that ensure compliance with applicable federal, state, and local laws and has a knowledgeable, accessible, and professional staff to the program in the areas of recruitment and retention, training, professional development, compensation and benefits, performance appraisal, and organizational governing personnel development.

Indicators	Areas of inquiry
Human Resources Staffing and Workplace Policies	
The program has sufficient, capable, trained, and effective professional staff assigned to human resources administration.	• Who is responsible for the human resources functions within the program? • If responsibilities are shared, how are duties defined? • What is the background, experience and training of staff responsible for handling human resources? • What is the interaction between the human resources and finance staff?
The program has an employment handbook or manual with policies on hiring, supervision, promotion, compensation, and termination that are in compliance with applicable federal, state, and local laws.	• Does the program have an employment handbook or manual with human resources policies? • Does the handbook or manual include Conflict of Interest and Whistleblower policies? • Does the handbook or manual include an ethics policy? • What is the program's plan to maintain HR's knowledge of best practices?
The program engages in human resources planning and policies are reviewed periodically.	• How often are the policies reviewed and updated?
The program maintains accurate and timely personnel files and protects the confidentiality of personnel records as required by applicable law and contract.	• Where are personnel files kept? • Are they paper or electronic? • Who is responsible for maintaining personnel files? • Are there procedures to control access to personnel files and protect the confidentiality of employees?
The program has a document retention policy for personnel files and that policy is adhered to by managers.	• Does the program have a document retention policy for personnel files? • How long are they kept? • Where are they stored after employees separate from the organization?
Program Staffing, Recruitment, and Retention	
The program has a capable, culturally competent, and diverse staff.	• What is the current composition of the staff? • Is the current composition of the program staff diverse in terms of experience, gender, race, and disability status? • Does management create and sustain an environment that values and supports a diverse workforce? • Has the program adopted a disability inclusion plan?
The program has a comprehensive recruitment strategy that employs a variety of methods and sources to recruit highly qualified candidates.	• What are the program's recruitment practices? • What recruitment methods and sources are used? (e.g., online employment sites, job boards, referrals, social media, search firms)? • Are the job descriptions up-to-date and do they accurately explain job functions and separate essential from nonessential functions? • Are there job descriptions for all positions?
The program has a formal orientation process for all new hires.	• Is there a new hire orientation and is the orientation period defined?
The program is able to forecast and determine its human resource needs and tracks fluctuations in the workforce, including turnover rates.	• What is the rate of turnover in the program? • Does the program evaluate internal and external factors related to turnover? • What is the average length of time an employee stays with the organization, by position type and category? • Does the program experience a high level of employee grievances? • Does the program have an effective plan to develop and retain new attorneys and paralegals (e.g. professional advancement along a defined career path)? • Are individual development plans created for each employee?
Compensation & Benefits Policies	
The program has a compensation and benefits structure that promotes staff recruitment, retention and professional development.	• What are the program's fringe benefits and retention policies, such as a loan repayment assistance program, retirement plans, health insurance, and other financial and non-financial benefits?
The program periodically assesses salaries, employee benefits, bonuses and COLAs.	• Does the program regularly review its compensation structure and benefits? • Does that review include assessing market-based compensation studies?
Staff Evaluation and Training	
The program conducts regular and effective evaluations of all staff.	• Does the program conduct performance evaluations or appraisals? • If yes, how often? • Does the program use a performance evaluation instrument? • Is this evaluation linked to the program's goals, vision, or strategic initiatives? • Do such evaluations include setting goals for staff? • Does the program foster an environment that emphasizes continuous learning, constructive feedback, improvement and excellence?
The program leverages its budget appropriately for training opportunities that would benefit its entire staff.	• What training is available to staff? • Do all staff members have access to training opportunities?

Indicators	Areas of inquiry
The program conducts ongoing training for all staff on program policies, procedures, technology, and in substantive legal areas and advocacy skills.	• Is there a formal, ongoing training for employees and managers (e.g., procedures, policies, technology, substantive legal areas)? • Who is responsible for planning and conducting training of existing employees? • Does the program ensure all staff receive regular training on the LSC Code of Conduct and LSC's Grant Terms and Compliance requirements? • Does the program have a policy highlighting the importance of alerting the Office of Inspector General (OIG) to potential indicators of fraud, waste, and abuse of program funds and the requirement to do so promptly for loss over $200? • Does the program have a policy for identifying compliance concerns? Does the program train staff on the policy and reporting compliance concerns?
The program provides effective training for management and administrative staff.	• Does the program provide effective leadership and management training and support to mid-level supervisors and personnel engaged in administration and management?
The program regularly conducts cultural competency training for all staff.	• Is there cultural competency training for all staff? • Have they attended?
Staff Morale and Workplace Climate	
To the extent that there are or have been serious morale or other internal personnel problems, the program is addressing or has addressed them effectively, and is taking or has taken appropriate steps to prevent their recurrence.	• What is the recent history and current status of staff morale? • Does LSC's employee survey indicate significant leadership challenges? • Does LSC's employee survey indicate friction among staff members?
The program has developed a process to address internal complaints, suggestions, and feedback.	• Does the program have a process accepting and resolving employee grievances?
Program offices are professional and provide adequate space for conducting the program's work.	• Are program offices professional? • Do they provide adequate space for conducting the program's work, provide appropriate privacy? • Does the program provide adequate maintenance services?

Criterion 6. Overall management and administration. The program is well managed and administered: Including management structure; processes and systems to ensure compliance with all funder requirements and state and federal law; capacity to address problems quickly and effectively, robust intra-staff and staff-management communications; effective administrative procedures; allocation of appropriate resources to management functions; and periodic evaluations of administrative operations.

Indicators	Areas of inquiry
Allocation of Resources	
The program devotes appropriate resources to management	• Does the program devote an appropriate level of resources to management and administration? • What is the span of control in each division (i.e. what is the management to direct reporting ratios within the organization)?
The program has a management structure that effectively uses middle managers.	• How many middle managers are there?
The mix of program staff (managers, case handlers, and administrative staff) maximizes program resources to ensure the effective and efficient delivery of client services.	• Has the program made considered choices regarding the proportionality of non-advocacy staff as compared to case handlers, consistent with program resources, number of case handlers, and type of work? • Has the program established a risk management program/group to review and mitigate management systems risks? Such risks could include: Performance management (failure to achieve performance goals including implementation of the Strategic Plan); human capital management (failure to attract, motivate, and retain high quality staff); information management (failure to collect and share vital operational data and inability to support stable and safe IT operations, including the case management system); acquisitions management (higher contract costs and possible fraud, waste, and abuse risks).
The program allocates appropriate resources to internal compliance.	• Does the program have a compliance officer (or someone who serves in that role) to ensure compliance concerns are reported and managed effectively and efficiently?
Decision Making Processes	
The program makes major decisions in a way that incorporates relevant information and input.	• What is the program's decision making process? • Is decision making authority clear when delegated? • Is decision making timely and effective? • Do staff members know whom to go to for decisions?

Indicators	Areas of inquiry
The program has procedures for obtaining input on significant decisions, and for resolving complaints and problems effectively and timely.	• Do staff feel that their input is sought on significant decisions? • Do staff feel that decisions are quickly and effectively communicated to all who are affected? • Does the program resolve employee complaints and problems effectively and timely?
The program's administrative structure, processes, and systems support compliance with state and federal laws, rules, and regulations.	• Is there any evidence of non-compliance with state and federal laws, rules, and regulations?
The program's administrative structure, processes, and systems support compliance with funder requirements.	• Is there any evidence of non-compliance with funder requirements?
Continuity of Operations	
The program has developed and regularly updates an emergency plan to maintain operations and to minimize disruption in the event of an emergency.	• Does the program have a plan in the event of an emergency or disaster? • If yes, does the plan include: —The preservation of files, equipment, and computer data bases; —A process for communication between staff and management; —For the relocation of the program's work sites? • Does the program attempt to coordinate with state/local emergency response and preparedness entities?
The program has a plan for providing client services in the event of a disaster or emergency affecting its client community.	• Does the program have a plan for providing client services in the event of a disaster or emergency affecting the client population?

Criterion 7. General resource development. Consistent with the program's mission, the program seeks to maintain and expand its base of funding with the goal of enhancing program services and organizational sustainability. The program implements a strategy designed to identify funding sources to advance the mission and goals of the program.

Indicators	Areas of inquiry
Staffing	
The program has attempted to develop, and to the extent possible, has effective relationships with other major institutional resources in the service area that are involved or might be able to provide some support in the provision of legal assistance to eligible clients, as well as help in expanding program funding.	• Who are the program's other major funders? • What percentage of non-LSC funding does the program receive? • How many of the funders have funded before or made multi-year commitments?
The program has sufficient, capable, trained, and effective staff dedicated to resource development, or uses consultant(s) or other organizations to supplement or lead that effort.	• Who is responsible for the resource development efforts within the program? • Is the number of staff assigned to resource development appropriate given the size of the program and level of funding? • What are the duties for the person(s) responsible for these efforts? • How are those responsible for resource development evaluated for this work?
The program has delineated responsibilities for resource development staff and communication (if applicable) staff.	• How are the resource development activities integrated with the program's external communication efforts? • Does the program employ a separate staff person to handle the program's communications?
The program has engaged the board and staff in resource development and has provided adequate training.	• Are staff and board actively engaged around resource development efforts? • Have staff and/or board members received training on resource development or fundraising? • If yes, who conducted the training? • Does the program have an advisory board that focuses on resource development, or does the board have a resource development committee focused on such activities? • Does the program's governing body involve non-members with expertise in resource development?
Resource Development Plan & Implementation	
The program has a written plan describing its strategy to ensure that the program is supported by sufficient financial resources consistent with its mission.	• Does the program have a written resource development plan, and is resource development a part of its overall strategic plan? • Does the plan identify possible funding sources and specific and realistic fundraising goals? • How often is this plan reviewed by management? By the board? • Does the program employ social media as a tool for increasing program revenue?
The program has a diverse funding stream and continually explores opportunities for increased funding.	• Has the program achieved diversity in funding: federal, state, local governments; individual donors; law firms; foundations; bar campaigns, restricted/unrestricted gifts? • What is the percentage of each funder type of the current budget?

Indicators	Areas of inquiry
The program is innovative in trying to develop new sources ..	• What tools does the program employ to engage new and existing donors? • How are new and existing donors cultivated? • How are donors acknowledged? • Has the program conducted a feasibility study to determine the benefits and risks associated with its funding efforts? • Does the program have an endowment? • If yes, what are the permissible uses of the endowment?
The program uses former and existing clients and former board members as a part of its funding efforts.	• Does the program engage former clients in its funding efforts? • Does the program engage former board members in fundraising and encourage them to contribute themselves?
The program sponsors events and activities to recognize its individual donors and supporters.	• Does the program host donor recognition and cultivation events? How often?
Monitoring and Evaluation	
The resource development plan has been approved by the board, is reviewed annually, and is consistent with the program's budget.	• Is the cycle of organizational budgeting in line with the resource development plan?
The program has a process to evaluate cost effectiveness of resource development activities.	• How does the program evaluate the cost effectiveness?
The program has carefully evaluated whether the requirements of prospective funding sources are consistent with the program's mission, goals, priorities, objectives, and strategies.	• How does the program decide the priorities for funding?
The program has developed a system to track donor gifts and other funding. This system is integrated with other systems including the accounting software.	• How does the program track gifts from donors and other funding sources? • Does the program use fundraising or donor software? • If so, which one?
The program monitors its efforts to ensure that its mission is being communicated accurately and clearly to potential donors and funders.	• What efforts does the program make to ensure that its mission is being communicated accurately and clearly to the potential donors and funders?
The program seeks both monetary and in-kind support from donors, corporations, and other funders.	• What is the mix of support the grantee receives from various donors?

Criterion 8. Coherent and comprehensive delivery structure. Overall, the program management maintains a delivery structure and approach that effectively utilizes and integrates staff, private attorneys, and other components; emphasizes innovation and creativity in delivery; is informed by current information concerning delivery research; is well-suited to meeting the most pressing legal needs of the service area; and, given available resources, constitutes an effective and economical balancing of expenditures on the various functions and activities described in the four Performance Areas.

Indicators	Areas of inquiry
The program has a reasonable, thoughtful and effective overall delivery system, which utilizes and integrates staff, private attorneys, volunteers, branch offices, outreach, and alternative delivery methods, and which strikes an effective balance on key issues such as specialization, experience of staff, use of attorneys and paralegals, and other major design choices. The program's choices about allocation of resources to competing activities and functions are reasonable and balanced, and consistent with its mission, goals, priorities, objectives, and strategies.	• Does the program have in place and regularly use systems to gauge the efficiency and effectiveness of its overall delivery system? • Is there evidence of actual assessment of efficiency and effectiveness? • Is there evidence of change as a result of that assessment? • Is there evidence of experimentation and innovation?

Criterion 9. Participation in an integrated legal services delivery system. The program participates in, and seeks to expand and improve, statewide (and regional if relevant) legal assistance delivery systems to achieve equal access to justice and to meet the civil legal needs for low-income persons in the state.

Indicators	Areas of inquiry
The program participates in statewide (and regional if relevant) efforts to provide low-income persons in the state with equal access to a full range of civil legal assistance services in all forums.	• Is the program engaged in statewide efforts (and regional efforts if relevant) to achieve the availability of a full range of civil legal assistance in all available forums? • Does the program participate in statewide (and regional if relevant) oversight activities to achieve an integrated statewide delivery system? • Is the program engaged in statewide efforts (and regional efforts if relevant) to eliminate barriers to access and provide meaningful services to low-income persons in the state?

Indicators	Areas of inquiry
The program participates in local, statewide (and regional if relevant) efforts to maximize the effective use of available human and financial resources and to increase such resources to better address the civil legal needs of the state's low-income populations.	• Is the program engaged in statewide efforts (and regional efforts if relevant) to utilize existing financial and human resources effectively and efficiently? • Is the program engaged in statewide efforts (and regional efforts if relevant) to increase potential sources of funding, including financial resources, volunteer and in-kind resources?
The program coordinates with other providers, the bar, law schools, and other relevant entities in seeking to ensure that support is provided to advocates and managers, including training, dissemination and exchange of information, and communication and coordination among practitioners in key areas of law and practice.	• Is the program engaged in statewide efforts (and regional efforts if relevant) to provide support to advocates and managers, including training, dissemination and exchange of information, and communication and coordination among practitioners in key areas of law and practice?
The program participates in statewide planning and oversight activities to achieve an integrated statewide delivery system, and coordinates and collaborates with other civil legal aid providers, private attorneys, government and corporate attorneys, the organized bar, courts and court personnel, law schools, and other public and private entities that provide legal and other social services to low-income persons.	• As part of its efforts to expand access, provide a full range of services, maximize resources, and ensure support within the state, does the program coordinate and collaborate with other civil legal aid providers, private attorneys, government and corporate attorneys, the organized bar, courts and court personnel, law schools, and other public and private entities that provide legal and social services to low-income persons?

Dated: March 27, 2018.

Stefanie K. Davis,

Assistant General Counsel.

[FR Doc. 2018–06532 Filed 3–30–18; 8:45 am]

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LEGAL SERVICES CORPORATION

Sunshine Act Meeting

DATE AND TIME: The Legal Services Corporation's Board of Directors and its six committees will meet April 8–10, 2018. On Sunday, April 8, the first meeting will commence at 2:00 p.m., Eastern Daylight Time (EDT). On Monday, April 9, the first meeting will commence at 9:00 a.m., EDT, with the next meeting commencing promptly upon adjournment of the immediately preceding meeting. On Tuesday, April 10, the first meeting will commence at 9:00 a.m., EDT and will be followed by the closed session meeting of the Board of Directors that will commence promptly upon adjournment of the prior meeting.

LOCATION: Legal Services Corporation, 3333 K Street NW, 3rd Floor F. William McCalpin Conference Center, Washington, DC 20007.

PUBLIC OBSERVATION: Unless otherwise noted herein, the Board and all committee meetings will be open to public observation. Members of the public who are unable to attend in person but wish to listen to the public proceedings may do so by following the telephone call-in directions provided below.

Call-In Directions for Open Sessions

- Call toll-free number: 1–866–451–4981;
- When prompted, enter the following numeric pass code: 5907707348
- Once connected to the call, your telephone line will be *automatically* ''MUTED''.
- To participate in the meeting during public comment press #6 to ''UNMUTE'' your telephone line, once you have concluded your comments please press *6 to ''MUTE'' your line.

Members of the public are asked to keep their telephones muted to eliminate background noises. To avoid disrupting the meeting, please refrain from placing the call on hold if doing so will trigger recorded music or other sound. From time to time, the presiding Chair may solicit comments from the public.

MEETING SCHEDULE

	Time *
Sunday, April 8, 2018:	
1. Operations & Regulations Committee	2:00 p.m.
Monday, April 9, 2018:	
1. Finance Committee ...	9:00 a.m.
2. Audit Committee.	
3. Institutional Advancement Committee.	
4. Communications Subcommittee of the Institutional Advancement Committee.	
5. Governance and Performance Committee.	
6. Delivery of Legal Services Committee.	
7. Board of Directors.	
Tuesday, April 10, 2018:	
1. Board of Directors	9:00 a.m.

* Please note that all times in this notice are in *Eastern Daylight Time.*

STATUS OF MEETING: Open, except as noted below.

Board of Directors—Open, except that, upon a vote of the Board of Directors, a portion of the meeting may be closed to the public to hear briefings by management and LSC's Inspector General, and to consider and act on the General Counsel's report on potential and pending litigation involving LSC, and on a list of prospective funders.**

Institutional Advancement Committee—Open, except that, upon a vote of the Board of Directors, the meeting may be closed to the public to consider and act on recommendation of new Leaders Council invitees and to receive a report on Development activities.**

Audit Committee—Open, except that the meeting may be closed to the public to hear a briefing on the Office of Compliance and Enforcement's active enforcement matters.**

Governance and Performance Review Committee—Open, except that the meeting may be closed to the public to hear a report on the President's evaluation of other officers.**

A verbatim written transcript will be made of the closed session of the Board, Institutional Advancement Committee, and Audit Committee meetings. The transcript of any portions of the closed sessions falling within the relevant provisions of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(6) and (10), will not be available for public inspection. A copy of the General Counsel's Certification that, in his opinion, the closing is authorized by law will be available upon request.

** Any portion of the closed session consisting solely of briefings does not fall within the Sunshine Act's definition of the term ''meeting'' and, therefore, the requirements of the Sunshine Act do not apply to such portion of the closed session. 5 U.S.C. 552b (a) (2) and (b). *See also* 45 CFR 1622.2 & 1622.3.

Matters to be Considered

April 8, 2018

Operations & Regulations Committee

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting of January 21, 2018
3. Discussion regarding documents and information for orientation of and transition to new Committee members
4. Consider and act on Final Rule to repeal 45 CFR part 1603—State Advisory Councils
   - Ron Flagg, General Counsel and Vice President for Legal Affairs
   - Stefanie Davis, Assistant General Counsel
   - Zoe Osterman, Law Fellow
5. Consider and act on Final Rule to adopt a Touhy rule for LSC's process to respond to subpoenas
   - Ron Flagg, General Counsel and Vice President for Legal Affairs
   - Stefanie Davis, Assistant General Counsel
   - Kristin Martin, Law Fellow
6. Consider and act on commencing rulemaking to revise 45 CFR part 1607—Governing Bodies
   - Ron Flagg, General Counsel and Vice President for Legal Affairs
   - Stefanie Davis, Assistant General Counsel
7. Consider and act on the 2018–2019 Rulemaking Agenda
   - Ron Flagg, General Counsel and Vice President for Legal Affairs
   - Stefanie Davis, Assistant General Counsel
8. Update on performance management and human capital management
   - Traci Higgins, Director of Human Resources
9. Report on collection and improvement of data regarding grantee services
   - Carlos Manjarrez, Director, Office of Data Governance and Analysis
10. Public comment
11. Consider and act on other business
12. Consider and act on adjournment of meeting

April 9, 2018

Finance Committee

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting on January 21, 2018
3. Approval of minutes of the Combined Finance and Audit Committees' Open Session meeting on January 21, 2018
4. Discussion regarding documents and information for orientation of and transition to new Committee members
5. Presentation of LSC's Financial Report for the first five months of FY 2018
6. Discussion of LSC's FY 2018 appropriations
   - Carol Bergman, Vice President for Government Relations & Public Affairs
7. Consider and act on *Resolution #2018–XXX,* LSC's Revised Operating Budget for FY 2018
   - David Richardson, Treasurer and Comptroller
8. Discussion of LSC's FY 2019 appropriations request
   - Carol Bergman, Director of Government Relations & Public Affairs
9. Management discussion regarding process and timetable for FY 2020 budget request
   - Carol Bergman, Director of Government Relations & Public Affairs
   - Jim Sandman, President
10. Public comment
11. Consider and act on other business
12. Consider and act on adjournment of meeting

April 9, 2018

Audit Committee

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting on January 21, 2018
3. Approval of minutes of the Combined Audit and Finance Committees' Open Session meeting on January 21, 2018
4. Discussion regarding documents and information for orientation of and transition to new Committee members
5. Briefing of Office of Inspector General
   - Jeffrey Schanz, Inspector General
   - Roxanne Caruso, Assistant Inspector General for Audits
6. Pursuant to Section VIII(A)(6) of the Committee Charter, review and discuss with LSC Management assessment regarding financial business processes
   - Jim Sandman, President
7. Management update regarding risk management
   - Ron Flagg, General Counsel and Vice President for Legal Affairs
8. Briefing about follow-up by the Office of Compliance and Enforcement on referrals by the Office of Inspector General regarding audit reports and annual Independent Public audits of grantees
   - Lora Rath, Director of Compliance and Enforcement
   - Roxanne Caruso, Assistant IG for Audits
9. Public comment
10. Consider and act on other business
11. Consider and act on motion to adjourn the open session meeting and proceed to a closed session

Closed Session

12. Approval of minutes of the Committee's Closed Session meeting of January 21, 2018
13. Briefing by the Office of Compliance and Enforcement on active enforcement matter(s) and follow-up to open investigation referrals from the Office of Inspector General
    - Lora Rath, Director of Compliance and Enforcement
14. Consider and act on adjournment of meeting

April 9, 2018

Institutional Advancement Committee

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting of January 22, 2018
3. Discussion regarding documents and information for orientation of and transition to new Committee members
4. Update on Leaders Council
   - John G. Levi, Chairman of the Board
5. Development report
   - Nadia Elguindy, Director of Institutional Advancement
6. Consider and act on *Resolution 2018–XXX,* Minnesota Charitable Organization Annual Report Form
7. Public Comment
8. Consider and act on other business
9. Consider and act on motion to adjourn the open session meeting and proceed to a closed session

Closed Session

10. Approval of minutes of the Committee's Closed Session meeting of January 22, 2018
11. Development activities report
12. Consider and act on motion to approve Leaders Council invitees
13. Consider and act on motion to adjourn the meeting

April 9, 2018

Communications Subcommittee of the Institutional Advancement Committee

Open Session

1. Approval of agenda
2. Approval of minutes of the Subcommittee's Open Session meeting of January 22, 2018

3. Communications analytics update
   - Carl Rauscher, Director of Communications and Media Relations
4. Public comment
5. Consider and act on other business
6. Consider and act on motion to adjourn the meeting

April 9, 2018

Governance and Performance Review Committee

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting on January 21, 2018
3. Discussion regarding documents and information for orientation of and transition to new Committee members
4. Report on foundation grants and LSC's research agenda
   - Jim Sandman, President
5. Report on transition planning
   - Ron Flagg, General Counsel and Vice President for Legal Affairs
   - Carol Bergman, Vice President for Government Relations & Public Affairs
6. Public comment
7. Consider and act on other business
8. Consider and act on adjournment of meeting

Closed Session

9. Report on evaluations of LSC's Comptroller, Vice President for Grants Management, Vice President for Government Relations and Public Affairs, and Vice President for Legal Affairs
   - Jim Sandman, President
10. Consider and act on adjournment of meeting

April 9, 2018

Delivery of Legal Services Committee

Open Session

1. Approval of agenda
2. Approval of minutes of the Committee's Open Session meeting on January 22, 2018
3. Discussion regarding documents and information for orientation of and transition to new Committee members
4. Update of LSC revision of Performance Criteria
   - Lynn Jennings, Vice President for Grants Management
5. Presentation on grantee oversight by the Office of Program Performance
   - Lynn Jennings, Vice President for Grants Management
   - Ed Caspar, Director, Office of Program Performance
   - Althea Hayward. Deputy Director, Office of Program Performance
6. Public comment
7. Consider and act on other business
8. Consider and act on motion to adjourn the meeting

April 9 & 10, 2018

Board of Directors

Open Session—April 9 & 10

1. Pledge of Allegiance
2. Approval of agenda
3. Approval of minutes of the Board's Open Session meeting of January 23, 2018
4. Chairman's Report
5. Members' Report
6. President's Report
7. Inspector General's Report
8. Consider and act on the report of the Operations and Regulations Committee
9. Consider and act on the report of the Finance Committee
10. Consider and act on the report of the Audit Committee
11. Consider and act on the report of the Institutional Advancement Committee
12. Consider and act on the report of the Governance and Performance Committee
13. Consider and act on the report of the Delivery of Legal Services Committee
14. Consider and act on *Resolution 2018–XXX,* Establishing a Disaster Relief Taskforce
15. Consider and act on *Resolution 2018–XXX,* Establishing an Opioid Taskforce
16. Consider and act on *Resolution 2018–XXX,* In Recognition of Terry Brooks
17. Consider and act on *Resolution 2018–XXX,* In Recognition of Rosalie ''Lisa'' Chavez
18. Consider and act on *Resolution 2018–XXX,* In Recognition of Senator Thad Cochran
19. Consider and act on *Resolution 2018–XXX,* In Memoriam Senator Pietro ''Pete'' Domenici
20. Public Comment
21. Consider and act on other business
22. Consider and act on whether to authorize a closed session of the Board to address items listed below

Closed Session—April 10

23. Approval of minutes of the Board's Closed Session meeting of January 23, 2018
24. Management briefing
25. Inspector General briefing
26. Consider and act on General Counsel's report on potential and pending litigation involving LSC
27. Consider and act on list of prospective Leaders Council members
28. Consider and act on motion to adjourn meeting

CONTACT PERSON FOR INFORMATION: Katherine Ward, Executive Assistant to the Vice President & General Counsel, at (202) 295–1500. Questions may be sent by electronic mail to *FR_NOTICE_QUESTIONS@lsc.gov.*

NON-CONFIDENTIAL MEETING MATERIALS: Non-confidential meeting materials will be made available in electronic format at least 24 hours in advance of the meeting on the LSC website, at *http://www.lsc.gov/board-directors/meetings/board-meeting-notices/non-confidential-materials-be-considered-open-session.*

ACCESSIBILITY: LSC complies with the American's with Disabilities Act and Section 504 of the 1973 Rehabilitation Act. Upon request, meeting notices and materials will be made available in alternative formats to accommodate individuals with disabilities. Individuals who need other accommodations due to disability in order to attend the meeting in person or telephonically should contact Katherine Ward, at (202) 295–1500 or *FR_NOTICE_QUESTIONS@lsc.gov,* at least 2 business days in advance of the meeting. If a request is made without advance notice, LSC will make every effort to accommodate the request but cannot guarantee that all requests can be fulfilled.

Dated: March 29, 2018.

Katherine Ward,

Executive Assistant to the Vice President for Legal Affairs, General Counsel & Corporate Secretary.

[FR Doc. 2018–06782 Filed 3–29–18; 4:15 pm]

BILLING CODE 7050–01–P

MERIT SYSTEMS PROTECTION BOARD

Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: U.S. Merit Systems Protection Board.

ACTION: Notice and request for comments.

SUMMARY: This notice announces that the U.S. Merit Systems Protection Board (MSPB) will submit the information collection abstracted below, OMB No. 3124–0015, to the Office of Management and Budget (OMB) for review and clearance of an extension, without

change, of a currently approved collection in accordance with the requirements of the Paperwork Reduction Act of 1995. MSPB's Information Collection Request (ICR) is set to expire on April 30, 2018. The ICR describes the nature of the information collection and its expected burden. This information collection was developed as part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery.

DATES: Consideration will be given to all comments received by May 2, 2018.

ADDRESSES: Submit written comments on the proposed information collection to the MSPB Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, 735 17th Street NW, Washington, DC 20503.

Written comments may also be submitted by Fax: 202–395–5806; or by email to *oira.submission@omb.eop.gov.* All comments must reference OMB Control No. 3124–0015. Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail to Merit Systems Protection Board, Office of the Clerk of the Board, 1615 M Street NW, Washington, DC 20419; or by email to *mspb@mspb.gov.* All submissions received will be posted, without change, to MSPB's website (*www.mspb.gov*) and will include any personal information you provide. Therefore, submitting this information makes it public.

FOR FURTHER INFORMATION CONTACT: Jennifer Everling, Acting Clerk of the Board, Merit Systems Protection Board, 1615 M Street NW, Washington, DC 20419; phone: (202) 653–7200; fax: (202) 653–7130; or email: *mspb@mspb.gov.* You may contact the Office of the Clerk of the Board for copies of the proposed collection of information at: *mspb@mspb.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection previously was published in the **Federal Register** on January 9, 2018, at 83 FR 2821 with a 60-day public comment period. No comments were received. The purpose of this 30-day notice is to notify the public that MSPB will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Information Collection Requirement:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Number: 3124–0015.

Type of Information Collection: Extension, without change, of a currently approved collection.

ICR Status: This ICR is currently scheduled to expire on April 30, 2018. 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.

Abstract of Proposed Collection: This collection is part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery and provides a means to obtain qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with MSPB's commitment to improving service delivery. Responses to any collection of information under this ICR are voluntary.

Affected Public: Individuals and Households; Businesses and Organizations; State, Local or Tribal Government.

Estimated Total Number of Respondents: 3,000.

Estimated Frequency of Responses: Once per request.

Estimated Total Average Number of Responses for Each Respondent: 1.

Estimated Total Annual Burden Hours: 1,500.

Estimated Total Cost: $50,100.

Comments: Comments should be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to: (a) Evaluate whether the collection of information is necessary for the proper performance of the functions of MSPB, including whether the information shall have practical utility; (b) evaluate the accuracy of MSPB's estimate of the burden of the collection of information; (c) enhance the quality, utility, and clarity of the information to be collected; (d) minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) evaluate the estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Jennifer Everling,

Acting Clerk of the Board.

[FR Doc. 2018–06587 Filed 3–30–18; 8:45 am]

BILLING CODE 7400–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Planning and Procedures; Notice of Meeting

The ACRS Subcommittee on Planning and Procedures will hold a meeting on April 4, 2018, 11545 Rockville Pike, Room T–2B3, Rockville, Maryland 20852.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, April 4, 2018—12:00 p.m. until 1:00 p.m.

The Subcommittee will discuss proposed ACRS activities and related matters. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Quynh Nguyen (Telephone 301–415–5844 or Email: *Quynh.Nguyen@nrc.gov*) five days prior to the meeting, if possible, so that arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 4, 2017 (82 FR 46312).

Information regarding changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS

meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the DFO if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, Maryland 20852. After registering with Security, please contact Mr. Theron Brown at 301–415–6702 to be escorted to the meeting room.

Dated: March 27, 2018.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2018–06644 Filed 3–30–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2017–0210]

Information Collection: Requests to Non-Agreement States for Information

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''Requests to Non-Agreement States for Information.''

DATES: Submit comments by June 1, 2018. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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

- *Federal Rulemaking website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0210. Address questions about NRC dockets to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–2 F43, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Incollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2017–0210 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0210.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The supporting statement is available in ADAMS under Accession No. ML17353A363.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

Please include Docket ID NRC–2017–0210 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

I. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Requests to Non-Agreement States for Information.
2. *OMB approval number:* 3150–0200.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* Not Applicable.
5. *How often the collection is required or requested:* On Occasion.
6. *Who will be required or asked to respond:* Non-Agreement States.
7. *The estimated number of annual responses:* 136 responses.
8. *The estimated number of annual respondents:* 17 respondents.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 952 hours.
10. *Abstract:* Occasionally, requests may be made of Non-Agreement States to provide a more complete overview of the national program for regulating radioactive materials. This information would be used in the decision-making of the Commission. The legal basis is that Section 274(a)(3) of the Atomic Energy Act authorizes and directs the NRC to cooperate with the States to promote an orderly regulatory pattern between the Commission and State governments with respect to nuclear development and use and regulation of byproduct, source, and special nuclear materials. Information requests sought from Non-Agreement States may take the form of one-time surveys, *e.g.,* telephonic and electronic surveys/polls and facsimiles (questionnaires).

II. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 26th day of March 2018.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2018–06594 Filed 3–30–18; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Standard Form 2800—Application for Death Benefits Under the Civil Service Retirement System (CSRS); Standard Form 2800A—Documentation and Elections in Support of Application for Death Benefits When Deceased Was an Employee at the Time of Death (CSRS)

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: Retirement Operations, Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a revision of a currently approved information collection, Standard Form 2800—Application for Death Benefits (CSRS) and Standard Form 2800A—Documentation and Elections in Support of Application for Death Benefits When Deceased Was an Employee at the Time of Death (CSRS).

DATES: Comments are encouraged and will be accepted until May 2, 2018.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, *Attention:* Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this information collection, with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 OPM is soliciting comments for this collection. The information collection (OMB No. 3206–0156) was previously published in the **Federal Register** on November 21, 2017, at 82 FR 55422, allowing for a 60-day public comment period. No comments were received for this collection. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of 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.

Standard Form 2800 is needed to collect information so that OPM can pay death benefits to the survivors of Federal employees and annuitants. Standard Form 2800A is needed for deaths in service so that survivors can make the needed elections regarding military service.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Application for Death Benefits under the Civil Service Retirement System (SF 2800); and Documentation and Elections in Support of Application for Death Benefits When Deceased Was an Employee at the Time of Death (SF 2800A).

OMB Number: 3206–0156.

Frequency: On occasion.

Affected Public: Individual or Households.

Number of Respondents: SF 2800 = 40,000; SF 2800A = 400.

Estimated Time per Respondent: SF 2800 = 45 minutes; SF 2800A = 45 minutes.

Total Burden Hours: 30,300 (SF 2800 = 30,000 hours; SF 2800A = 300 hours).

Office of Personnel Management.

Jeff T.H. Pon,

Director.

[FR Doc. 2018–06613 Filed 3–30–18; 8:45 am]

BILLING CODE 6325–38–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2018–192]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* April 4, 2018.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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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 3007.40.

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 3010, and 39 CFR part 3020, 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 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2018–192; *Filing Title:* Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 8 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* March 27, 2018; *Filing Authority:* 39 CFR 3015.50; *Public Representative:* Matthew R. Ashford; *Comments Due:* April 4, 2018.

This Notice will be published in the **Federal Register**.

Stacy Ruble,

Secretary.

[FR Doc. 2018–06643 Filed 3–30–18; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Wednesday, April 4, 2018.

PLACE: Closed Commission Hearing Room 10800.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

Commissioner Peirce, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matters of the closed meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Brent J. Fields from the Office of the Secretary at (202) 551–5400.

Dated: March 28, 2018.

Brent Fields,

Secretary.

[FR Doc. 2018–06695 Filed 3–29–18; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82949; File No. SR–CBOE–2018–016]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Order Approving a Proposed Rule Change To Amend Rules Related to the Complex Order Book

March 27, 2018

I. Introduction

On February 2, 2018, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to allow market makers and option specialists to rest orders in the Complex Order Book (''COB'') under certain circumstances. The proposed rule change was published for comment in the **Federal Register** on February 16, 2018.[3] The Commission received no comments regarding the proposal. This order approves the proposed rule change.

II. Description of the Proposed Rule Change

CBOE Options Rule 6.53C(c)(i) allows the Exchange to determine which classes and which complex order origin types (*i.e.,* non-broker-dealer public customer, broker-dealers that are not market-makers or specialists on an options exchange, and/or market-makers or specialists on an options exchange) are eligible for entry into the COB and whether such complex orders can route directly to the COB and/or from PAR to the COB. Cboe Options has determined that the complex orders of market-makers (origin code ''M'') and market-makers or specialists on an options exchange (''away market-makers'') (origin code ''N'') in options on the S&P 500 (''SPX'' and ''SPXW'') and the Cboe Volatility Index (''VIX'') are not eligible for entry into the COB.[4] The Exchange proposes to amend Cboe Options Rule 6.53C(c)(i) to provide that in a class in which the Exchange determines that the complex orders of market-makers and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 82689 (February 12, 2018), 83 FR 7092 (''Notice'').

[4] *See* Notice, 83 FR at 7092. *See also* Cboe Options Regulatory Circular RG15–195. To the extent an origin type is not eligible for entry into the COB, complex orders with that origin type may be entered into the Exchange's System as opening-only or immediate-or-cancel because these orders would not rest in the COB when the Exchange is open for trading.

specialists on an options exchange are not eligible for entry into the COB, the Exchange may determine that market-makers and specialists may enter their complex orders into the COB under two circumstances. First, market-makers and specialists will be permitted to enter their complex orders in the COB if their orders are on the opposite side of a priority customer complex order(s) resting in the COB with a price not outside the national spread market (''NSM'').[5] Cboe Options notes that, unlike the leg markets in which market-makers provide liquidity through quotes, market-makers are unable to submit quotes in the COB that indicate to customers the price at which they are willing to trade.[6] Cboe Options believes that allowing market makers to enter their orders in the COB will provide priority customers with information about where market makers are willing to trade, thus creating potential execution opportunities for priority customers whose orders are not satisfied by the leg markets or other complex orders.[7]

Second, the proposal will allow market-makers and options specialists to enter their complex orders in the COB if their orders are on the opposite side of order(s) for the same strategy on the same side that initiated a Complex Order Auction (''COA'') if there are ''x'' number of COAs within ''y'' milliseconds, counted on a rolling basis (the Exchange will determine the number ''x'' (which must be at least two) and time period ''y'' (which may be no more than 2,000)).[8] Cboe Options believes that it may be difficult for market-makers to respond to multiple auctions that occur within a short time period while managing risk related to the amount executed during those auctions.[9] In this regard, the Exchange states that market-makers have complicated risk modeling associated with their trading activity, which factors in the size, price, and frequency at which they trade with orders.[10] To help ensure that a market-maker does not trade with potentially erroneous orders and become overexposed to risk, the Exchange states that a market-maker may set its risk controls to stop responding to COAs when multiple COAs in a strategy occur within a short timeframe (*e.g.,* a market-maker may program its system to respond only to a specific number of auctions within a time period), which reduces auction liquidity and potential price improvement for COA orders.[11] The Exchange notes, however, that multiple non-erroneous auctions in a strategy may occur within a short time period if, for example, a market participant's algorithmic trading breaks up a large order into a number of smaller orders.[12] Accordingly, the proposal will allow a market-maker that determines that it is appropriate to trade with COA orders under these circumstances to submit an order to the COB that would be available to trade against multiple COA orders up to the amount the market-maker is willing to trade for the strategy within its risk controls.[13]

The rule will require market-makers and specialists to cancel any unexecuted complex orders in the COB no later than a specified time (which the Exchange will determine and may be no more than five minutes) after the time the COB receives the order.[14] Cboe Options states that it intends to set these parameters at levels that it believes will permit market-makers to have sufficient time to submit orders into the COB to participate in COAs, a determination that the Exchange will make based on market-maker feedback, business conditions, and data (including trading volume data and information regarding the number of executions of market-maker orders against complex orders).[15] In addition, Cboe Options states the time period within which a market-maker must cancel its complex order will provide the market-maker with sufficient time for the opposing customer to potentially re-price its order for execution against the market-maker's order or for the market-maker's order to execute against an order following a COA.[16]

The Exchange states that it will have surveillance to enforce the proposed rule change, which will monitor whether market-maker and away market-maker orders have been entered only in the circumstances permitted under the proposal, and whether any unexecuted orders have been cancelled by the deadline imposed by the proposal.[17]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[18] In particular, for the reasons discussed below, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[19] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission believes that allowing market-makers and specialists to enter orders in the COB on the opposite side of the market from priority customer orders resting in the COB, or on the opposite side of the market when orders on the same side of the market for a particular strategy have initiated a number of COAs within a short time period, as described more fully above, is designed to result in the provision of additional liquidity to trade with customer orders, potentially providing additional execution and price improvement opportunities for those customer orders. As noted above, CBOE believes that allowing market-makers and specialists to rest orders in the COB opposite priority customer interest in the COB that is not outside the NSM could provide an execution opportunity for a priority customer order that has not executed against other complex order or leg market interest by providing the customer with information concerning the price at which a market maker is willing to trade with the customer's order; this information currently is not available because the COB has no market maker quotes indicating the price at which liquidity providers are willing to trade against

[5] *See* Cboe Options Rules 6.53C(c)(i)(A)(1) and 1.1(bbbb) (defining ''national spread market'').

[6] *See* Notice, 83 FR at 7093.

[7] *See id. See also* Notice, 83 FR at 7094, Examples 1 and 2.

[8] *See* Cboe Options Rule 6.53C(c)(i)(A)(2).

[9] *See* Notice, 83 FR at 7093.

[10] *See id.*

[11] *See id.*

[12] *See id.*

[13] *See id.* Cboe Options notes that pursuant to Cboe Options Rule 6.53C(d), the order of a market-maker or options specialist resting in the COB on the opposite side of an auctioned order may be available for execution against any contracts of the auctioned order that did not execute during the auction. *See id.*

[14] *See* Cboe Options Rule 6.53C(c)(i)(B). The Exchange will announce to Trading Permit Holders all determinations it makes pursuant to Cboe Options Rule 6.53C via Regulatory Circular. *See* Cboe Options Rule 6.53C, Interpretation and Policy .01. The Exchange states that it will provide Trading Permit Holders with sufficient advanced notice prior to changing any parameters its sets under the proposal. *See* Notice, 83 FR at 7093 n.5.

[15] *See* Notice, 83 FR at 7093.

[16] *See id.* at 7094.

[17] *See id.* at 7094.

[18] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 15 U.S.C. 78f(b)(5).

customer orders.[20] Allowing market-makers and specialists to place orders in the COB following a number of COAs for the same strategy on the same side of the market could allow a market maker to determine to provide additional liquidity for customer orders, within the market-maker's risk controls, in circumstances where the market-maker's system has stopped responding to COAs.[21] The Commission notes that Cboe Options has represented that it will have surveillance to monitor compliance with the requirements of the rule.[22]

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[23] that the proposed rule change (SR–CBOE–2018–016) is approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Jill Peterson,

Assistant Secretary.

[FR Doc. 2018–06569 Filed 3–30–18; 8:45 am]

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[20] *See* Notice, 83 FR at 7093.

[21] *See id.*

[22] *See id.* at 7094.

[23] 15 U.S.C. 78s(b)(2).

[24] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33058; 812–14670]

Aberdeen Asset Management Inc., et al.

March 27, 2018.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an order under sections 6(c) and 17(b) of the Investment Company Act of 1940 (''Act'') for exemptions from section 17(a) of the Act, and under section 17(d) of the Act and rule 17d–1 thereunder to permit certain joint transactions.

SUMMARY OF APPLICATION: Applicants requests an order to permit certain registered open-end and closed-end management investment companies or series thereof to invest in a private investment vehicle established by their investment advisers for the purpose of investing in China A Shares and certain other Chinese securities.

APPLICANTS: Aberdeen Asset Management Inc. (''AAMI''), Aberdeen Asset Managers Limited, (''AAML''), Aberdeen Asset Management Asia Limited (''AAMAL,'' and together with AAMI and AAML, the ''Initial Advisers''), Aberdeen Funds (the ''Trust''), Aberdeen Greater China Fund, Inc. (''GCH''), and Aberdeen Institutional Commingled Funds, LLC (the ''Commingled LLC'').

FILING DATES: The application was filed on July 20, 2016, and amended on February 10, 2017, September 22, 2017, January 18, 2018, and March 19, 2018.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on April 23, 2018, 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.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. Applicants: 225 Liberty Street, New York, NY 10281.

FOR FURTHER INFORMATION CONTACT: Kieran G. Brown, Senior Counsel, at (202) 551–6773, or Robert H. Shapiro, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations:

1. The Trust is a Delaware statutory trust and is registered under Act as an open-end management investment company. GCH is a Maryland corporation and is registered under the Act as a closed-end management investment company. Each of Aberdeen Asia-Pacific (ex-Japan) Equity Fund, Aberdeen Emerging Markets Fund and Aberdeen China Opportunities Fund (together with GCH, collectively, the ''Initial Funds'') is a series of the Trust.

2. The Commingled LLC is a limited liability company under the Delaware Limited Liability Company Act, which relies on the exemption from registration under the Act provided by section 3(c)(7) of the Act.[1]

3. Each Adviser is registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''), and AAMI, AAML and AAMAL are wholly-owned subsidiaries of Aberdeen Asset Management PLC. AAMI serves as the investment adviser to the series of the Trust pursuant to an investment advisory agreement between AAMI and the Trust, on behalf of its series (the ''AAMI Agreement''). AAMAL and AAML both serve as sub-advisers (collectively, and in this capacity, the ''Sub-Advisers'') to certain series of the Trust, including Aberdeen Asia-Pacific (ex-Japan) Equity Fund, Aberdeen Emerging Markets Fund and Aberdeen China Opportunities Fund, pursuant to sub-advisory agreements by and among the Trust, AAMI and the respective Sub-Adviser (the ''Sub-Advisory Agreements''). The Initial Advisers also serve as sub-adviser to a number of other registered management investment companies or series thereof.[2] AAMAL

[1] Each entity that currently intends to rely on the requested relief, other than the Initial Sub-Advised Funds (defined below), has been named as an applicant. Any existing or future registered open-end or closed-end management investment companies or series thereof for which an Initial Adviser, or an Initial Adviser's successor, or any person controlling, controlled by, or under common control with an Initial Adviser (an ''Aberdeen Affiliate'') acts as investment adviser or sub-adviser (each such Initial Adviser or Aberdeen Affiliate acting as investment adviser or sub-adviser, an ''Adviser'') that may rely on the requested relief in the future is a ''Future Fund''. For purposes of the requested order, the term ''successor'' is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization. The Initial Funds, Sub-Advised Funds (as defined below) and Future Funds are referred to collectively as the ''Funds'' or individually as a ''Fund''. Each Fund or other entity that may rely on the requested relief in the future will do so only in accordance with the terms and conditions of the requested order.

[2] The following registered management investment companies or series of registered management investment companies are sub-advised by an Adviser and, to the Adviser's knowledge, currently intend to rely on the requested relief, subject to approval by their respective primary investment advisers and boards of directors or trustees: First Trust/Aberdeen Emerging Opportunity Fund, Brighthouse/Aberdeen Emerging Markets Equity Portfolio, Emerging Markets Equity Portfolio, Thrivent Partner Emerging Markets Equity Fund, Thrivent Partner Worldwide Allocation Fund, Thrivent Partner Emerging Markets Equity Portfolio and Thrivent Partner Worldwide Allocation Portfolio (collectively, the ''Initial Sub-Advised Funds,'' and together with any other existing or future registered open-end or closed-end management investment company or series thereof that is sub-advised by an Adviser that may rely on the requested relief in the future, the ''Sub-Advised

serves as the investment manager to GCH pursuant to an investment management agreement (together with the AAMI Agreement and Sub-Advisory Agreements, the ''Advisory Agreements''). The Initial Advisers are responsible for making investment decisions for the Initial Funds and Initial Sub-Advised Funds that they advise or sub-advise, as applicable, and for administering the business and affairs of such Initial Funds. The Initial Advisers are entitled, under the terms of the Advisory Agreements, to receive management fees directly from the Initial Funds, or in the case of the Sub-Advisers, from AAMI, in each case at specified rates. In the case of the Initial Sub-Advised Funds, the Initial Advisers receive a sub-advisory fee from the applicable Unaffiliated Manager (defined below) at specified rates.[3] As investment adviser, investment manager and/or sub-adviser, AAMI's, AAML's and AAMAL's activities are subject to the oversight of the Board of Trustees of the Trust and the Board of Directors of GCH, as applicable (each Fund's Board of trustees/directors, a ''Board''), at least a majority of whose members are not ''interested persons'' of the Trust or GCH, as defined in section 2(a)(19) of the Act (the members of a Fund's Board who are not ''interested persons'' of the relevant Fund, as defined in Section 2(a)(19) of the Act, the ''Independent Board Members'').

4. The Advisers also advise or may advise collective investment trusts, private pooled investment vehicles and investment companies registered in other jurisdictions (together, the ''Other Vehicles''), as well as separately managed accounts (together with the Other Vehicles, ''Other Accounts'').[4] Applicants state that these Other Accounts may have similar investment objectives and strategies as the Funds and will invest in an Aberdeen China A Fund Series (defined below) along with one or more Funds.

5. The Funds desire to purchase and redeem limited liability company interests (''Interests'') of separately identified series of the Commingled LLC (each separate series of the Commingled LLC, an ''Aberdeen China A Fund Series''). Each Aberdeen China A Fund Series invests in securities of Chinese companies, including without limitation, class A Shares listed on People's Republic of China (''PRC'') stock exchanges, rights to invest in such class A Shares or other equivalent securities authorized by the China Securities Regulatory Commission for purchase by non-Chinese investors or ''qualified foreign institutional investors'' (''QFII''), corporate or government bonds listed on PRC stock exchanges or traded in the over-the-counter markets of the PRC and warrants listed on PRC stock exchanges (together, ''Chinese Securities'').[5] Notwithstanding the foregoing, a security will only be a ''Chinese Security'' if it is subject to the quota systems described in the application (as such quota systems may be amended or altered from time to time). Interests in the Aberdeen China A Fund Series will be sold only to the Funds and the Other Accounts. The initial Aberdeen China A Fund Series will be the China A Share Equity Fund (the ''Initial Aberdeen China A Fund'').

6. Applicants assert that, for a variety of reasons, it is not practical or economical for the Funds to invest a significant amount of assets directly in Chinese Securities. Applicants state that, until 2002, the Chinese government restricted investment in China A Shares and other Chinese Securities to domestic (*i.e.,* Chinese) investors.[6] According to Applicants, since 2002, the Chinese Government has permitted certain non-Chinese investors to invest in China A Shares and gradually has liberalized applicable rules to permit non-Chinese investors to invest in other types of Chinese Securities. However, subject to limited exceptions described in the application, to do so, a foreign investor must receive a license as a QFII or Renminbi Qualified Foreign Institutional Investor (''RQFII'') and be allotted a quota, representing the amount in renminbi of Chinese Securities that the investor may purchase. As described more fully in the application, individual applications on behalf of each Fund or Other Account would generally not be practical or feasible. Accordingly, AAMAL has obtained QFII and RQFII licenses and quota so that it can invest in Chinese Securities on behalf of the Funds and Other Accounts and the Advisers are applying for additional quota under the RQFII to be made available to the Initial Aberdeen China A Fund and the Other Accounts.

7. Applicants state that while some of the Initial Funds currently invest in China A Shares (pursuant to quota allocated by AAMAL) and other Chinese Securities, the use of the Aberdeen China A Fund Series would allow the Funds, and Other Accounts, to gain dedicated exposure to Chinese Securities and provide numerous additional investment opportunities for the Funds that are consistent with their investment objectives and policies. Additionally, being able to pool investments into China A Shares with Future Funds and Other Accounts will provide more diversification with respect to China A Share investments. Future Funds would obtain access to China A Shares without having to obtain individual licenses as QFIIs or RQFIIs, and without having to comply with the reporting required for each fund or account that is allocated quota from an Adviser with an existing QFII or RQFII license. Applicants state that each Aberdeen China A Fund Series will invest only in Chinese securities and cash and cash equivalents.

8. The Commingled LLC is organized as a Delaware limited liability company. AAMI serves as the managing member of the Commingled LLC. The Commingled LLC does not have a board of directors or trustees. Each Fund or Other Account may purchase interests of an Aberdeen China A Fund Series; if there is more than one Aberdeen China A Fund Series, a Fund or Other Account may invest in some or all of the different Aberdeen China A Fund Series.[7] Each Aberdeen China A Fund Series will have its own portfolio manager or portfolio management team at AAMI and/or AAMAL who will be responsible for selecting particular Chinese Securities for investment by that Aberdeen China A Fund Series. Each Fund or Other Account investing in an Aberdeen China A Fund Series will hold Interests which will represent a proportionate share of the Aberdeen China A Fund Series' net assets and a proportionate claim on the Aberdeen China A Fund Series' net income. Interests in an Aberdeen China A Fund

Funds''). Only the portion of a Sub-Advised Fund managed by an Adviser would be permitted to make investments into an Aberdeen China A Fund Series (defined below) in reliance on the requested order.

[3] Pursuant to condition 10, an Unaffiliated Manager (defined below) would be required to contractually agree to comply with the applicable conditions of the requested order as a prerequisite to a Sub-Advised Fund's reliance on the requested order.

[4] The Applicants acknowledge that they are neither seeking nor receiving relief with respect to the separately managed accounts.

[5] Applicants represent that the Aberdeen China A Fund Series will not invest in derivatives or in other pooled investment vehicles.

[6] Applicants assert that, for a variety of reasons, China A Shares are a more attractive means to invest in Chinese companies than are other categories of stock that are available on the Shanghai, Shenzhen and Hong Kong Stock Exchanges (which is where a significant majority of publicly traded Chinese companies list their shares).

[7] Applicants state that one Aberdeen China A Fund Series is contemplated, but in the future additional Aberdeen China A Fund Series may be established to invest in different issuers, or types, of Chinese Securities based generally on the particular characteristics of those issuers, or types, of Chinese Securities.

Series used by the Funds will be valued daily in accordance with the Funds' valuation procedures as approved by each Fund's Board and in accordance with section 2(a)(41) of the Act. Each Interest would have the same rights as any other Interest, and the Aberdeen China A Fund Series would not issue preferred interests.

9. The Advisers will not charge advisory fees to an Aberdeen China A Fund Series used by the Funds. The Advisers will, however, be entitled to receive applicable advisory fees from the Funds or Other Accounts. Expenses of the Aberdeen China A Fund Series will be charged to the Aberdeen China A Fund Series as a whole and accrue on a daily basis.[8] The books of each Aberdeen China A Fund Series will be accounted for under standard accounting principles and in accordance with U.S. Generally Accepted Accounting Principles (''GAAP''), and they will be audited annually by a nationally recognized and PCAOB-registered audit firm in accordance with U.S. Generally Accepted Auditing Standards (''GAAS'').[9] An Aberdeen China A Fund Series in which a Fund invests will not engage in leverage or borrow except that an Aberdeen China A Fund Series may borrow in amounts not exceeding 5% of its total assets for temporary or emergency purposes or for the clearance of transactions, but not for speculative investment purposes, and may pledge its assets to secure such borrowings.

10. A Fund's decision to invest in an Aberdeen China A Fund Series will be made by a Fund's portfolio manager(s). Although daily repatriation is permitted under the RQFII open ended fund model, it is possible that proceeds from sales of portfolio investments in liquid or illiquid Chinese Securities may not be able to immediately be repatriated to a foreign investor such as an Aberdeen China A Fund Series at the approximate value at which the Aberdeen China A Fund Series has valued the investment. Accordingly, each Fund will treat its entire investment in an Aberdeen China A Fund Series as an investment that is not liquid for purposes of any applicable rules or guidance of the Commission or its staff regarding the management of liquidity with respect to open-end and/or closed-end funds, as applicable, and will otherwise be subject to the limits described in condition 4.

11. Applicants state that access by the Funds and Other Accounts to the quota (*i.e.,* to Chinese Securities) through the Aberdeen China A Fund Series is not expected to be limited. On a day to day basis, each Aberdeen China A Fund Series will utilize the quota that has been allocated by the respective Adviser or Aberdeen Affiliate. When an Aberdeen China A Fund Series has used up approximately 70% of the quota allocated to it, the respective Adviser or Aberdeen Affiliate will apply for additional quota. Before any additional quota is approved, in the event that there is a shortfall or an anticipated shortfall in available quota, the Adviser or Aberdeen Affiliate will review whether there is any surplus quota allocated to a Fund, Other Account or Aberdeen China A Fund Series that could be reallocated to the Aberdeen China A Fund Series. In the unlikely circumstances that there are times when an Aberdeen China A Fund Series' investments will be limited by quota limitations, access by the Funds and Other Accounts to Aberdeen China A Fund Series Interests will be allocated in accordance with the Advisers' trade order aggregation and trade allocation policies and procedures (the ''Advisers' Trade Allocation Policy''). Under the Advisers' Trade Allocation Policy, if fewer Interests are available than are requested by the portfolio managers of the Funds and Other Accounts, Interests will generally be allocated across participating accounts on a *pro rata* basis according to requested order size.[10] However, there may be certain circumstances where the Advisers, consistent with the Trade Allocation Policy as it will be amended, may take into account other factors such that there is a deviation from an exact *pro rata* allocation in an effort to allocate Interests fairly across accounts. For example, given that it can take several months to receive additional quota under the RQFII structure, there may be an instance where one Fund requests additional Interests months before they are available, while another Fund requests additional Interests a day before they are available. In that case, the Advisers may take the timing of the request into account and fulfill the first Fund's entire request for additional Interests and offer the second Fund the remainder, if any, while the Advisers put in an additional request for quota so that it can satisfy the second Fund's request. Similarly, if more than one Fund or Other Account seeks to repatriate proceeds at or about the same time, and Chinese regulations limit the aggregate amount of proceeds that may be repatriated at any given time to a level below the aggregate amount sought to be repatriated, the requests by the applicable portfolio manager(s) will be aggregated, if received at or about the same time, and proceeds available for repatriation will be allocated *pro rata* among requesting Funds and Other Accounts.[11] The Advisers will not consider the potential impact on the quota when making investment decisions for the Funds or Other Accounts.[12]

[8] Expenses of the Aberdeen China A Fund Series will include basic fees and expenses of service providers, such as the administrator, transfer agent, accountant, local custodian and legal counsel. No fees will be paid by an Aberdeen China A Fund Series to an administrator or transfer agent that is an Aberdeen Affiliate or Unaffiliated Manager (defined below) except in accordance with condition 3.

[9] Applicants state that the GAAS standards applicable to the audit of an Aberdeen China A Fund Series would be the same standards as those applicable to a registered investment company. Further, applicants state that GAAP would apply to both the Aberdeen China A Fund Series audit and a registered investment company audit. Thus, applicants assert that critical accounting policies governing security valuation, accounting for investment transactions, recognition of investment income and of expenses, and accrual of expenses, which are often the critical policies applicable to investment companies, would apply in substantially the same manner for the audit of the Aberdeen China A Fund Series.

[10] Currently, AAMAL manages one other client to which it has granted quota under its RQFII license, which is the Aberdeen Global—China A Share Equity Fund, a collective investment vehicle incorporated in Luxembourg (the ''Luxembourg China A Fund'') that is not available for sale to U.S. investors. The Luxembourg China A Fund investors are generally not permitted to invest in the Aberdeen China A Fund Series due to their residency outside of the U.S. AAMAL expects that both funds will continue to be offered despite their duplication in strategy, in order to make the strategy available in multiple jurisdictions. Additionally, AAMAL could, but is currently not expected to, grant RQFII quota to similar collective investment vehicles or other clients in the future (together with the Luxembourg China A Fund and the Aberdeen China A Fund Series, ''Aberdeen China Accounts''). In the event that quota is exhausted by the Luxembourg China A Fund or other client(s) prior to the launch of the Initial China A Fund Series, AAMAL intends to apply for additional quota. To the extent there is demand for additional Chinese Securities through the RQFII license from multiple Aberdeen China Accounts or from other clients of the Advisers who are allocated quota through a QFII license, allocations of Chinese Securities, like allocations of other investment opportunities among Funds and Other Accounts, will be subject to the Advisers' Trade Allocation Policy. Similarly, consistent with the Advisers' Trade Allocation Policy, in the event that AAMAL receives additional RQFII quota, such additional RQFII quota will be allocated amongst Aberdeen China Accounts pro rata based on amounts requested by such Aberdeen China Accounts.

[11] Applicants are not seeking comfort nor is the Commission providing any opinion on whether the Advisers' Trade Allocation Policy meets the standards applicable under the Act or the Advisers Act.

[12] Applicants state that the quota may be reduced or revoked if AAMAL (or if other Advisers in the future receive a license, by the relevant Adviser) does not invest the full amount of its quota over a phase-in period, or if it repatriates its investments below the quota amount.

12. Applicants state that AAMI contemplates making a nominal investment (*i.e.* expected to be $1,000 and in no case more than $10,000) in the Initial Aberdeen China A Fund. AAMI will acquire Interests in the Initial Aberdeen China A Fund having rights, duties and obligations that are identical in all respects to Interests purchased by other investors in the Initial Aberdeen China A Fund. The sole purpose of the proposed investment is to permit AAMI to serve as the tax matters partner of the Initial Aberdeen China A Fund, which intends to be treated as a partnership for U.S. federal tax purposes. Applicants state that in the absence of AAMI's investment, it is likely that the U.S. Internal Revenue Service would appoint a non-managing member partner of the Commingled LLC to serve as tax matters partner of the Initial Aberdeen China A Fund in an audit proceeding. In addition, absent AAMI's investment, the tax matters partner could change from year-to-year, which may disrupt preparation of the Initial Aberdeen China A Fund's annual tax return.

Applicants' Legal Analysis

Section 17(a)—Purchase and Sale of Interests

1. Section 17(a) generally provides, in part, that it is unlawful for any affiliated person of a registered investment company (''first-tier affiliate''), or any affiliated person of such person (''second tier affiliate''), acting as principal, to sell or purchase any security or other property to or from such investment company. Section 2(a)(3) of the Act defines an ''affiliated person'' of another person to include (a) any person directly or indirectly owning, controlling, or holding with power to vote, 5% or more of the outstanding voting securities of the other person; (b) any person 5% or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with the power to vote by the other person; and (c) any person directly or indirectly controlling, controlled by, or under common control with the other person. Section 2(a)(9) defines ''control'' to mean ''the power to exercise a controlling influence over the management or policies of a company, unless such power is solely the result of an official position with such company.''

2. Applicants state that the Funds and the Aberdeen China A Fund Series are expected to be affiliated persons under section 2(a)(3) of the Act, because it is expected that one or more Funds and Other Vehicles will own at least 5%, and potentially, more than 25% of the Interests of an Aberdeen China A Fund Series. While Interests of an Aberdeen China A Fund Series will be non-voting interests, a Fund or Other Vehicle could have power to exercise a controlling influence over the management or policies of an Aberdeen China A Fund Series and be deemed an affiliated person of the Aberdeen China A Fund Series under section 2(a)(3)(C). Furthermore, as the investment advisers to the Funds, the Advisers are affiliated persons of the Funds that they advise under section 2(a)(3)(E) and, because AAMI is the managing member of the Commingled LLC, an Aberdeen China A Fund Series may be deemed to be under AAMI's control under section 2(a)(3)(C), resulting in each Aberdeen China A Fund Series being deemed an affiliated person of an affiliated person of certain, if not all, of the Funds. Since the Funds and the Aberdeen China A Fund Series may share a common investment adviser or investment advisers that are wholly-owned by the same parent company, they may be deemed to be first-tier affiliates by virtue of arguably being under common control for purposes of section 2(a)(3)(C).

3. If a Fund and an Aberdeen China A Fund Series are deemed affiliates of each other, or even second-tier affiliates, the sale of Interests of the Aberdeen China A Fund Series to the Fund, and the redemption of such Interests by the Fund, would be prohibited under section 17(a) of the Act.

4. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if the terms of the proposed transaction, including the consideration to be paid or received, are fair and reasonable and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of each registered investment company involved and with the general purposes of the Act. Section 6(c) of the Act permits the Commission to exempt any person or transactions from any provisions of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

5. Applicants submit that the proposed arrangement satisfies the standards for relief under sections 17(b) and 6(c) of the Act. For the reasons discussed below, Applicants submit that the terms of the arrangement, including the consideration to be paid, are fair and reasonable and do not involve overreaching on the part of any person concerned, and that the proposed transactions are consistent with the policy of each registered investment company concerned and with the general purposes of the Act. Applicants further submit that the Funds' participation in the Aberdeen China A Fund Series will be necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policies and provisions of the Act.

6. Applicants state that each Fund and Other Account will be treated identically as a holder of Interest in the Aberdeen China A Fund Series, and each Fund and Other Account will purchase and sell Interests of an Aberdeen China A Fund Series on the same terms and on the same basis as each other Fund and Other Account that invests in that Aberdeen China A Fund Series. Applicants note that no Adviser, Aberdeen Affiliate, or investment manager to a Sub-Advised Fund that is not an Initial Adviser or Aberdeen Affiliate or any person controlling, controlled by or under common control with such investment manager (any such investment manager to a Sub-Advised Fund or control affiliate of such investment manager, an ''Unaffiliated Manager'') will receive an advisory fee from an Aberdeen China A Fund Series used by the Funds. The Funds, as holders of Interests of the Aberdeen China A Fund Series, will not be subject to any sales load, redemption fee, distribution fee or service fee, except that the Aberdeen China A Fund Series will have the discretion to impose a redemption fee in accordance with applicable law or regulation for the purpose of offsetting brokerage, tax or other costs. If a redemption fee is charged by an Aberdeen China A Fund Series, such fee will be limited in accordance with the then-current requirements of the Commission applicable to management investment companies offering redeemable securities as if the Aberdeen China A Fund Series were an open-end investment company. The financial statements of the Aberdeen China A Fund Series will be audited. Moreover, administrative fees and transfer agent fees will be paid by an Aberdeen China A Fund Series used by the Funds to an Adviser, Aberdeen Affiliate, or Unaffiliated Manager only upon the determination by each Fund's Board, including a majority of Independent Board Members, that the fees are (i) for services in addition to, rather than duplicative of, services rendered to the Funds directly and (ii) fair and

reasonable in light of the usual and customary charges imposed by others for services of the same nature and quality. Applicants argue that the fees payable to the Aberdeen China A Fund Series' service providers will be for distinct services, and the costs of such fees will be outweighed by opportunity to invest in Chinese Securities.

Section 17(d)

7. Section 17(d) of the Act and rule 17d–1 under the Act generally prohibit joint transactions involving registered investment companies and their affiliates unless the Commission has approved the transaction. In considering whether to approve a joint transaction under rule 17d–1, the Commission considers whether the proposed transaction is consistent with the provisions, policies, and purposes of the Act, and the extent to which the participation of the investment companies is on a basis different from or less advantageous than that of the other participants.

8. Applicants state that the Funds (by purchasing Interests of the Aberdeen China A Fund Series), the Advisers (by managing the portfolio securities of the Aberdeen China A Fund Series and the Funds at the same time that the Funds are invested in Interests of the Aberdeen China A Fund Series and/or by providing a nominal tax matters partner investment in the Aberdeen China A Fund Series), and the Aberdeen China A Fund Series (by selling its Interests to, and redeeming its Interests from, the Funds), could be deemed to be participants in a joint enterprise or arrangement within the meaning of section 17(d) and rule 17d–1.

9. Applicants request an order pursuant to section 17(d) and rule 17d–1 to permit the proposed transactions with the Aberdeen China A Fund Series. Applicants submit that the investment by the Funds in the Aberdeen China A Fund Series on the basis proposed is consistent with the provisions, policies and purposes of the Act, and that each Fund will invest in Interests of the Aberdeen China A Fund Series on the same basis as any other shareholder (*i.e.,* the other Funds and Other Accounts). Applicants further state that the Advisers will take reasonable steps to make sure that allocations among the Funds and Other Accounts are fair and equitable. Allocations of Chinese Securities to different Aberdeen China A Fund Series, and allocations of opportunities to invest in the Aberdeen China A Fund Series, by Funds and Other Accounts, will be subject to the Advisers' Trade Allocation Policy, under the supervision of the Advisers' and the Funds' Chief Compliance Officer, and compliance with the Advisers' Trade Allocation Policy will be overseen by each Fund's Board.

10. Applicants do not believe that AAMI's nominal investment as tax matters partner in the Initial Aberdeen China A Fund poses any potential conflict of interest not addressed by the conditions contained in the application. AAMI will acquire Interests having rights, duties and obligations that are identical in all respects to Interests purchased by other investors in the Initial Aberdeen China A Fund.

Section 17(a)—Cross Transactions

11. Applicants propose that the Funds be permitted to continue to engage in certain purchase and sale cross transactions in securities (''Cross Transactions'') between a Fund seeking to implement a portfolio strategy and an Other Vehicle seeking to raise or invest cash. The Funds currently rely on rule 17a–7 to engage in such Cross Transactions; however, if a Fund and an Other Vehicle were deemed to be second-tier affiliates of each other by virtue of their ownership or control affiliations with an Aberdeen China A Fund Series, the Funds may not be entitled to rely on rule 17a–7 because they would no longer be affiliated solely for the reasons permitted by the rule.

12. Applicants assert that the potential affiliations created by the Aberdeen China A Fund Series structure do not affect the other protections provided by the rule, including the integrity of the pricing mechanism employed, and oversight by each Fund's Board. Applicants represent that the Funds and Other Vehicles will comply with the requirements set forth in rule 17d–(7)(a) through (g). Applicants thus believe that Cross Transactions will be reasonable and fair, and will not involve overreaching, and will be consistent with the purposes of the Act and the investment policy of each Fund.

Applicants' Conditions

Applicants agree that any order granting the requested relief shall be subject to the following conditions:

1. The Funds' investments in Interests of an Aberdeen China A Fund Series will be undertaken only in accordance with the Funds' stated investment restrictions and will be consistent with their stated investment policies.

2. The Advisers, their affiliated persons and Unaffiliated Managers will receive no advisory fee from an Aberdeen China A Fund Series in connection with the Funds' investment in the Aberdeen China A Fund Series. The Advisers, their affiliated persons and Unaffiliated Managers will receive no commissions, fees, or other compensation (except for administrative and/or transfer agent fees that are paid in accordance with condition 3 as described in the application) from a Fund or an Aberdeen China A Fund Series in connection with the purchase or redemption by the Funds of Interests in the Aberdeen China A Fund Series. Interests of an Aberdeen China A Fund Series will not be subject to a sales load, redemption fee, distribution fee or service fee, except that the Aberdeen China A Fund Series will have the discretion to impose a redemption fee in accordance with applicable law or regulation for the purpose of offsetting brokerage, tax or other costs. If a redemption fee is charged by an Aberdeen China A Fund Series, such fee will be limited in accordance with the then-current requirements of the Commission applicable to management investment companies offering redeemable securities as if the Aberdeen China A Fund Series were an open-end investment company registered under the Act.

3. Administrative fees and transfer agent fees will be paid by an Aberdeen China A Fund Series used by the Funds to an Adviser, Aberdeen Affiliate or Unaffiliated Manager only upon a determination by each Fund's Board, including a majority of its Independent Board Members, that the fees are (i) for services in addition to, rather than duplicative of, services rendered to the Funds directly and (ii) fair and reasonable in light of the usual and customary charges imposed by others for services of the same nature and quality. If such determination is not made by a Fund's Board, the Fund's Adviser will reimburse to that Fund the amount of any administrative fee and transfer agent fee borne by that Fund as an investor in the Aberdeen China A Fund Series.

4. Each Fund will treat its entire investment in an Aberdeen China A Fund Series as an investment that is not liquid for purposes of any applicable rules or guidance of the Commission or its staff regarding the management of liquidity. For example, under current guidelines, each Fund that is an open-end fund must not purchase an illiquid security if, as a result, more than 15% of its net assets would be invested in illiquid assets, which for purposes of the requested relief include any investments in an Aberdeen China A Fund Series. In addition, each Fund will, at all times, limit its holdings in the Aberdeen China A Fund Series to no more than 15% of its net assets.

5. Each Fund's Board, including a majority of the Independent Board Members, will determine initially and no less frequently than annually that the Fund's investment in the Aberdeen China A Fund Series is, and continues to be, in the best interests of the Fund and the Fund's shareholders. As part of this determination, each Fund's Board will consider the custody arrangements for the Aberdeen China A Fund Series' foreign securities (under rule 17f–5) and the bonding arrangements in place for certain of the Aberdeen China A Fund Series' officers and employees (under rule 17g–1).

6. The Advisers will make the accounts, books and other records of each Aberdeen China A Fund Series available for inspection by the Commission staff and, if requested, will furnish copies of those records to the Commission staff.

7. Each Aberdeen China A Fund Series will comply with the following sections of the Act as if the Aberdeen China A Fund Series were an open-end management investment company registered under the Act, except as noted: Section 9; section 12 (except that each Aberdeen China A Fund Series shall be permitted to sell Interests to Funds in excess of the limits set out in section 12(d)(1)(B)); section 13 (the Interests issued by the Aberdeen China A Fund Series will be regarded as voting securities under section 2(a) (42) of the Act for purposes of applying this condition and the offering memorandum utilized by the Aberdeen China A Fund Series to offer and sell Interests will be regarded as a registration statement for purposes of applying this condition); section 17(a) (except as described in the application); section 17(d) (except as described in the application); section 17(e); section 17(f); section 17(h), section 18 (the Interests issued by the Aberdeen China A Fund Series will be regarded as voting securities under section 2(a)(42) of the Act for purposes of applying this condition); section 21; section 36; and sections 37–53. In addition, the Aberdeen China A Fund Series will comply with the rules under section 17(f) [13] and section 17(g) of the Act, and rule 22c–1 under the Act as if the Aberdeen China A Fund Series were an open-end management investment company registered under the Act. This condition 7 will apply only to Aberdeen China A Fund Series in which a Fund has invested; this condition 7 will not apply to Aberdeen China A Fund Series invested in exclusively by Other Accounts except insofar as necessary for the Aberdeen China A Fund Series invested in by a Fund to comply with this condition.

The Advisers will adopt procedures designed to ensure that each Aberdeen China A Fund Series complies with the aforementioned sections of the Act and rules under the Act. The Advisers will periodically review and periodically update as appropriate such procedures and will maintain books and records describing such procedures, and maintain the records required by rules 31d–1(b)(1), 31d–1(b)(2)(ii) and 31d–1(b)(9) under the Act. In addition, in connection with the determination required by condition 5 above, the Advisers will provide annually to each Fund's Board a written report about the Advisers' and the Aberdeen China A Fund Series' compliance with this condition.

All books and records required to be made pursuant to this condition will be maintained and preserved for a period of not less than six years from the end of the fiscal year in which any transaction occurred, the first two years in an easily accessible place, and will be subject to examination by the Commission and its staff.

For purpose of implementing condition 7, any action that the above-referenced statutory and regulatory provisions require to be taken by the directors, officers and/or employees of a registered investment company will be performed by AAMI (or its successor) [14] as the managing member of the Commingled LLC, except to the extent that the order requires the Funds' Boards to exercise oversight or take action with respect to the Aberdeen China A Fund Series as an extension of such Boards' duties to the Funds.

8. To engage in Cross Transactions, the Funds will comply with rule 17a–7 under the Act in all respects other than the requirement that the parties to the transaction be affiliated persons (or affiliated persons of affiliated persons) of each other solely by reason of having a common investment adviser or investment advisers which are affiliated persons of each other, common officers, and/or common directors, solely because a Fund and Other Vehicle might become affiliated persons within the meaning of section 2(a)(3)(A), (B) or (C) of the Act because of their investments in an Aberdeen China A Fund Series.

9. An Aberdeen China A Fund Series in which a Fund invests will not engage in leverage or borrow except that an Aberdeen China A Fund Series may borrow in amounts not exceeding 5% of its total assets for temporary or emergency purposes or for the clearance of transactions, but not for speculative investment purposes, and may pledge its assets to secure such borrowings.

10. A Sub-Advised Fund may not invest in an Aberdeen China A Fund Series in reliance on the order unless the Sub-Advised Fund's Unaffiliated Manager has executed an agreement with the Aberdeen China A Fund Series stating that the Unaffiliated Manager understands the terms and conditions of the order and agrees to comply with conditions 1, 2, 3, 4, 5 and 8 of the order.

For the Commission, by the Division of Investment Management, under delegated authority.

Jill Peterson,

Assistant Secretary.

[FR Doc. 2018–06567 Filed 3–30–18; 8:45 am]

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[13] The Applicants note that they will operate each Aberdeen China A Fund Series such that rule 17f–1, rule 17f–2, and rule 17f–3 will not be applicable to it.

[14] *See supra,* footnote 1.

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–267, OMB Control No. 3235–0272]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 11a–2

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 11a–2 (17 CFR 270.11a–2) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) permits certain registered insurance company separate accounts, subject to certain conditions, to make exchange offers without prior approval by the Commission of the terms of those offers. Rule 11a–2 requires disclosure, in certain registration statements filed pursuant to the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) of any administrative fee or sales load imposed in connection with an exchange offer.

There are currently 673 registrants governed by Rule 11a–2. The

Commission includes the estimated burden of complying with the information collection required by Rule 11a–2 in the total number of burden hours estimated for completing the relevant registration statements and reports the burden of Rule 11a–2 in the separate Paperwork Reduction Act (''PRA'') submissions for those registration statements (see the separate PRA submissions for Form N–3 (17 CFR 274.11b), Form N–4 (17 CFR 274.11c) and Form N–6 (17 CFR 274.11d). The Commission is requesting a burden of one hour for Rule 11a–2 for administrative purposes.

The estimate of average burden hours is made solely for the purposes of the PRA, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules or forms. With regard to Rule 11a–2, the Commission includes the estimate of burden hours in the total number of burden hours estimated for completing the relevant registration statements and reported on the separate PRA submissions for those statements (see the separate PRA submissions for Form N–3, Form N–4 and Form N–6).

The information collection requirements imposed by Rule 11a–2 are mandatory. Responses to the collection of information will not be kept confidential. 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 control number.

The public may view the background documentation for this information collection at the following website, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: March 27, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–06658 Filed 3–30–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82948; File No. SR–IEX–2018–06]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing of Proposed Rule Change To Establish a New Optional Listing Category on the Exchange, ''LTSE Listings on IEX''

March 27, 2018.

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 March 15, 2018, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''SEC'' or ''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

Pursuant to the provisions of Section 19(b)(1) under the Act of 1934,[4] and Rule 19b–4 thereunder,[5] IEX is filing with the Commission a proposed rule change to establish a new optional listing category on the Exchange, which provides a differentiated choice for issuers and investors that prefer listing standards explicitly designed to promote long-term value creation. The text of the proposed rule change is available at the Exchange's website at *www.iextrading.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 the 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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization 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

(1) Overview

On June 17, 2016, the Commission granted the Exchange's application for registration as a national securities exchange under Section 6 of the Act,[6] including approval of rules applicable to the qualification, listing and delisting of companies on the Exchange. The Exchange has since adopted additional rules to create a listing venue to provide a new alternative for companies seeking to list their securities for trading on a registered national securities exchange.[7]

The Exchange is proposing to adopt rules to facilitate the creation of a new optional listing category on the Exchange for common equity securities, referred to as the ''LTSE Listings on IEX'' or ''LTSE Listings.'' The proposed rules for LTSE Listings, to be contained in new Chapter 14A of the Exchange's rules (the ''LTSE Listings Rules''), were initially developed by LTSE Holdings, Inc. (together with its affiliates, ''LTSE''), and provide a differentiated choice for issuers and investors that prefer listing standards explicitly designed to promote long-term value creation. The Exchange understands that LTSE anticipates separately registering a subsidiary as a national securities exchange in the future, but has entered into an arrangement with the Exchange in order to make the LTSE Listings Rules available to potential interested companies in advance of its own subsidiary's registration as a national securities exchange.

Becoming subject to the LTSE Listings Rules would be an optional election. Companies listed on the Exchange that do not elect to be subject to the LTSE Listings Rules would not be required to comply with Chapter 14A. However, companies that list on LTSE Listings (''LTSE Listings Issuers'') would be subject to the LTSE Listings Rules, as well as the quantitative listing requirements set forth in IEX Rule Series 14.300, and all other applicable listing rules of the Exchange set forth in Chapter 14 of the IEX Rulebook, except

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(1).

[5] 17 CFR 240.19b–4.

[6] 15 U.S.C. 78f.

[7] *See, e.g.,* Securities Exchange Act Release No. 80453 (April 13, 2017), 82 FR 18507 (April 19, 2017); Securities Exchange Act Release No. 81316 (August 4, 2017), 82 FR 37474 (August 10, 2017); Securities Exchange Act Release No. 80905 (June 12, 2017), 82 FR 27748 (June 16, 2017).

as they may be specifically modified for LTSE Listings Issuers.

At this time, the Exchange is limiting the availability of LTSE Listings to companies seeking to list on LTSE Listings concurrently with their initial public offering (whether listing on LTSE Listings only or dually listing on LTSE Listings and another national securities exchange). The Exchange would not permit issuers already listed on another national securities exchange to transfer to LTSE Listings.

The Exchange believes that the new LTSE Listings category will introduce a differentiated choice for issuers and investors that prefer listing standards explicitly designed to promote long-term value creation, potentially enhancing opportunities for capital formation, as well as contributing to greater competition for listings among national securities exchanges. At the same time, as LTSE Listings will be an entirely optional listing category, the introduction of LTSE Listings will not impact companies that elect to list on the Exchange under its existing listing rules.

(2) Background

(A) Concerns about Short-Termism in the Markets

Many academics, commentators, market participants,[8] as well as certain current and former members of the Commission [9] have voiced concerns regarding so-called ''short-termism'' and the risk that some investors' focus on short-term results could put pressure on companies to sacrifice long-term value creation in order to reach quarterly or other short-term expectations.

Commenters have pointed to the dramatically declining average amount of time that an investor holds a stock as evidence of a greater short-term focus.[10] Share turnover data suggests that investors held stocks for an average of about eight years in 1960, compared with about eight months in 2015.[11] While a great deal of this turnover may be attributable to the growth of high-frequency trading strategies (which accounted for about 50% of all U.S. trade volume in 2016),[12] more traditional institutional investors have shown reduced holding periods as well. A 2013 survey showed that 96% of institutional investors executed round-trip trades that lasted less than one month, with 23% of their trading volume relating to trades that are held for less than three months.[13]

Some commenters believe that current public market dynamics subject public companies to intense pressure to meet quarterly performance targets, resulting in negative consequences for long-term value creation.[14] One study found that 80% of chief financial officers of public companies acknowledge that they would forego long-term value creation initiatives like research and development in order to avoid missing quarterly targets.[15] Further, a 2013

[8] *See, e.g.,* McKinsey & Company, McKinsey Global Institute, *Measuring the Economic Impact of Short-Termism* (February 2017), *available at http://www.mckinsey.com/~/media/mckinsey/global%20themes/long%20term%20capitalism/where%20companies%20with%20a%20long%20term%20view%20outperform%20their%20peers/measuring-the-economic-impact-of-short-termism.ashx* (''Our findings show that companies we classify as 'long term' outperform their shorter-term peers on a range of key economic and financial metrics.''); Aspen Institute, *American Prosperity Project* (December 2016*), available at https://assets.aspeninstitute.org/content/uploads/2017/01/American-Prosperity-Project_Policy-Framework_FINAL-1.3.17.pdf* (''Perverse incentives in our corporate governance system undermine the health of capitalism itself. Short-termism is baked into our tax system and is evident in the decisions, regulations and rules that govern corporations and capital markets. Changes to the rules of the game are a necessary step to rebuild the public's trust in our economic system.''); Martin Lipton, *The New Paradigm* (January 11, 2017), *available at http://www.wlrk.com/docs/thenewparadigm.pdf* (''The economic impact of a short-term myopic approach to managing and investing in businesses has become abundantly clear and has been generating rising levels of concern across a broad spectrum of stakeholders, including corporations, investors, policymakers and academics. The proposition that short-term financial activists and reactive corporate behavior spur sustainable improvements in corporate performance, and thereby systemically increase rather than undermine long-term economic prosperity and social welfare, has been overwhelmingly disproved by the real world experience of corporate decision-makers as well as a growing body of academic research.''); Chief Justice Leo Strine, *Who Bleeds When the Wolves Bite? A Flesh-and-Blood Perspective on Hedge Fund Activism and Our Strange Corporate Governance System* (April 2017), *available at https://ssrn.com/abstract=2921901* (''Rather, human investors would see great benefit from reforms encouraging the agents responsible for their money to adopt the long-term horizon held by their principals, *i.e.,* human investors.''); Travis Baratko, *A Times-Mirror Conversation With Sen. Mark Warner,* The Loudoun Times-Mirror (July 27, 2015), *available at http://www.loudountimes.com/news/article/a_loudoun_times_mirror_conversation_with_sen._mark_warner432* (quoting Senator Mark Warner as noting that ''[P]eople being investors who are only focused on short-termism, too often you can squeeze a quarterly profit out at the expense of a long-term value proposition.'').

[9] *See, e.g.,* Jay Clayton, Hearing before the Senate Banking Committee on the Nomination of Jay Clayton, of New York, to be a Member of the Securities and Exchange Commission (March 23, 2017), *available at https://www.gpo.gov/fdsys/pkg/CHRG-115shrg24998/html/CHRG-115shrg24998.htm* (''In my experience, certain companies view the operational and other pressures inherent in quarterly earnings as costly, including because they detract from long-term planning and strategic initiatives''); Commissioner Daniel M. Gallagher, Activism, Short-Termism, and the SEC: Remarks at the 21st Annual Stanford Directors' College (June 23, 2015), *available at https://www.sec.gov/news/speech/activism-short-termism-and-the-sec.html* (''[T]here seems to be a predominance of short-term thinking at the expense of long-term investing. Some activists are swooping in, making a lot of noise, and demanding one of a number of ways to drive a short-term pop in value: spinning off a profitable division, beginning a share buy-back program, or slashing capital expenditures or research and development expenses.''); Commissioner Kara M. Stein, Toward Healthy Companies and a Stronger Economy: Remarks to the U.S. Treasury Department's Corporate Women in Finance Symposium (April 30, 2015), *available at https://www.sec.gov/news/speech/stein-toward-healthy-companies.html* (''The heart of the argument is that short-term pressures from certain investors, and markets in general, compel companies to look narrowly at the short-term. As a result, companies become overly focused on meeting quarterly earnings targets. . .To meet these demands, companies have to cut back on capital expenditures, research and development, workforce training, and other investments that lead to new innovation, higher productivity, and future growth.'').

[10] *See, e.g.,* Dominic Barton, *Capitalism for the Long Term,* Harvard Business Review (March 2011), *available at https://hbr.org/2011/03/capitalism-for-the-long-term;* Tragedy of the Horizon Project, *The Long and Winding Road: How Long-Only Equity Managers Turn Over Their Portfolios Every 1.7 Years* (February 2017), *available at http://www.tragedyofthehorizon.com/The-Long-And-Winding-Road.pdf;* Martin Cremers, Ankur Pareek and Zacharias Sautner, *Short-Term Investors, Long-Term Investments, and Firm Value* (March 14, 2017), *available at https://ssrn.com/abstract=2720248;* Alana Semuels, How to Stop Short-Term Thinking at America's Companies, The Atlantic (December 30, 2016), *available at https://www.theatlantic.com/business/archive/2016/12/short-term-thinking/511874;* Roger L. Martin, Yes, Short-Termism Really is a Problem, Harvard Business Review (October 9, 2015), *available at https://hbr.org/2015/10/yes-short-termism-really-is-a-problem.*

[11] New York Stock Exchange, Annual Reported Volume, Turnover Rate, Reported Trades (2004), *available at http://www.nyxdata.com/nysedata/asp/factbook/viewer_edition.asp?mode=table&key=2206&category=4;* World Bank, Stocks Traded, Turnover Ratio of Domestic Shares (2015), *available at https://data.worldbank.org/indicator/CM.MKT.TRNR?end=2015&locations=US&start=1975* (hereinafter ''Turnover Ratio of Domestic Shares'').

[12] Ana Avramovic, *Credit Suisse Market Commentary: We're All High-Frequency Traders Now* (March 15, 2017), *available at https://edge.credit-suisse.com/edge/Public/Bulletin/Servefile.aspx?FileID=28410&m=-1290757752.*

[13] Bidisha Chakrabarty, Pamela C. Moulton and Charles Trzcinka, *Institutional Holding Periods* (April 29, 2013), *available at https://scholarship.sha.cornell.edu/cgi/viewcontent.cgi?article=1001&context=conf.*

[14] McKinsey Global Institute, *Measuring the Economic Impact of Short-Termism* (February 2017), *available at http://www.mckinsey.com/~/media/mckinsey/global%20themes/long%20term%20capitalism/where%20companies%20with%20a%20long%20term%20view%20out perform%20their%20peers/measuring-the-economic-impact-of-short-termism.ashx. C.f.* James B. Stewart, Amazon Says Long Term And Means It, N.Y. Times (December 16, 2011) (noting Amazon.com's willingness to invest in long-term initiatives notwithstanding the impact on its short-term quarterly earnings).

[15] John R. Graham, Campbell R. Harvey, Shiva Rajgopal, *Value Destruction and Financial Reporting Decisions* (September 6, 2006), *available at https://www0.gsb.columbia.edu/mygsb/faculty/research/pubfiles/12924/Rajgopal_value.pdf* (''80%

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study found that companies projected to just miss their earnings per share (''EPS'') forecasts by a few cents are significantly more likely to repurchase shares than companies that beat their EPS forecasts by a few cents, suggesting efforts to increase EPS through financial engineering rather than growth.[16] At the same time, this study found that in the calendar year following repurchases, these same companies decreased their number of employees, investment in research and development, and capital expenditures, which the study authors found suggests that these companies may have been willing to forego investment in long-term growth in order to meet short-term financial targets.[17]

The greater focus on short-term financial performance noted by these commenters also coincides with a reduction in the number of private companies seeking to undertake initial public offerings (''IPOs'') and list their shares on the U.S. public markets. From 2001 through 2016, the U.S. averaged approximately one-third of the IPOs per year than it did each year between 1998 and 2000.[18] Calendar year 2016 had the fewest number of IPOs since the financial crisis years of 2008 and 2009,[19] although there was a relative increase in 2017.[20] The total number of listed companies in the United States also fell by almost 50% in the twenty year period from 1996 through 2016, down from over 8,000 companies listed on U.S. exchanges in 1996 to 4,333 in June of 2016.[21]

This decline is driven by fewer companies going public, existing public companies going private or merging with other public companies, and those companies that undertake an IPO doing so at a much later stage. Between 1980 and 2000, companies that went public typically did so about 7.6 years after founding.[22] Since then, that timespan has grown longer; between 2001 and 2016, the average age of a company at its IPO was nearly 12 years.[23]

The Exchange believes that these trends have significant consequences for companies, investors, and the economy as a whole. A 2011 report by the IPO Task Force reported that ''up to 22 million jobs may have been lost'' as a result of the decline in IPOs.[24] The trend toward companies staying private also limits the investment opportunities for ordinary investors,[25] as most retail investors are not ''accredited investors'' eligible to invest in private placements pursuant to Rule 506 of Regulation D[26] under the Securities Act of 1933.[27] Although institutional investors may provide the investment capital that these companies need, some have voiced concerns that private markets lack the transparency, liquidity, price discovery, and protections of the public marketplace.[28]

Although there are a number of potential causes for the decline in the number of IPOs and the number of public companies,[29] some commenters believe that the short-term pressures placed on public companies have discouraged some newer companies from conducting initial public offerings,[30] and have led others to go private.[31] Indeed, even when newer companies do undertake an IPO, in recent years many have sought to do so in a way that limits the public market's short-term pressures, by retaining for the founders much of the voting control.[32]

(B) Listing Standards for Long-Term Focused Companies and Investors

The Exchange believes that companies should be able to maintain a public listing on an exchange that provides a differentiated choice for issuers and investors that prefer listing standards explicitly designed to promote long-term value creation. While all companies that may list on the Exchange can focus on long-term value creation, providing a listing category with listing rules that address some of

of survey participants report that they would decrease discretionary spending on R&D, advertising and maintenance to meet an earnings target'').

[16] Heitor Almeida, Vyacheslav Fos, Mathias Kronlund, *The Real Effects of Share Repurchases* (June 8, 2015), *available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2276156.*

[17] *Id.*

[18] Jay R. Ritter, *Initial Public Offerings: Updated Statistics* (August 8, 2017), *available at https://site.warrington.ufl.edu/ritter/files/2017/08/IPOs2016Statistics.pdf.*

[19] *Id.*

[20] Ernst & Young, *Global IPO Trends: Q3 2017* (2017), *available at http://www.ey.com/Publication/vwLUAssets/ey-global-ipo-trends-q3-2017/$FILE/ey-global-ipo-trends-q3-2017.pdf* (noting 111 IPOs in the U.S. through the third quarter of 2017, a 35% increase year-over-year).

[21] See U.S. Dept. of the Treasury, A Financial System that Creates Economic Opportunities: Capital Markets at p. 21 (October 2017), available at *https://www.treasury.gov/press-center/press-releases/Documents/A-Financial-System-Capital-Markets-FINAL-FINAL.pdf.*

[22] Ritter, *supra* note 18.

[23] *Id.*

[24] IPO Task Force, *Rebuilding the IPO On-Ramp* (October 20, 2011), *available at https://www.sec.gov/info/smallbus/acsec/rebuilding_the_ipo_on-ramp.pdf.*

[25] *See* U.S. Dept. of the Treasury, *A Financial System that Creates Economic Opportunities: Capital Markets* at p. 27 (October 2017), *available at https://www.treasury.gov/press-center/press-releases/Documents/A-Financial-System-Capital-Markets-FINAL-FINAL.pdf* (''If a company decides not to go public and instead raises capital in the private market or as an exempt offering, it could be subject to investor qualification requirements and/or offering limitations. This could result in the average investor being deprived of an opportunity to consider investing in that enterprise.'').

[26] 17 CFR 230.506.

[27] 15 U.S.C. 77a *et seq.*

[28] Commissioner Kara M. Stein, Lighting our Capital Markets (July 11, 2017), *available at https://www.sec.gov/news/speech/stein-lighting-our-capital-markets-071117.*

[29] Jay R. Ritter, Xiaohui Gao Bakshi, Zhu, Zhongyan, *Where Have All the IPOs Gone?* (August 26, 2013), *available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1954788* (hypothesizing that economies of scope make it more attractive for companies to sell themselves to a larger organization than remain independent); Elisabeth de Fontenay, *The Deregulation of Private Capital and the Decline of the Public Company,* Duke Law School Public Law & Legal Theory Series No. 2017–33 (April 11, 2017), *available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2951158* (suggesting that the easing of regulation on private securities offerings and transactions have decreased the incentive for firms to become public); PwC, *Considering an IPO? The costs of going and being public may surprise you* (September 2012), *available at http://www.pwc.com/us/en/deals/publications/assets/pwc-cost-of-ipo.pdf* (discussing cost of initial IPO and remaining public); Michael J. Mauboussin, *The Incredible Shrinking Universe of Stocks,* Credit Suisse Global Financial Strategies (March 22, 2017), *available at https://research-doc.credit-suisse.com/docView?language=ENG&format=PDF&sourceid=em&document_id=1072753661&serialid=h%2B%2FwLdU%2FTIaitAx1rnamfYsPRAuTFRGdTSF4HZIvTkA%3D* (suggesting causes including regulatory compliance costs, increased merger and acquisition activity, and availability of late-stage venture capital).

[30] Avi Steinlauf, The Case for Staying Private (and Why IPOs Are Overrated), Inc., available at *https://www.inc.com/avi-steinlauf/why-we-are-staying-private.html* (arguing that public companies are subject to ''short-term market players [that] have no vested long-term interest'' in the company, while ''private organizations can preserve their focus on what is truly best for the organization's overall success''); Maureen Farrell, America's Roster of Public Companies Is Shrinking Before Our Eyes, Wall Street Journal (January 6, 2017), available at *https://www.wsj.com/articles/americas-roster-of-public-companies-is-shrinking-before-our-eyes-1483545879* (citing University of Michigan Ross School of Business professor Jerry Davis, who believes that ''[t]he dangers of being a public company are really evident,'' among them, ''having an investor base that clamors for short-term stock gains''); Jonathan Macey, As IPOs Decline, the Market is Becoming More Elitist, L.A. Times (January 10, 2017), available at *http://www.latimes.com/opinion/op-ed/la-oe-macey-ipo-democracy-20170110-story.html* (Op-Ed by professor Macey noting, among other things, that ''[o]ne drawback to going public is shareholders' sometimes excessive focus on short-term stock price fluctuations'').

[31] *See, e.g.,* Michael Dell, Going Private is Paying Off for Dell, Wall Street Journal (November 24, 2014) (''As a private company, Dell now has the freedom to take a long-term view. No more pulling R&D and growth investments to make in-quarter numbers . . . No more trade-offs between what's best for a short-term return and what's best for the long-term success of our customers'').

[32] Wall Street Journal Business Blog, *The Big Number* (August 17, 2015), *available at https://www.wsj.com/articles/the-big-number-1439865699;* Ken Bertsch, *Snap and the Rise of No-Vote Common Shares,* Harvard Law School Forum on Corporate Governance and Financial Regulation (May 26, 2017), *available at https://corpgov.law.harvard.edu/2017/05/26/snap-and-the-rise-of-no-vote-common-shares.*

the concerns regarding short-termism could encourage greater participation in the public markets by long-term focused companies and investors, potentially increasing the number of companies willing to become public.

The Exchange understands that LTSE engaged in a multiyear effort to develop the LTSE Listings Rules based on its analysis of academic research, market experience, and input from a wide variety of long-term focused stakeholders. The LTSE Listings Rules are designed to promote the interests of companies that seek to focus on long-term value creation as well as the transparency and governance concerns of long-term focused investors. LTSE's analysis found that, although individual stakeholders may favor or disfavor particular LTSE Listings Rules, long-term focused companies and investors' concerns with particular LTSE Listings Rules were offset by the benefits they saw from the package of the LTSE Listings Rules as a whole.

The Exchange acknowledges that many, if not all, of the proposed requirements contained in the LTSE Listings Rules could be undertaken voluntarily by any company even in the absence of the LTSE Listings category. However, the Exchange understands that many long-term focused investors indicated to LTSE that they would view a company that affirmatively chose to list on an exchange (or listing category thereof) that required compliance with these rules, therefore subjecting itself to compliance as a regulatory condition to continued listing, as demonstrating a greater commitment to long-term focus than one that voluntarily undertook to abide by similar practices, but could readily choose to change its practices thereafter. In addition, because an exchange, as a self-regulatory organization, is required to monitor and enforce compliance with its rules,[33] the Exchange believes that long-term focused investors appreciate and have confidence in the oversight that a national securities exchange provides to ensure that a company complies with its exchange listing obligations. Similarly, the Exchange understands that many long-term focused companies believe that they would be better able to withstand short-term pressures if they were subject to rules that explicitly required them to disclose actions promoting a long-term focus. Further, rather than each company acting independently, requiring investors to analyze each company's governance separately, investors familiar with LTSE Listings would quickly know the rules that apply to an LTSE Listings Issuer.

The Exchange has entered into an arrangement with LTSE to authorize the Exchange to make the LTSE Listings Rules available as a listing category of the Exchange. Through extensive discussions, LTSE has provided the Exchange with background information on the purpose of each of the LTSE Listings Rules, with which the Exchange agrees. As a result, statements herein that describe the Exchange's belief are informed by information provided by LTSE. Although the LTSE Listings Rules were developed by LTSE, the Exchange will retain full self-regulatory responsibility for determining initial and continuing compliance with the Exchange's listing standards, including for those companies that elect to be subject to the LTSE Listings Rules. In conducting its LTSE Listings business, IEX will retain, as its agents, a small number of staff that also are employed by LTSE (the ''LTSE Listings Agents''), but will not receive regulatory services from LTSE itself. The sole responsibility of LTSE Listings Agents will be to provide IEX with expertise in interpreting the LTSE Listings Rules and assistance in conducting the LTSE Listings business, and their involvement will not extend to other matters within the Exchange's jurisdiction. The LTSE Listings Agents will be subject to the Exchange's oversight and regulatory authority as the responsible self-regulatory organization.[34]

(3) Proposed LTSE Listings Rules

The proposed LTSE Listings Rules that would apply to LTSE Listings Issuers fall into five general categories: (i) Board of directors and committee requirements, (ii) rules requiring supplemental long-term disclosures, (iii) rules requiring long-term alignment of executive compensation, (iv) rules requiring long-term shareholder voting structure, and (v) certain other rules that further encourage LTSE Listings Issuers to focus on long-term value creation. In addition, the Exchange is proposing rules that would clarify the application of certain existing Exchange rules to LTSE Listings Issuers.

(A) Board of Directors and Committee Requirements

The proposed LTSE Listings Rules would create new requirements for the boards of directors and board committees of LTSE Listings Issuers designed to align the board with the objectives of the LTSE Listings Rules. Specifically, the LTSE Listings Rules would require each LTSE Listings Issuer to establish a board committee dedicated to overseeing the issuer's strategies for creating and sustaining long-term growth and a committee dedicated to selecting or recommending qualified director nominees. The LTSE Listings Rules would also impose

[33] *See* 15 U.S.C. 78s(g)(1)(A).

[34] Notwithstanding the services provided by the LTSE Listings Agents to the Exchange, all actions taken by the Exchange will ultimately be based on the Exchange's determination that the action is appropriate and consistent with the Act, the Commission's rules thereunder and the Exchange's rules. Pursuant to the Exchange's retention of LTSE Listings Agents, the LTSE Listings Agents will provide certain advisory, marketing, public communications, and sales services to IEX in connection with LTSE Listings. For example, LTSE Listings Agents will evaluate issuers seeking to list on the Exchange under the LTSE Listings Rules and will assist in monitoring LTSE Listings Issuers for compliance with the LTSE Listing Rules. The Exchange expects that the LTSE Chief Regulatory Officer will be a LTSE Listings Agent (and other LTSE regulatory personnel that do not have direct involvement in LTSE's commercial operations may also be retained by the Exchange to serve as LTSE Listings Agents). At all times, LTSE Listings Agents will be subject to the satisfaction and the oversight of the Exchange's Chief Regulatory Officer, with all actions proposed by LTSE Listings Agents subject to the Exchange's regulatory authority. Separately, the Exchange will permit LTSE to use and redistribute written marketing, public communications, and sales materials concerning the LTSE Listings business, subject to the Exchange's consent (not to be unreasonably withheld). Further, the Exchange's arrangement with LTSE Listings Agents is subject to important restrictions designed to protect the Exchange's responsibilities as a self-regulatory organization and the confidentiality of its books and records pertaining thereto. First, each LTSE Listings Agent is considered to be an agent of the Exchange in connection with performance of services under the Exchange's arrangement with LTSE, pursuant to Article XI, Section 4 of the Amended and Restated Operating Agreement of Investors' Exchange LLC. Thus, as appropriate, information pertaining to the self-regulatory function of the Exchange may be made available to a LTSE Listings Agent to the extent necessary or appropriate to properly discharge the self-regulatory responsibilities of the Exchange. However, pursuant to the Exchange's arrangement with LTSE, the Exchange will not share confidential regulatory information with LTSE (other than with LTSE regulatory personnel that are LTSE Listings Agents and that do not have direct involvement in LTSE's commercial operations). Additionally, LTSE has agreed that each LTSE Listings Agent will be required to consent in writing to the application to them of the following provisions, which are consistent with Article VII of the Bylaws of IEX Group, Inc.: Non-interference with, and due regard for, the Exchange's self-regulatory function; confidentiality of the Exchange's books and records pertaining to its self-regulatory function; maintenance of books and records related to services under the Exchange's arrangement with LTSE and services provided to the Exchange by LTSE Listings Agents at a location within the United States; compliance with the federal securities laws and the rules and regulations promulgated thereunder and cooperation with the SEC in respect of the SEC's oversight responsibilities regarding the Exchange and the self-regulatory functions and responsibilities of the Exchange; and consent to jurisdiction of the United States federal courts, the SEC and the Exchange for purposes of any suit, action or proceeding arising out of or relating to services provided to the Exchange and the Exchange's arrangement with LTSE.

additional obligations on audit committees and compensation committees designed to increase oversight and transparency, among other things. These corporate governance requirements are discussed further below.

(i) Long-Term Strategy and Product Committee

Proposed Rule 14A.405(c)(1) would require that each LTSE Listings Issuer's board of directors maintain a committee specifically dedicated to overseeing the LTSE Listings Issuer's strategic plans for long-term growth (the ''LTSP Committee''). Proposed Rule 14A.405(c)(3) would require that an LTSE Listings Issuer adopt a formal written LTSP Committee charter (and that the LTSP Committee will review and reassess the adequacy of the charter on an annual basis) specifying, among other things, the scope of the LTSP Committee's responsibilities, and how it will carry out those responsibilities, including structure, processes and membership requirements, and that the LTSP Committee must report regularly to the board of directors. The requirement to report regularly is intended to ensure that the board of directors has insight into the LTSP Committee's work and input into the LTSE Listings Issuer's strategic objectives.

Although LTSE Listings Issuers would have some flexibility in designing their LTSP Committee, in order to ensure that adequate board focus is placed on long-term strategy, proposed Rule 14A.405(c)(4) would require that the LTSP Committee include a minimum of three members of the board and that a majority of the LTSP Committee members be independent. This majority independence requirement is intended to mitigate potential conflicts of interest and ensure that outside perspectives are brought into discussions and decisions regarding the company's long-term strategy.

Proposed Rule 14A.405(c)(3)(C) would require that the LTSP Committee's charter be made available on or through the LTSE Listings Issuer's website. The Exchange believes that increased transparency about the LTSP Committee's functions and policies is in the best interest of investors, and companies that hold themselves to a set of long-term standards should make such information available. The Exchange notes that Item 407 of Regulation S–K [35] requires that a public company's audit, nominating and compensation committee charters be either available to security holders on the company's website or as an appendix to its proxy or information statement provided to security holders at least once every three fiscal years, or if the charter has been materially amended since the beginning of the company's last fiscal year. The Exchange understands that many long-term focused investors expect to be able to readily access corporate governance information, such as board committee charters, on a company's website rather than by searching through a company's SEC filings, and accordingly the Exchange believes that it is appropriate to explicitly impose this requirement.

Proposed Rule 14A.405(c)(2) would provide LTSE Listings Issuers with additional flexibility by permitting the board of directors to allocate the LTSP Committee's responsibilities to committees of their own denomination, provided that the committee (i) is subject to a formal written charter that satisfies the requirements of proposed Rule 14A.405(c)(3), including that such committee report regularly to the board of directors, and (ii) complies with the committee composition requirements set forth in proposed Rule 14A.405(c)(4). However, proposed Rule 14A.405(c)(1) would prohibit the LTSP Committee from assuming any roles or responsibilities that are required to be undertaken by an LTSE Listings Issuer's independent board committees, since the LTSP Committee is not required to be composed of all independent directors.

(ii) Nominating/Corporate Governance Committee

IEX Rule 14.405(e)(1)(A) requires that director nominees may be selected (or recommended for selection by the board of directors) by either independent directors constituting a majority of the board's independent directors or a nominations committee compromised solely of independent directors. With respect to LTSE Listings Issuers, proposed Rule 14A.405(d)(1) would require that director nominees must be selected (or recommended for selection by the board of directors) by a nominating/corporate governance committee comprised solely of independent directors, rather than independent directors constituting a majority of the board's independent directors. The Exchange believes that, in view of the differentiated focus of the LTSE Listings category, requiring LTSE Listings Issuers to maintain a separate, independent nominating/corporate governance committee would better facilitate selection of directors that are aligned with such focus. In addition, another national securities exchange has a substantially similar requirement, requiring that listed companies select director nominees through a separate nominating committee composed entirely of independent directors.[36]

Notwithstanding the requirement that the nominating/corporate governance committee be comprised solely of independent directors, proposed Rule 14A.405(d)(2) would provide that the nominating/corporate governance committee may include a non-independent director if the board, under exceptional and limited circumstances, determines that such individual's membership on the committee is required by the best interests of an LTSE Listings Issuer and its shareholders and certain other conditions are satisfied. In addition, proposed Rule 14A.405(d)(3) would provide that exclusively independent director oversight of director nominations shall not be required in cases where the right to nominate a director legally belongs to a third party; provided that an LTSE Listings Issuer would still be obligated to comply with all committee composition requirements. These limited exceptions are consistent with exceptions contained in the Exchange's corresponding rules for companies other than LTSE Listings Issuers.[37]

IEX Rule 14.405(e)(5) provides that the requirements regarding director nominations set forth in IEX Rule 14.405 do not apply if the issuer is subject to a binding obligation that requires a director nomination structure inconsistent with IEX Rule 14.405 and such obligation pre-dates the approval of IEX Rule 14.405. Proposed Rule 14A.405(d)(4), however, would provide that LTSE Listings Issuers may not rely on this exception. The Exchange believes that this provision, which would permit a nomination process and board composition based on a pre-existing obligation that pre-dates when the IEX rules were approved, is inconsistent with the goal of allowing longer-term shareholders to gain voting rights over time and the flexibility is unnecessary given that the required timing for the pre-existing obligation is so limited.

Proposed Rule 14A.405(d)(6)(A) would require that each LTSE Listings Issuer adopt a formal written nominating/corporate governance committee charter (and that the nominating/corporate governance committee review and reassess the adequacy of the formal written charter

[35] 17 CFR 229.407.

[36] *See* NYSE Listed Company Manual, Rule 303A.04.

[37] *See* IEX Rules 14.405(e)(3) and (4).

on an annual basis) specifying, among other things, the scope of the nominating/corporate governance committee's responsibilities, and how it will carry out those responsibilities, including structure, processes and membership requirements, and that the nominating/corporate governance committee must report regularly to the board of directors. The explicit requirement to report regularly is intended to ensure that the board of directors has insight into the nominating/corporate governance committee's work.

Proposed Rule 14A.405(d)(6)(B) would require that the nominating/corporate governance committee's charter be made available on or through an LTSE Listings Issuer's website. The Exchange believes that increased transparency about the nominating/corporate governance committee's functions and policies is in the best interest of long-term investors, and companies that hold themselves to a set of long-term standards should make such information available. The Exchange notes that Item 407 of Regulation S–K [38] requires that a public company's nominating committee charter be either available to security holders on the company's website or as an appendix to its proxy or information statement provided to security holders at least once every three fiscal years, or if the charter has been materially amended since the beginning of the company's last fiscal year. The Exchange understands that many long-term focused investors expect to be able to readily access corporate governance information, such as board committee charters, on a company's website rather than by searching through a company's SEC filings, and accordingly the Exchange believes that it is appropriate to explicitly impose this requirement.

Proposed Rule 14A.405(d)(5) would provide LTSE Listings Issuers additional flexibility by permitting the board of directors to allocate the nominating/corporate governance committee's responsibilities to committees of their own denomination, provided that the committee is comprised entirely of independent directors and that such committee is subject to a formal written charter that satisfies the requirements of proposed Rule 14A.405(d)(6), including that such committee report regularly to the board of directors.

(iii) Additional Audit Committee and Compensation Committee Requirements

As is the case with all issuers listed on the Exchange, LTSE Listings Issuers are required to comply with the audit committee and compensation committee requirements set forth in IEX Rules 14.405(c) and (d). LTSE Listings Issuers, however, would additionally be required to comply with audit committee and compensation committee requirements set forth in proposed Rule 14A.405.

Specifically, under proposed Rules 14A.405(a) and 14A.405(b)(2), the audit committee and compensation committee charters must specify that each committee will report regularly to the board of directors. While the Exchange believes that it is inherent in any public company's board and committee organizational structure that board committees report regularly to the board, in view of the focus of the LTSE Listings category, the Exchange also believes it is appropriate to make this requirement explicit for LTSE Listings Issuers. In addition, the charters of each of the audit committee and compensation committee must be made available on or through an LTSE Listings Issuer's website. The Exchange notes that Item 407 of Regulation S–K [39] under the Securities Act of 1933 [40] requires that a public company's audit and compensation committee charters be either available to security holders on the company's website or as an appendix to its proxy or information statement provided to security holders at least once every three fiscal years, or if the charter has been materially amended since the beginning of the company's last fiscal year. The Exchange understands that many long-term focused investors expect to be able to readily access corporate governance information, such as board committee charters, on a company's website rather than by searching through a company's SEC filings, and accordingly the Exchange believes that it is appropriate to explicitly impose this requirement. The Exchange further notes that another national securities exchange requires companies listed on their exchange to meet similar requirements with respect to their audit committee and compensation committee.[41]

In addition to the foregoing charter requirements, proposed Rule 14A.405(b)(2)(A)(ii) would require that the compensation committee charter specify that the compensation committee must adopt executive compensation guidelines. Proposed requirements with respect to executive compensation guidelines are described under ''Long-Term Alignment of Executive Compensation'' below. Proposed Rule 14A.405(b)(1) would provide LTSE Listings Issuers additional flexibility by permitting the board of directors to allocate the compensation committee's responsibilities to committees of their own denomination, provided that the committee is comprised entirely of independent directors and that such committee is subject to a formal written charter that satisfies the requirements of IEX Rule 14.405(d)(1) and proposed Rule 14A.405(b)(2), including that such committee report regularly to the board of directors.

(iv) Corporate Governance Guidelines

Pursuant to proposed Rule 14A.409, each LTSE Listings Issuer would be required to adopt and disclose corporate governance guidelines. These corporate governance guidelines would be required to address director qualification standards, director responsibilities, director access to management, and director orientation and continuing education, among other things. In view of the differentiated focus of the LTSE Listings category, the Exchange believes that increased disclosure about the company's approach to corporate governance through the adoption and disclosure of corporate governance guidelines is appropriate for LTSE Listings Issuers. In addition, the Exchange notes that the proposed corporate governance guideline requirements are similar to the requirements imposed by the listing rules of another national securities exchange.[42]

Although proposed Rule 14A.409 would generally track the New York Stock Exchange's (''NYSE'') corporate governance guidelines requirements, the LTSE Listings Rules would deviate from these requirements in certain respects. Specifically, proposed Rule 14A.409(a)(4) would require that a significant portion—no less than 40%—of director compensation be paid in stock-based compensation tied to long-term periods. An LTSE Listings Issuer would be required to disclose in its corporate governance guidelines what it considers to be ''long-term'' for this purpose. In addition, this proposed rule would require that LTSE Listings Issuers adopt director stock ownership guidelines, which must include minimum ownership requirements that can be met over the length of board service. These provisions are designed to ensure that LTSE Listings Issuers

[38] 17 CFR 229.407.

[39] 17 CFR 229.407.

[40] 15 U.S.C. 77a *et seq.*

[41] *See* NYSE Listed Company Manual, Rules 303A.05(b) and 303A.07(b).

[42] *See* NYSE Listed Company Manual, Rule 303A.09.

incentivize directors to focus on the long-term, but also provide LTSE Listings Issuers with flexibility to design their own plans for director compensation. In addition, the Exchange does not believe that these requirements would impose a significant burden on LTSE Listings Issuers, as the Exchange believes that issuers have already trended toward having equity represent a large portion of director compensation.[43] Proposed Rule 14A.409(a)(4) would also provide that LTSE Listings Issuers consider other means of aligning director compensation with long-term strategies, including deferred share delivery, vesting periods or similar measures.

(B) Long-Term Strategy and Product Disclosures

The Exchange understands that LTSE's analysis indicated that long-term investors generally value information regarding a company's long-term plans and objectives, that may not otherwise be required to be disclosed. In particular, this information could (i) provide long-term investors with greater information upon which to evaluate a company's progress toward long-term goals and (ii) allow companies to be evaluated based on whether they are making prudent management and strategic decisions that investors believe enhance long-term growth. The proposed LTSE Listings Rules would therefore require—in addition to and separate from all disclosures required under applicable securities laws, the Commission's rules and the Exchange's other rules—that LTSE Listings Issuers provide certain supplemental disclosures regarding an LTSE Listings Issuer's long-term strategy and products (the ''LTSP Disclosures'').[44] The LTSP Disclosure requirements are supplemental to and would not supersede or impact other disclosure obligations. The LTSP Disclosures would be subject to all securities law requirements just as other public company disclosures. Proposed Rule 14A.207(a) would remind LTSE Listings Issuers that all disclosures must comply with applicable law and Commission rules and regulations, including rules and regulations pertaining to the use and reconciliation of non-GAAP financial measures and any securities law obligations regarding updating or correcting prior public statements or disclosures.

(i) Disclosure of Long-Term Growth Strategy

Proposed Rule 14A.207(c) would require each LTSE Listings Issuer to include in its LTSP Disclosures a discussion of the company's ''Long-Term Growth Strategy.'' Long-Term Growth Strategy would be defined for these purposes as ''the strategy, as determined by management and the board of directors and approved by the LTSP Committee, that is focused on achieving long-term growth.''[45] This requirement is designed to increase transparency for shareholders on the strategic goals of the company's managers and provide for greater alignment and accountability between a company's long-term vision and investor expectations. By disclosing a Long-Term Growth Strategy, managers have the opportunity to explain to shareholders the long-term goals and objectives specific to their company, and then be held responsible for achieving those objectives. While the disclosure of the Long-Term Growth Strategy must include the information described below, an LTSE Listings Issuer is otherwise free to design its Long-Term Growth Strategy with the explicit oversight and approval of its LTSP Committee.

Proposed Rule 14A.207(c)(1)(A) would require that each Long-Term Growth Strategy disclosure describe how the LTSE Listings Issuer defines ''long-term'' for purposes of its Long-Term Growth Strategy and how it made this determination.[46] Under proposed Rule 14A.207(c)(1)(B), LTSE Listings Issuers would be required to include in the Long-Term Growth Strategy disclosure a discussion of the ''Leading Indicators'' that the company uses to measure its progress toward its long-term goals. ''Leading Indicators'' are defined as those quantitative metrics, either financial or non-financial, that an LTSE Listings Issuer's management uses to help it forecast revenue, profit, or other common after-the-event measures of long-term success.[47] By way of example, a biotech company may use as a Leading Indicator the number of patents it has obtained. A media company, on the other hand, may prefer to use as a Leading Indicator the number of page views or ad clicks its website has received.

LTSE Listings Issuers must also discuss key milestones that the LTSE Listings Issuer aims to achieve with respect to its Leading Indicators and must report on the progress the LTSE Listings Issuer has made in achieving these key milestones. The LTSP Disclosures require use of Leading Indicators and key milestones so that companies may define and share with investors those long-term metrics that the company itself views as critical to measuring its success, providing investors insight into the company's internal analysis and allowing investors to consider the company's progress towards these long-term goals.

Proposed Rule 14A.207(c)(1)(C) would require that each Long-Term Growth Strategy disclosure include a discussion of any changes to an LTSE Listings Issuer's Long-Term Growth Strategy since its last publication, including changes to Leading Indicators and/or key milestones. An LTSE Listings Issuer's Long-Term Growth Strategy may evolve as its business develops and new goals are created or changed. This disclosure requirement would provide greater transparency by ensuring that long-term investors are made aware of any such changes to the issuer's Long-Term Growth Strategy and are able to measure an LTSE Listings Issuer's progress toward these goals.

Pursuant to proposed Rule 14A.207(c)(2), the Long-Term Growth Strategy must include details relating to different businesses of the LTSE Listings Issuer if the information is material to the overall strategy. The purpose of this proposed rule is to account for the fact that issuers may have diverse businesses with different strategic objectives. For example, a company may operate in multiple industries or have products tailored to different markets. This rule requires LTSE Listings Issuers to provide information relating to different strategies if such information is material to the broader long-term strategy.

While transparency into long-term strategy is an important goal and critical for long-term focused investors, in certain situations the Exchange understands that public disclosure of this information could risk competitive harm to the company. In these limited situations, proposed Rule 14A.207(c)(3) would provide an exemption. Specifically, if an LTSE Listings Issuer's LTSP Committee makes a determination that disclosure of any aspect of the LTSE Listings Issuer's Long-Term

[43] *See* Yaron Nili, *Trends in Board of Director Compensation,* HLS Forum on Corporate Governance and Financial Regulation (April 13, 2015), *available at https://corpgov.law.harvard.edu/2015/04/13/trends-in-board-of-director-compensation.*

[44] An LTSE Listings Issuer would be required to include its LTSP Disclosures in its Annual Report Supplement. *See infra* Section II.A.1.(3)(B)(v) (Location and Manner of LTSP Disclosures).

[45] *See* proposed Rule 14A.002(a)(11).

[46] The Exchange understands that LTSE Listings Issuers in different industries may have different definitions of ''long-term.'' For example, a pharmaceutical company that must spend years researching and testing the efficacy of a proposed new drug may have a much longer definition of ''long-term'' than a clothing retailer.

[47] *See* proposed Rule 14A.002(a)(10).

Growth Strategy would be ''reasonably likely to result in material harm'' to the company's competitive position, the LTSE Listings Issuer could exclude such information from its LTSP Disclosures, so long as the LTSE Listings Issuer complies with all applicable securities laws.[48] Any such determination would be required to be documented by the LTSP Committee and made in accordance with its fiduciary duties. In addition, proposed Rule 14A.405(c)(3)(B)(iv) would require that an LTSE Listings Issuer's LTSP Committee develop and disclose in its charter a process for making this determination and for determining that withholding the disclosure would not contravene any applicable securities laws. In order to ensure that investors are aware that the LTSP Disclosures of an LTSE Listings Issuer relying on this exemption are incomplete, proposed Rule 14A.207(c)(3) would require that such an LTSE Listings Issuer disclose in its LTSP Disclosures that it is withholding certain information as a result of competitive concerns. To ensure that investors have the opportunity to assess the judgment of the LTSP Committee regarding the withholding of competitive information, upon the time that any withheld information is no longer competitively sensitive, proposed Rule 14A.207(c)(3) would require that an LTSE Listings Issuer disclose that information in its LTSP Disclosures, even though this information may no longer be relevant to its current Long-Term Growth Strategy.

(ii) Disclosure Related to Buybacks

As noted above,[49] particular concern has been raised regarding the risk that some companies pressured to meet short-term goals may spend cash to repurchase their own shares rather than on making long-term investments. As a result, the Exchange believes that some long-term investors are particularly interested in enhanced disclosure regarding companies' share repurchase activity. Proposed Rule 14A.207(d) would therefore require that each LTSE Listings Issuer disclose certain information relating to ''Buybacks'' or issuer repurchases in addition to those required to be disclosed pursuant to Item 703 of Regulation S–K[50] under the Securities Act of 1933.[51] Specifically, under proposed Rule 14A.207(d) each LTSE Listings Issuer would be required to disclose in its LTSP Disclosures its ''EPS Net of Buybacks,'' defined in proposed LTSE Listings Rule 14A.002(a)(6) as the quotient calculated by dividing (i) net income (as reported in the LTSE Listings Issuer's financial statements in its most recent Annual Report) by (ii) the sum of outstanding shares and shares that were subject to a Buyback during the prior fiscal year. This disclosure requirement is designed to provide investors with transparency into the impact of Buybacks on a company earnings per share for any particular period, *i.e.,* by indicating what the company's earnings-per-share would have been had the company not engaged in repurchases.

(iii) Disclosure Related to Human Capital Investment

Proposed Rule 14A.207(e) would require that each LTSE Listings Issuer disclose in its LTSP Disclosures the extent to which the LTSE Listings Issuer's selling, general and administrative expenses (''SG&A'') (as reported in the LTSE Listings Issuer's most recent Annual Report)[52] consisted of ''Human Capital Investment.'' For these purposes, ''Human Capital Investment'' refers to the aggregate amount an LTSE Listings Issuer spends on formal training of workers in new skills to improve job performance, including, among other things, fees or expenses related to personnel hired or retained to train employees, training materials, tuition assistance and continuing education or similar programs.

Each LTSE Listings Issuer must also disclose the amount spent on Human Capital Investment per full-time equivalent employee. The Exchange understands that long-term investors generally are interested in this metric, and the disclosure requirement is thus designed to enable long-term investors to conduct a comparative analysis of Human Capital Investment per employee across LTSE Listings Issuers of different sizes.

The costs related to Human Capital Investment are generally accounted for within SG&A, and therefore considered an expense rather than an investment. The Exchange understands that long-term focused investors and companies believe that it is in the long-term interest of companies to make investments in their workforce to retain them and improve their skills. Although, as an accounting matter, these may be viewed as a short-term costs, the Exchange believes that long-term focused investors value information regarding the extent to which companies are making investments in the long-term development and success of its employees.

(iv) Disclosure Related to Research and Development

The Exchange understands that investments in research and development (''R&D'') are generally considered long-term investments for companies. LTSE's analysis indicated that additional data on R&D investment is particularly sought after by long-term focused investors. Therefore, proposed Rule 14A.207(f) would require that each LTSE Listings Issuer disclose in its LTSP Disclosures the amount of R&D spending that is short-term focused and the amount that is long-term focused. This requirement is intended to provide investors with greater transparency into an LTSE Listings Issuer's planning and goals around R&D programs, particularly in light of the risk that a company may under-invest in R&D in order to meet shorter-term financial metrics. Because each company and industry differs in its definition of long-term and short-term time horizons, proposed Rule 14A.207(f) provides flexibility by allowing LTSE Listings Issuers to determine their own definitions of short-term and long-term R&D programs, provided that an LTSE Listings Issuer disclose the definitions used and the process by which they determined them.

(v) Location and Manner of LTSP Disclosures

Proposed Rule 14A.207(b) would require an LTSE Listings Issuer to make its LTSP Disclosures publicly available pursuant to a supplement to the LTSE Listings Issuer's Annual Report (an ''Annual Report Supplement''). The Annual Report Supplement must be distributed to shareholders along with, and in the same manner as, the LTSE Listings Issuer's Annual Report. In addition, an LTSE Listings Issuer would

[48] This proposed requirement has the same objective as Instruction 4 of Item 402(b) of Regulation S–K, which provides that an SEC reporting company is not required to disclose in SEC filings certain information regarding compensation ''involving confidential trade secrets or confidential commercial or financial information, the disclosure of which would result in competitive harm for the registrant.'' *See also* Question 118.04 of Regulation S–K Questions and Answers of General Applicability (September 21, 2017), *available at https://www.sec.gov/divisions/corpfin/guidance/regs-kinterp.htm.*

[49] *See supra* notes 16–17 and accompanying text.

[50] 17 CFR 229.703.

[51] 15 U.S.C. 77a *et seq.*

[52] ''Annual Report'' is defined in Proposed Rule 14A.002(a)(1) as ''consistent with IEX Rule 14.207(d), the annual report made available to Shareholders containing audited financial statements of the LTSE Listings Issuer and its subsidiaries (which, for example, may be on Form 10–K, 20–F, 40–F or N–CSR) within a reasonable period of time following the filing of the annual report with the Commission.''

be required to make the Annual Report Supplement available on or through its website and include a statement in its Annual Report that the LTSP Disclosures are available in the Annual Report Supplement and provide the website address. These requirements are designed to facilitate transparency and ensure that shareholders are aware of and able to access an LTSE Listings Issuer's LTSP Disclosures. LTSE Listings Issuers would also be required to notify IEX Regulation [53] once its Annual Report Supplement has been made publicly available on its website. This requirement is designed to help the Exchange monitor for compliance with the LTSP Disclosure requirements.

(vi) Review by LTSP Committee

Pursuant to proposed Rule 14A.207(b), the LTSP Disclosures would be required to be reviewed and approved by the LTSP Committee on at least an annual basis. Based on its review, the LTSP Committee must determine whether to recommend to the board of directors that the LTSP Disclosures be included in the Annual Report Supplement.[54] Any board and committee approvals should be reflected in board resolutions as appropriate. This requirement is intended to increase alignment between board members and company managers on the company's long-term focus and helps to ensure that adequate board focus is placed on long-term strategy.

(vii) Disclosures Upon Initial Listing

As described above, an LTSE Listings Issuer would be required to include its LTSP Disclosures in its Annual Report Supplement. However, a newly public LTSE Listings Issuer may not provide its Annual Report Supplement to shareholders until months after its initial public offering. Therefore, to ensure that shareholders obtain information on a timely basis, the LTSE Listings Rules would include transitional disclosure provisions for newly listed issuers. Specifically, proposed Rule 14A.207(g)(1) would provide that, no later than at the time of its initial listing, an LTSE Listings Issuer must make the disclosure required by proposed Rule 14A.207(c)(1) (Disclosure of Long-Term Growth Strategy) publicly available on its website. Such disclosure must be made in compliance with applicable rules and regulations relating to the dissemination of free writing prospectuses. After its initial listing, an LTSE Listings Issuer would provide this disclosure in its Annual Report Supplement, as described above. Similarly, proposed Rule 14A.207(g)(2) would provide that, after initial listing, an LTSE Listings Issuer must make the disclosures required by proposed Rule 14A.207(d) (Disclosure Related to Buybacks), Rule 14A.207(e) (Disclosure Related to Human Capital Investment) and Rule 14A.207(f) (Disclosure Related to Research and Development) publicly available on its website by the earlier of when the company files its next Form 10–K or Annual Report Supplement.[55] After its initial listing, an LTSE Listings Issuer would provide this disclosure in its Annual Report Supplement, as described above.

(C) Long-Term Alignment of Executive Compensation

The Exchange believes that long-term focused companies seek to align the compensation of their Executive Officers [56] with the long-term performance of the company, while excessively short-term compensation instruments could promote incentives that are not aligned with long-term performance. Proposed Rule 14A.405(b)(3) would therefore require that an LTSE Listings Issuer's compensation committee adopt a set of executive compensation guidelines applicable to Executive Officers that are designed to link executive compensation to the long-term value of the LTSE Listings Issuer. The compensation committee would be required to include in the executive compensation guidelines general principles for determining the form and amount of Executive Officer compensation (and for reviewing those principles, as appropriate). In addition, the executive compensation guidelines would be required to be consistent with certain minimum standards described below. These requirements are intended to ensure that LTSE Listings Issuers design their executive compensation plans in accordance with specified long-term parameters, but also provide sufficient flexibility to allow such issuers to remain competitive in crafting individual compensation packages.

(i) Consistency With Long-Term Growth Strategy

Proposed Rule 14A.405(b)(3)(A) would require that the compensation committee ensure that the time periods and performance metrics used to determine Incentive-Based Compensation [57] for Executive Officers are consistent with an LTSE Listings Issuer's Long-Term Growth Strategy. Since the members of the LTSP Committee would be the directors with the greatest involvement in the LTSE Listings Issuer's Long-Term Growth Strategy, the compensation committee may consult with the LTSP Committee in assessing whether such time periods and performance metrics are consistent with the LTSE Listings Issuer's Long-Term Growth Strategy.

In addition, an LTSE Listings Issuer would be required to disclose in its proxy statement or, if no proxy statement is filed, its Annual Report Supplement, whether or not the compensation committee has determined that the time periods and performance metrics used to determine Incentive-Based Compensation for Executive Officers are consistent with LTSE Listings Issuer's Long-Term Growth Strategy.

(ii) Long-Term Compensation and Vesting Periods

Proposed Rule 14A.405(b)(3)(B)(i) would prohibit an LTSE Listings Issuer from providing Executive Officers with any Incentive-Based Compensation that is tied to a financial or performance metric that is measured over a time period of less than one year, or grant any time-based equity compensation that has any portion that vests in less than a year from the grant date (or from the hire date, in the case of new hire grants). By requiring Incentive-Based Compensation and time-based equity compensation to be tied to time periods of at least one year, the LTSE Listings Rules are designed to require that LTSE Listings Issuers avoid creating potential incentives to manage for short-term results, encouraging management to focus on longer-term time horizons.

Proposed Rule 14A.405(b)(3)(B)(ii) would require that equity compensation awarded to Executive Officers vest over a period (the ''Vesting Period'') of at

[53] IEX Regulation is the department of the Exchange or designated employees of the Exchange that supervise, administer, or perform the regulatory functions of the Exchange, including the administration of any regulatory services agreements with another self-regulatory organization to which the Exchange is a party. *See* IEX Rule 1.160(q).

[54] This proposed requirement is modeled after the audit committee paradigm in Regulation S–K, which requires the audit committee to state whether it recommends to the board of directors that the audited financial statements be included in the annual report on Form 10–K. *See* 17 CFR 229.407(d)(3)(i)(D).

[55] The disclosures are required to be made the ''earlier of'' when a company files a Form 10–K or Annual Report Supplement to account for the fact that, for an IPO company, a 10–K filing may significantly precede the first annual meeting.

[56] IEX Rule 14.405(a)(1) defines ''Executive Officer'' for these purposes as persons meeting the definition of ''officer'' under Rule 16a–1(f) under the Act.

[57] Pursuant to proposed Rule 14A.002(a)(8), Incentive-Based Compensation would be defined as ''any variable compensation, fees, or benefits that serve as an incentive or reward for performance.''

least five years. This minimum five-year Vesting Period is intended to ensure that executive compensation is tied to long-term company performance. In addition, while LTSE Listings Issuers would have flexibility in determining the specific vesting schedule within the Vesting Period (*i.e.,* the percentage of total equity compensation vested per year), the vesting schedule would be required to reflect the long-term focus of the equity grant. For example, a ten-year vesting schedule that vested 90% of the total equity compensation in the first year would not be consistent with a long-term focus.

The Exchange understands, however, that there may be certain situations in which accelerated vesting would be appropriate and would not undermine the underlying purpose of this provision. As a result, proposed Rule 14A.405(b)(3)(B)(ii) would allow for accelerated vesting upon the death of an Executive Officer or the occurrence of a disability that renders an Executive Officer permanently unable to remain employed at the LTSE Listings Issuer in any capacity. Whether to adopt exceptions of this type would be left to the discretion of the LTSE Listings Issuer and would be required to be outlined in the agreement providing the equity grant.

While the LTSE Listings Rules seek to maintain a long-term focus in compensation, there may be exceptional circumstances in which the payment of shorter-term Incentive-Based Compensation or shorter-term Vesting Periods are consistent with this focus and may be required for specific business purposes. Therefore, proposed Rule 14A.405(b)(3)(B)(iii) would provide that the compensation committee may provide alternative time periods for incentive and equity compensation if there is a business necessity and the LTSE Listings Issuer discloses and explains such business necessity in the LTSE Listings Issuer's proxy statement, or if the LTSE Listings Issuer does not file a proxy statement, in the LTSE Listings Issuer's Annual Report Supplement. To ensure that this exception remains limited, the rule would also prohibit the amount of equity awards granted in the aggregate that vests before the first anniversary of the grant date, or that does not meet the minimum five-year vesting schedule, from exceeding 5% of the total number of shares authorized for grant in any fiscal year.

Proposed Rule 14A.405(b)(3)(B)(iv) would provide that the compensation committee must determine appropriate Vesting Periods and amounts, as well as holding periods, for equity compensation awarded to Executive Officers that apply following an Executive Officer's retirement or resignation. Such Vesting Periods and amounts would also be required to be consistent with the requirements set forth in proposed Rule 14A.405(b)(3)(B)(ii) described above. The compensation provisions of the LTSE Listings Rules are premised on the idea that Executive Officers having financial interests in the long-term performance of the company—even after their departure from the company—will have a greater incentive to conduct business with long-term performance in mind and to undertake efforts for effective succession and departure planning. The Exchange understands that business needs and market practice may vary for different companies in different industries and sectors. Therefore, the specific schedule for vesting and holding is left for determination by the individual LTSE Listings Issuer, but each LTSE Listings Issuer is required to provide such a schedule to promote these underlying purposes.

(iii) Exemption for Existing Agreements Prior to Listing

The Exchange appreciates that an issuer may have entered into compensation arrangements prior to deciding whether to list on LTSE Listings and recognizes that it may impose an undue burden on such companies if they were required to unwind executive compensation plans that have been in effect for an extended period of time in order to list on LTSE Listings. Therefore, proposed Rule 14A.405(b)(3)(C) would provide an exemption from the executive compensation requirements contained in the LTSE Listings Rules for any executive compensation that is subject to an existing written agreement entered into at least one year prior to the initial listing of an LTSE Listings Issuer on the Exchange. The proposed exemption for preexisting compensation arrangements contains a one-year look-back period that is designed to assure that the exempted compensation arrangements were bona fide preexisting arrangements, and not entered into shortly before applying for listing on LTSE Listings in order to avoid the restrictions contained in the LTSE Listings Rules. In addition, the use of this exemption must be disclosed in the Annual Report Supplement.

(iv) Smaller Reporting Companies

IEX Rule 14.405(d)(5) exempts ''Smaller Reporting Companies,'' as defined in Rule 12b–2 under the Act,[58] from certain compensation committee requirements. Notwithstanding these exemptions that otherwise apply to companies listed on the Exchange, proposed Rule 14A.405(b)(4) would provide that an LTSE Listings Issuer that is a Smaller Reporting Company must adopt the executive compensation guidelines described above. In addition, such an issuer would be required to certify that it has adopted a formal written compensation committee charter or board resolution that specifies the additional compensation committee charter requirements for LTSE Listings Issuers—that the compensation committee must report regularly to the board of directors and adopt executive compensation guidelines in accordance with proposed Rule 14A.405(b)(2). The Exchange believes that, notwithstanding that Smaller Reporting Companies may have less resources than other issuers, these compensation committee requirements are an important feature of the LTSE Listings Rules and are a key part of the differentiated choice provided by the LTSE Listings category that long-term focused investors find important, and that accordingly, Smaller Reporting Companies electing to list on LTSE Listings should be required to comply with such compensation committee requirements.

(D) Long-Term Shareholder Voting Structure

Consistent with the focus of the LTSE Listings category to provide a differentiated choice for issuers and investors that prefer listing standards explicitly designed to promote long-term value creation, proposed Rule 14A.413(b) would require that LTSE Listings Issuers maintain certain voting rights provisions in their corporate organizational documents that provide all shareholders with the ability, at the shareholders' option, to accrue additional voting power over time. As described more fully below, these provisions are designed to align with the long-term focus of the LTSE Listings category by providing long-term investors in an LTSE Listings Issuer with a greater role in corporate governance than short-term shareholders. The Exchange believes that long-term investors in a public company are more likely than short-term shareholders to exercise their voting rights in a manner that prioritizes long-term growth over short-term results.

Specifically, as of the date of the company's initial listing on LTSE

[58] *See* 17 CFR 240.12b–2.

Listings, each holder of equity securities listed on LTSE Listings must be entitled to an equal number of votes per share (the ''Initial Voting Power'') on a per class basis.[59] For each full calendar month in which a shareholder maintains continuous record ownership of shares, the voting power of such shares for so long as they are held of record by such shareholder would increase by at least one twelfth (1/12th) over the shares' Initial Voting Power on the last business day of the month, up to an amount that is ten times their Initial Voting Power.[60] If, at any time, a shareholder transfers its shares out of record ownership (whether for purposes of sale or otherwise), then on the date of such transfer, such shares will revert to entitling the shareholder to the Initial Voting Power of such shares. Because each holder of a class of equity securities listed on LTSE Listings would have an equal number of votes per share on the date of initial listing, each investor would have an equal opportunity to obtain increased voting rights over time and no shareholders would receive a preference over others.

(i) Mechanism for Tracking Holding Periods

The Exchange notes that tracking the ultimate beneficial ownership and length of continued ownership may be difficult or impossible for shares held through the common ''street name'' ownership system. Shares held in street name are registered on the books of an issuer's transfer agent in the name of a nominee selected by the Depository Trust Company's (''DTC''), with DTC maintaining records of the number of shares held for its various brokerage firm participants, and those brokerage firms each maintaining records of the number of shares held for its particular customers.[61] As a result, an issuer reviewing its own books and records maintained by its transfer agent may be unable to definitively determine who its ultimate ''street name'' shareholders are, or for how long they have held their shares.

In order to track ownership for purposes of those shareholders opting to accrue additional voting power, the LTSE Listings Rules require that LTSE Listings Issuers look to whether a beneficial owner is also the holder of the shares in the LTSE Listings Issuer's records, *i.e.,* as a holder of record. A shareholder that purchases its shares through a brokerage firm may initially receive shares held on its behalf in street name through the brokerage firm. However, through a Direct Registration Program (''DRP''),[62] a shareholder maintaining its shares in street name may request that its shares (or some portion of its shares) be transferred to instead be held in record ownership on the books of the issuer's transfer agent, or transferred back to its brokerage account.[63] For these purposes, a shareholder will be deemed to have record ownership as of the date the shareholder appears as the record owner on the books of the LTSE Listings Issuer directly, or through a third-party transfer agent. In addition, for these purposes, record owners of shares listed on LTSE Listings would include those holding a physical paper certificate of such shares and those holding such shares through a DRP.

Although requiring that shares be held in record ownership in order to accrue additional voting rights may raise administrative burdens on shareholders, the Exchange believes the ability for LTSE Listings Issuers to verify and track the ownership of these shareholders for purposes of calculating voting rights outweighs these burdens. In addition, because only those shareholders that expect to hold their shares for the long-term would opt to do so, the Exchange does not believe that electronically transferring the shares through a DRP would present a significant burden.

Calculating voting rights in accordance with the provisions of proposed Rule 14A.413(b) will be novel to LTSE Listings Issuers and their shareholders and may present challenges. However, the Exchange understands that several transfer agents have indicated to LTSE that they are able to develop software or systems to assist LTSE Listings Issuers with tracking their shareholder voting rights as calculated in accordance with proposed Rule 14A.413(b). In order to ensure that LTSE Listings Issuers have such tools available to them and facilitate accurate calculation of their shareholders' voting rights, proposed Rule 14A.413(b)(5) would require that, prior to listing securities on LTSE Listings, a prospective LTSE Listings Issuer must obtain from its transfer agent a certification confirming that the transfer agent has software or other systems or processes available to the LTSE Listings Issuer that will enable the transfer agent and the LTSE Listings Issuer to determine, as of a particular record date, the LTSE Listings Issuer's shareholders' voting rights calculated in accordance with LTSE Listings Rule 14A.413(b).

(ii) Shareholders Holdings Through Custodians

As noted above, in order to track ownership for purposes of those shareholders opting to accrue additional voting power, the LTSE Listings Rules require that LTSE Listings Issuers look to whether a beneficial owner is also the holder of the shares in the LTSE Listings Issuer's records, *i.e.,* as a holder of record. The Exchange understands, however, that for various reasons, including regulatory requirements applicable to registered investment advisers and registered investment companies,[64] there may be shareholders that maintain ownership of securities through a third-party custodian, rather than in their own name. To accommodate such investors, proposed Supplementary Material .01(e) to proposed Rule 14A.413 would permit an LTSE Listings Issuer to recognize a shareholder as a holder of record solely for purposes of proposed Rule 14A.413(b), therefore entitled to increase its voting power over time, so long as the custodian for such shareholder becomes the shareholder of record and maintains its record

[59] The Exchange notes that all shares listed on LTSE Listings must have a minimum level of Initial Voting Power and conform to the voting rights set forth in proposed Rule 14A.413. However, proposed Supplementary Material .01(a) to proposed Rule 14A.413 clarifies that proposed Rule 14A.413(b) would not prevent an LTSE Listings Issuer, so long as not inconsistent with IEX Rule 14.413, from (i) maintaining multiple classes of securities, including shares that have voting power per share in excess of the Initial Voting Power of the securities listed on the Exchange, and/or (ii) establishing or maintaining classes of shares not listed on the Exchange that do not meet the requirements of proposed Rule 14A.413(b).

[60] Pursuant to proposed Supplementary Material .01(b) to proposed Rule 14A.413, an LTSE Listings Issuer would be permitted to provide that the voting rights of shareholders holding of record increase at a rate *greater* than one twelfth (1/12th) per month, provided that the voting power of such shares may not increase to a level that exceeds ten times their Initial Voting Power.

[61] *See generally* Securities Exchange Act Release No. 76743 (December 22, 2015), 80 FR 81947 (December 31, 2015).

[62] The Exchange's rules already require that any issuer listed on the Exchange, including on the LTSE Listings, be eligible for a DRP. *See* IEX Rule 14.208. Because the ability to transfer shares to and from record ownership through a DRP is critical to tracking of long-term shareholders' voting rights for LTSE Listings Issuers, the exception contained in Rule 14.208(c) that allows certain foreign issuers to list securities on the Exchange that are not eligible for a DRP would not be available to LTSE Listings Issuers. *See* proposed Rule 14A.208.

[63] *See* Securities Exchange Act Release No. 76743 (December 22, 2015), 80 FR 81947 (December 31, 2015) at text accompanying n.92–93.

[64] *See, e.g.,* 17 CFR 275.206(4)–2 (with respect to registered investment advisers) and 15 U.S.C. 80a–17(f) and 17 CFR 270.17f–1–f–7 (with respect to registered investment companies).

ownership in a manner that indicates the name of the ultimate beneficial owner. By way of example, if Investment Fund ABC maintains custody of its assets through Bank XYZ, an LTSE Listings Issuer may recognize Investment Fund ABC as the record holder of the shares of an LTSE Listings Issuer solely for purposes of this rule if Bank XYZ registers the shares on the books of the LTSE-Listed Issuer as being owned by ''Bank XYZ, as custodian for Investment Fund ABC.'' The Exchange believes that maintaining record ownership in this manner would allow an LTSE Listings Issuer to track that [sic] the period of time during which the shares have been held by the underlying investor, even if held through the custodian, while meeting the needs of those shareholders that wish to maintain custody of their assets through a separate custodian.

(iii) Technical Changes in Record Ownership

Because of the mechanics of tracking long-term ownership, the term of ownership for purposes of LTSE Listings Issuers calculating a shareholder's increased voting rights is tied not to the actual date of a shareholder's acquisition or disposition of beneficial ownership, but the date the shares are transferred into or out of record ownership, *i.e.,* the date that the name of the owner on the LTSE Listings Issuer's books is changed. The Exchange acknowledges that this may result in situations where technical changes to ownership structure could cause a shareholder to lose any accrued long-term voting. As a general matter, the Exchange believes that a bright-line rule that can be clearly and consistently applied is preferable to the need to analyze the surrounding circumstances regarding particular changes to record ownership. Nonetheless, the Exchange recognizes that particular LTSE Listings Issuers may wish to allow a shareholder to maintain any accrued long-term voting that would otherwise be lost as a result of technical changes. As a result, proposed Supplementary Material .01(d) to proposed Rule 14A.413 would permit (but not require) an LTSE Listings Issuer to adopt a process by which a shareholder may demonstrate that, notwithstanding a technical change in record ownership, a change in beneficial ownership for purposes of this rule has not occurred. LTSE Listings Issuers choosing to do so may develop their own list of changes for which such waivers may be granted, so long as they are of a purely technical nature that clearly did not involve a change of beneficial ownership (such as re-titling ownership of shares due to a name change or a change from sole ownership to joint ownership with a spouse) rather than an actual change of the person holding voting and investment discretion.

(iv) Potential Evasion of Loss of Long-Term Voting Upon Sale

The ability to accrue long-term voting is intended to incentivize those beneficial owners with voting and investment discretion over an LTSE Listings Issuer's shares to become long-term shareholders, provide a mechanism by which such long-term shareholders can evidence their long-term ownership (*i.e.,* by becoming record holders), and increase the relative role of such long-term shareholders in the governance of an LTSE Listings Issuer. There may be situations where it becomes apparent to an LTSE Listings Issuer that, notwithstanding the record holder of its shares remaining the same, the beneficial ownership has changed, in an effort to evade the purposes of long-term voting. For example, the Exchange recognized the risk that a person may create a special-purpose entity (an ''SPE'') to hold shares of an LTSE Listings Issuer and register the SPE as the owner of the shares on the books of the LTSE Listings Issuer. Over time, the shares held by the SPE would accrue additional voting rights. Ordinarily, once those shares are transferred, they would lose any accrued long-term voting and revert to their Initial Voting Power. However, if the person were to instead transfer the ownership of the SPE to a third party, that transfer may not result in a change of ownership of the underlying shares of the LTSE Listings Issuer on the books and records of the LTSE Listings Issuer's transfer agent.

To address this situation, proposed Supplementary Material .01(c) to proposed Rule 14A.413 would permit (but not require) an LTSE Listings Issuer to include provisions in its governance documents such that if its board of directors adopted a resolution reasonably determining that, notwithstanding technical compliance with the provisions of an LTSE Listings Issuer's governance documents relating to the increasing voting power of long-term shareholders and continuity of record ownership, there has in fact been a change in beneficial ownership with respect to shares held of record that would evade the purposes of LTSE Listings Rule 14A.413(b), such shares may be treated as being entitled only to their Initial Voting Power. Any LTSE Listings Issuer that provides for such a process in its governance documents must also provide a process through which a shareholder directly affected by such a determination may challenge it. The Exchange believes that, together, this should protect LTSE Listings Issuers from an attempt by shareholders to improperly sell increased voting rights to new shareholders, while affording affected shareholders with an opportunity to present additional information demonstrating that a change of beneficial ownership has not occurred.

(v) Consistency With the Exchange's Voting Rights Policy

The Exchange believes that LTSE Listings Rule 14A.413(b) is fully consistent with IEX Rule 14.413 (the Exchange's ''Voting Rights Policy''). The Voting Rights Policy provides that the voting rights of existing shareholders of publicly traded common stock registered under Section 12 of the Act may not be disparately reduced or restricted through any corporate action or issuance. The Voting Rights Policy provides examples of corporate actions or issuances that could violate this policy, including the adoption of time-phased voting plans, which could encompass structures whereby investors gain additional voting rights over time.[65] While the requirements of LTSE Listing Rule 14A.413(b) could be viewed as similar to time-phased voting plans, the Exchange does not believe that complying with LTSE Listing Rule 14A.413(b) would be inconsistent with the Voting Rights Policy, which bars a company already listed on the Exchange from undertaking the prohibited corporate actions. Because LTSE Listings Issuers would be required, as a pre-condition to listing on LTSE Listings, to already have in place a voting rights structure as of its date of its initial listing that complies with LTSE Listings Rule 14A.413(b), no new corporate action that disparately reduces voting rights would be taken

[65] Another example of such a corporate action enumerated in the Voting Rights Policy is the issuance of a new class of super-voting stock. Proposed Supplementary Material .01(f) to proposed Rule 14A.413 would provide that for purposes of LTSE Listings, a class of securities shall be considered super-voting stock if (i) the Initial Voting Power of such class of securities exceeds the Initial Voting Power of any of the LTSE Listings Issuer's existing classes of common stock listed on LTSE Listings or (ii) the rate at which the voting power of such class may increase over time is greater than the corresponding rate for any of the LTSE Listings Issuer's existing classes of common stock listed on LTSE Listings. An LTSE Listings Issuer would not be prohibited by proposed Rule 14.413 from issuing additional shares of a class of stock that is listed on LTSE Listings or from issuing shares of a new class of stock that does not constitute super-voting stock as described above.

subsequent to listing on the Exchange. In addition, pursuant to LTSE Listings Rule 14A.413(b), all shareholders of the same class of LTSE Listings Issuer's common stock listed on LTSE Listings will have the same voting rights in that any shareholder is eligible to accrue additional voting rights. To the extent that the effect of LTSE Listings Rule 14A.413(b) is that those shareholders that elect not to accrue additional voting power have their relative voting rights reduced relative to those that elect to accrue additional voting power, this impact is the result of a corporate action taken prior to listing on LTSE Listings, known to investors prior to their determining to purchase shares of an LTSE Listings Issuer, and the actions or inactions of shareholders subsequent to listing. Thus, the Exchange believes that compliance with LTSE Listings Rule 14A.413(b) will not cause existing shareholders' voting rights to be disparately reduced or restricted through any corporate action or issuance within the meaning of IEX Rule 14.413.

In addition to the fact that the voting rights structure required under LTSE Listings Rule 14A.413(b) must be in place prior to listing on the Exchange, Supplementary Material .01 to IEX Rule 14.413 provides that the Exchange's ''interpretations under the policy will be flexible, recognizing that both the capital markets and the circumstances and needs of the Exchange Companies change over time.'' Accordingly, the Exchange will interpret the policy flexibly with regard to its consistency with an LTSE Listings Issuer's voting structures designed to meet LTSE Listings Rule 14A.413(b). As the Commission recognized in approving the voting rights policies of other self-regulatory organizations that are substantively identical to IEX Rule 14.413, ''there may be valid business or economic reasons for corporations'' for companies to provide different voting rights to different shareholders, and that the voting rights policies ''provide issuers with a certain degree of flexibility in adopting corporate structures, so long as there is a reasonable business justification to so doing, and such transaction is not taken or proposed primarily with the intent to disenfranchise.'' [66] The Exchange believes that providing long-term investors with an opportunity for a greater voice in corporate governance is a reasonable business justification for an issuer to adopt the long-term voting structure required by proposed LTSE Listings Rule 14A.413(b) and that, because every shareholder has the opportunity to elect to accrue additional voting power, the structure would not be implemented with a primary purpose or intent to disenfranchise particular shareholders.

(E) Other Long-Term Requirements

The Exchange is proposing to include in the LTSE Listings Rules certain other rules also designed to encourage LTSE Listings Issuers to focus on long-term value creation. These proposed rules are described further below.

(i) Earnings Guidance

Proposed Rule 14A.420(a) would provide that LTSE Listings Issuers are generally prohibited from providing earnings guidance more frequently than annually. For these purposes, ''Earnings Guidance'' would be defined as any public disclosure made to shareholders containing a projection of the LTSE Listings Issuer's revenues, income (including income loss), or earnings (including earnings loss) per share.[67] As noted above, LTSE's research indicates that pressure to meet quarterly earnings guidance can cause managers to sacrifice long-term growth for short-term performance.[68] Proposed Rule 14A.420(a) is intended to help companies alleviate the pressures surrounding the quarterly earnings process with respect to guidance, with a goal to ultimately shift the focus of both companies and investors toward longer-term milestones.

Notwithstanding the general prohibition on providing Earnings Guidance more frequently than annually, proposed Rule 14A.420(a) would permit an LTSE Listings Issuer to update previously issued Earnings Guidance at any time if it believes that such disclosure would be required (i) by IEX Rule 14.207(b)(1), which requires an issuer to promptly disclose to the public any material information that would reasonably be expected to affect the value of the issuer's securities or influence investors' decisions; (ii) by other applicable law (including any of the Commission reporting rules); or (iii) to make the previously issued Earnings Guidance not misleading.

Proposed Rule 14A.420(b) would clarify that any Earnings Guidance provided by an LTSE Listings Issuer, including updates and supplementary disclosure related to Earnings Guidance, shall be considered material information for purposes of IEX Rule 14.207(b)(1). As a result, LTSE Listings Issuers would be required to comply with the disclosure and notification requirements set forth therein when disseminating such information.

(ii) Long-Term Stakeholder Policies

Proposed Rule 14A.425(a) would require that each LTSE Listings Issuer develop and publish a policy regarding the LTSE Listings Issuer's impact on the environment and community, and a policy explaining the LTSE Listings Issuer's approach to diversity. The Exchange believes that effective long-term planning is enhanced when companies consider their impact on various stakeholders and the sustainability of their business, and that long-term investors generally value such information. Each LTSE Listings Issuer may have different stakeholders and different views on these issues. The LTSE Listings Rules would not impose any requirements on the content of these policies. Rather, proposed Rule 14A.425(a) would only require that LTSE Listings Issuers adopt and publish a policy, providing LTSE Listings Issuers with flexibility in developing what they believe to be appropriate policies for their business, and providing investors with insight into an LTSE Listings Issuer's management of these issues.

Proposed Rule 14A.425(b) would require that each LTSE Listings Issuer review the policies required by proposed Rule 14A.425(a) at least annually and make such policies available on or through its website. In addition, each LTSE Listings Issuer would be required to disclose in its annual proxy statement or, if it does not file an annual proxy statement, in its Annual Report Supplement, that these policies are available on or through its website and provide the website address. These requirements are intended to ensure that investors are aware of and have access to an LTSE Listings Issuer's stakeholder policies. Although these policies must be made publicly available, proposed

[66] *See* Securities Exchange Act Release No. 35121 (December 19, 1994), 59 FR 66570 (December 27, 1994) (approving rule changes adopting voting rights policies of the New York Stock Exchange, American Stock Exchange, and National Association of Securities Dealers).

[67] *See* proposed Rule 14A.002(a)(6).

[68] *See* Graham, *supra* note 15; Yongtae Kim, Lixin (Nancy) Su, Xindong (Kevin) Zhu, *Does the Cessation of Quarterly Earnings Guidance Reduce Investors' Short-Termism?* (December 12, 2016), *available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2885624. See also* Chairman Jay Clayton, Hearing before the Senate Banking Committee on the Nomination of Jay Clayton, of New York, to be a Member of the Securities and Exchange Commission (March 23, 2017), available at *https://www.gpo.gov/fdsys/pkg/CHRG-115shrg24998/html/CHRG-115shrg24998.htm* (''In my experience, certain companies view the operational and other pressures inherent in quarterly earnings as costly, including because they detract from long-term planning and strategic initiatives.'').

Supplementary Material .01 to proposed Rule 14A.425 would provide that the required stakeholder policies need not be stand-alone documents and may be included as part of other LTSE Listings Issuer policies or reports.

(iii) Website Requirements

Proposed Rule 14A.430 would require LTSE Listings Issuers to have and maintain a publicly accessible website. In addition, to the extent that an LTSE Listings Issuer would be required under any applicable provision of the LTSE Listings Rules to make documents available on or through its website, an LTSE Listings Issuer would be required to ensure that the website is accessible from the United States, the website clearly indicates in the English language the location of such documents on the website and that such documents are available in a printable version in the English language. The Exchange understands that many long-term focused investors expect to be able to access corporate governance and other information regarding companies in which they have invested through the company's website, and accordingly the Exchange believes that it is appropriate to explicitly impose this website requirement. For transparency purposes, various proposed LTSE Listings Rules, as discussed above, would require that materials be made available on an LTSE Listings Issuer's website.[69]

Proposed Rule 14A.430 is intended to specify in further detail the manner in which LTSE Listings Issuers may satisfy these website posting requirements. The Exchange notes that the foregoing website requirements are substantially similar to the requirements imposed by the listing rules of another national securities exchange.[70]

(iv) Certification Requirements

Proposed Rule 14A.435 would require that LTSE Listings Issuers make certain certifications to the Exchange. Specifically, proposed Rule 14A.435(a) would require LTSE Listings Issuers certify [sic], at or before the time of listing, that all applicable listing criteria have been satisfied. This requirement is substantively identical to IEX Rule 14.202(b), which requires all issuers listed on the Exchange to submit such a certification. The Exchange proposes to repeat this requirement in the LTSE Listings Rules to clarify that the certification must include compliance with the LTSE Listings Rules, in addition to the Exchange's other listing rules.

Proposed Rule 14A.435(b) would require that the CEO of each LTSE Listings Issuer certify annually to the Exchange that the LTSE Listings Issuer is in compliance with proposed Rule Series 14A.400, which contain the corporate governance requirements of the LTSE Listings Rules, qualifying the certification to the extent necessary. Various IEX listing rules impose certification requirements,[71] and IEX Rule 14.207 requires that a listed company must provide the Exchange with prompt notification after an Executive Officer of the company becomes aware of any noncompliance by the company with the corporate governance requirements set forth in IEX Rule 14.400. However, given the unique nature of the LTSE Listings Rules, the Exchange believes that adding an annual certification requirement for LTSE Listings Issuers will assist the CEO and senior management of such issuers in overseeing and assuring compliance with LTSE Listings corporate governance requirements on an ongoing basis. In addition, the Exchange notes that another national securities exchange similarly requires that the CEO of a company listed on that exchange certify annually that he or she is not aware of any violation by the company of that exchange's corporate governance listing standards.[72] Proposed Rule 14A.435(b) would also require each LTSE Listings Issuer CEO certify [sic] annually to the Exchange that the LTSE Listings Issuer has designated an employee responsible for ensuring that the voting power of the LTSE Listings Issuer's securities is determined in accordance with proposed Rule 14A.413(b) (Long-Term Voting). The Exchange believes that such an annual certification requirement would help ensure that LTSE Listings Issuers establish internal systems reasonably designed to assure compliance with LTSE Listing's long-term voting provisions.

(v) Issuer Designation Requirements and Dually-Listed Securities

The Exchange proposes to permit an LTSE Listings Issuer to list a class of securities that, in connection with its initial public offering, has been approved for listing on another national securities exchange (''Dually-Listed Securities''). The Exchange expects that this would foster competition among markets and further the development of the national market system. The Exchange would make an independent determination of whether such companies satisfy applicable listing standards and would require such companies to enter into a dual-listing agreement with the Exchange.[73] In the event that a company chooses to dually-list on both LTSE Listings and another national securities exchange in connection with its IPO, the Exchange would expect such other national securities exchange to be the LTSE Listings Issuer's ''Primary Listing Market.'' [74] The Exchange is proposing certain additional rules to facilitate dual-listings.

Pursuant to proposed Rule 14A.210(b), an LTSE Listings Issuer that has Dually-Listed Securities would be required to notify the Exchange promptly if it receives oral or written notification from the other national securities exchange on which the LTSE Listings Issuer's Dually-Listed Securities are listed that such class of listed securities has fallen below the continued listing requirements of such other market. In addition, such an LTSE Listings Issuer would also be required to notify the other national securities exchange on which its Dually-Listed Securities are listed if it receives oral or written notification that such class of listed securities has fallen below the continued listing requirements of Chapter 14 of the IEX Rules or the LTSE Listings Rules contained in Chapter 14A of the IEX Rules.

[69] *See* proposed Rules 14A.207(a), 14A.207(f), 14A.405(a)(2), 14A.405(b)(1)(B), 14A.405(c)(2)(C), 14A.405(d)(2), 14A.405(d)(5)(B), 14A.407(a)(2)(B), 14A.409(b) and 14A.425(b).

[70] *See* NYSE Listed Company Manual, Rule 307.00.

[71] *See, e.g.,* IEX Rule 14.202(b) (requiring a company listing on the Exchange to certify, at or before the time of listing, that all applicable listing criteria have been satisfied); IEX Rule 14.405(c)(1) (requiring each company listed on the Exchange to certify that it has adopted a formal written audit committee charter and that the audit committee will review and reassess the adequacy of the formal written charter on an annual basis); IEX Rule 14.405(d)(1) (requiring each company listed on the Exchange to certify that it has adopted a formal written compensation committee charter and that the compensation committee will review and reassess the adequacy of the formal written charter on an annual basis).

[72] *See* NYSE Listed Company Manual, Rule 303A.12(a).

[73] The Exchange would also monitor the dually-listed LTSE Listings Issuer for compliance with all applicable IEX Rules on an ongoing basis, as it would for any other LTSE Listings Issuer.

[74] Pursuant to proposed Rule 14A.002(a)(14), ''Primary Listing Market'' would have the same meaning as that term is defined in the Nasdaq Unlisted Trading Privileges national market system plan and consistent with use of the term ''listing market'' in the Consolidated Quotation Service and Consolidated Tape Association national market system plans. Where an LTSE Listings Issuer is dually-listed on another national securities exchange, the initial trading of such issuer's securities on the Exchange would not occur until after the completion of the opening auction for such securities on the first day of listing on the Primary Listing Market.

Proposed Supplementary Material .01 to proposed Rule 14A.210 would clarify the application of certain IEX Rules, such as rules governing trading halts, for Dually-Listed Securities, given the fact that the Exchange would not be the Primary Listing Market. These proposed rules are designed to avoid creating potential confusion for investors and market participants with respect to Dually-Listed Securities. The Exchange notes that these provisions are substantially consistent with the rules of other national securities exchanges.[75]

(F) Proposed Rules Clarifying Application of Existing Exchange Rules

In addition to proposed rules that would encourage LTSE Listings Issuers to focus on long-term value creation, the Exchange is also proposing rules that would clarify the application of certain existing Exchange rules to LTSE Listings Issuers. These proposed rules are described further below.

(i) Supplemental Nature of LTSE Listings Rules

Proposed Rule 14A.001(a) would provide that the LTSE Listings Rules are supplemental listing standards applicable to LTSE Listings Issuers and that LTSE Listings Issuers must also fully qualify for listing under Chapter 14 of the Exchange's rules and the LTSE Listings Rules on an initial and ongoing basis. This provision is intended to clarify that LTSE Listings Issuers would be subject to the LTSE Listings Rules, as well as all other applicable listing rules of the Exchange, except as they may be specifically modified for LTSE Listings Issuers.

Proposed Rule 14A.001(b) would provide that LTSE Listings Issuers may only list common equity securities on LTSE Listings. Although the Exchange maintains listing rules relevant for other types of securities, such as American Depositary Receipts, preferred stock, rights and warrants, among others, such securities would not be eligible for listing on LTSE Listings. The Exchange is proposing to establish an LTSE Listings category to provide a differentiated choice for issuers and investors that prefer listing standards explicitly designed to promote long-term value creation. At this time, the Exchange believes that, given that corporate governance and voting rights are more typically associated with common equity than other securities, it is most appropriate for a company electing to become subject to the LTSE Listings Rules to list its common equity on LTSE Listings.

(ii) Change of Control and Reverse Mergers

IEX Rule 14.102(a) provides that an Exchange-listed company must apply for initial listing in connection with a transaction whereby the Exchange-listed company combines with, or into, an entity that is not listed on the Exchange, resulting in a change of control of the company and potentially allowing such entity to obtain an Exchange listing. The rule enumerates certain factors that the Exchange will consider in determining whether a change of control has occurred, including, but not limited to, changes in management, board of directors, voting power, ownership and financial structure. Proposed Rule 14A.102(a)(1) would impose an analogous requirement on LTSE Listings Issuers combining with, or into, an entity that is not listed on LTSE Listings, including an entity that is a not an LTSE Listings Issuer that is otherwise listed on the Exchange. The Exchange would consider the same factors enumerated in IEX Rule 14.102(a) when determining whether a change of control has occurred for purposes of proposed Rule 14A.201(a)(1). Proposed Rule 14A.102(a)(1) would also require that any combined entity applying for initial listing as permitted by this rule must agree to comply with all applicable requirements of Chapter 14A, including requirements relating to long-term voting set forth in proposed Rule 14A.413.

Proposed Rule 14A.102(a)(2) would clarify the impact of a change of control transaction on the proposed long-term voting provisions of LTSE Listings. Specifically, proposed Rule 14A.102(a)(2) would provide that if an initial listing following a change of control meets applicable listing requirements and the LTSE Listings Issuer is the surviving entity following the business combination, any shares of the LTSE Listings Issuer that have accrued additional voting power pursuant to proposed Rule 14A.413(b) prior to the business combination would retain such additional voting power following the business combination. On the other hand, if the non-LTSE Listings Issuer is the surviving entity or a new entity is formed following the business combination, all shares of the class or classes of securities to be listed on LTSE Listings will have voting power equal to their Initial Voting Power at the time of such listing. Any additional voting power accrued pursuant to Rule 14A.413(b) by the shareholders of the non-surviving LTSE Listings Issuer prior to the business combination would not be retained.

IEX Rule 14.102(c) provides that a company that is formed by a Reverse Merger[76] is eligible to submit an application for initial listing only if the combined entity has satisfied certain conditions. Proposed Rule 14A.102(b) would clarify that such an entity would not be eligible to apply for initial listing on LTSE Listings. The Exchange does not believe a reverse merger company would be able to satisfy the requirements of the LTSE Listings Rules.

(iii) General Procedures and Prerequisites for Initial and Continued Listing on LTSE Listings

Proposed Rule 14A.200 would establish general procedures and prerequisites for initial and continued listing on LTSE Listings. This rule series is intended to supplement and clarify the application of the general procedures and prerequisites set forth in the IEX Rule Series 14.200.

IEX Rule 14.200(a) requires a company seeking the initial listing of one or more classes of securities on the Exchange to participate in a free confidential pre-application eligibility review by the Exchange in order to determine whether it meets the Exchange's listing criteria. If, upon completion of this review, the Exchange determines that a company is eligible for listing, the Exchange will provide the company with a clearance letter, notifying the company that it has been cleared to submit an original listing application. Proposed Rule 14A.200(a) would clarify that if a company is seeking a listing on LTSE Listings, prior to providing a clearance letter, the Exchange must determine that the company is eligible for listing under the LTSE Listings Rules, in addition to the Exchange's other listing criteria.[77]

IEX Rule 14.200(b) outlines the applications and qualifications process for companies that have received a clearance letter. A company seeking to list on LTSE Listings would be required to follow this process, including executing a listing agreement and listing

[75] *See* Nasdaq Stock Market Equity Rules 5220 and IM–5220; CBOE BZX Exchange, Inc. Rule 14.3(d) and Rule 14.3 Interpretation and Policy .01.

[76] A ''Reverse Merger'' is generally defined as ''any transaction whereby an operating company becomes an Exchange Act reporting company by combining, either directly or indirectly, with a shell company which is an Exchange Act reporting company, whether through a reverse merger, exchange offer, or otherwise.'' *See* IEX Rule 14.002(a)(27).

[77] As is the case with other companies applying for listing on the Exchange, if the Exchange determines that a company is ineligible for listing on LTSE Listings, the company may request a review of IEX's determination pursuant to the process set forth in IEX Rule 9.555.

application, as required by IEX Rule 14.202(a). However, proposed Rule 14A.200(b) would clarify that a company seeking to list on LTSE Listings would execute a listing agreement and listing application on the forms designated by the Exchange for LTSE Listings Issuers. These forms and applications would be available from IEX Regulation.

IEX Rule 14.200(c) provides prerequisites for applying to list on the Exchange. A company seeking to list on LTSE Listings would be required to satisfy these prerequisites, except as otherwise provided by proposed Rule 14A.200(c). For example, IEX Rule 14.203(c) provides that all securities initially listed on the Exchange, but for securities which are in any event book-entry only, must be eligible for a DRP, except that a foreign issuer is not subject to this requirement if it submits to the Exchange a written statement from an independent counsel in such company's home country certifying that a law or regulation in the home country prohibits compliance with this requirement. Because eligibility for a DRP is essential to the proper functioning of LTSE Listings' long-term shareholder voting provisions, proposed Rule 14A.200(c)(1) would provide that foreign issuers may not rely on the exception in IEX Rule 14.203(c) from the DRP eligibility requirement.

IEX Rule 14.203(d) provides that a company applying to list on the Exchange must pay all applicable fees as described in Rule Series 14.600. Proposed Rule 14A.200(c)(3) would provide that in lieu of paying all applicable fees as described in IEX Rule Series 14.600, a company seeking the initial listing of one or more classes of securities on LTSE Listings would be required to pay all applicable fees as described in LTSE Listings Rule Series 14A.600. This provision is intended to clarify that companies seeking to list on LTSE Listings are not required to pay two separate listing fees.

Proposed Rule 14A.200(c)(2) would provide that at the time that a company initially lists on LTSE Listings, the company may not already have any security listed for trading either on the Exchange (*i.e.,* listed on IEX pursuant to IEX listing rules other than Chapter 14A) or on any other national securities exchange (unless dually listing on the other national securities exchange concurrently). The Exchange is initially limiting the availability of LTSE Listings to companies seeking to list on LTSE Listings concurrently with their initial public offering (whether listing on LTSE Listings only or dually-listing on LTSE Listings and another national securities exchange concurrently). The Exchange may in the future seek to expand the availability of LTSE Listings to other companies seeking to list on LTSE Listings that are otherwise already listed on a national securities exchange.

(iv) Exemptions From Certain Corporate Governance Requirements

IEX Rule 14.407 provides exemptions from the Exchange's corporate governance rules for certain types of companies, sets forth phase-in schedules for, among other things, initial public offerings and companies emerging from bankruptcy and describes the applicability of the corporate governance rules to Controlled Companies.[78] Proposed Rule 14A.407 would clarify the application of these rules with respect to the LTSE Listings Rules, as described below.

IEX Rule 14.407(a) provides exemptions to certain of the Exchange's corporate governance requirements for asset-backed issuers and other passive issuers, cooperatives, Foreign Private Issuers,[79] limited partnerships and management investment companies. Proposed Rule 14A.407(a) would provide that an LTSE Listings Issuer may not rely on these exemptions with respect to the LTSE Listings Rules. The Exchange believes that exemptions for these entities is either (i) not necessary because LTSE Listings is only available for common equity or (ii) not appropriate given that LTSE Listings is designed to require particular minimum corporate governance. However, proposed Rule 14A.407(a) would clarify that a Foreign Private Issuer that is able to meet all applicable requirements of Chapter 14A, including the requirement to distribute an Annual Report Supplement, would be permitted to list on LTSE Listings.

IEX Rule 14.407(b) allows a company listed on the Exchange to phase-in its compliance with certain Exchange rules over a period of time in certain situations, including for initial public offerings, companies emerging from bankruptcy, transfers from other markets, and companies ceasing to be a Smaller Reporting Company. These phase-in schedules would apply to LTSE Listings Issuers in the same manner as they would apply to other companies listed on the Exchange. In addition to these phase-in schedules, proposed Rule 14A.407(b) would provide that an LTSE Listings Issuer that is listing in connection with its initial public offering or that is emerging from bankruptcy is permitted to phase-in its compliance with the requirement that the LTSP Committee be comprised of a majority of independent directors. Specifically, this rule would provide that at least one member of the LTSP Committee must be an independent director at the time of listing and a majority of the members of the LTSP Committee must be independent within 90 days of listing. This phase-in schedule is substantially similar to the corresponding phase-in schedules applicable to other board committees.[80]

IEX Rule 14.407(c) outlines how the Exchange's listing rules apply to a Controlled Company. This rule provides that a Controlled Company is generally exempt from requirements to establish a compensation committee and requirements relating to independent director oversight of director nominations. These exemptions would apply to LTSE Listings Issuers in the same manner as they would apply to other companies listed on the Exchange. In addition to these exemptions, proposed Rule 14A.407(c)(1) would provide that a Controlled Company is exempt from the additional compensation committee and nominating/corporate governance committee requirements under proposed LTSE Listings Rules 14A.405(b) and 14A.405(d), except for the requirement to adopt executive compensation guidelines under proposed Rule 14A.405(b)(3). Proposed Rule 14A.407(c)(2) would provide that to the extent that a Controlled Company does not have a compensation committee, the independent directors on the LTSP Committee or the independent directors of the board of directors must be responsible for adopting the executive compensation guidelines.

(v) Notification of Noncompliance

IEX Rule 14.410 provides that a company listed on the Exchange must provide the Exchange with prompt notification after an Executive Officer of the company becomes aware of any noncompliance by the company with the requirements of Rule Series 14.400, which outlines the general corporate governance requirements for companies listed on the Exchange. Proposed Rule 14A.410 would supplement this requirement by requiring an LTSE Listings Issuer to provide the Exchange

[78] The term ''Controlled Company'' is defined in Rule 14.407(c)(1) as an Exchange-listed company of which more than 50% of the voting power for the election of directors is held by an individual, a group or another company.

[79] Pursuant to IEX Rule 14.002(a)(15), the term ''Foreign Private Issuer'' as used in the Exchange's rules has the same meaning as under Exchange Act Rule 3b–4.

[80] *See* IEX Rule 14.407(b)(1).

with prompt notification after an Executive Officer of the LTSE Listings Issuer becomes aware of any noncompliance by the LTSE Listings Issuer with the requirements of LTSE Listings Rule Series 14A.400, which contains the supplemental corporate governance requirements for LTSE Listings Issuers.

(vi) Shareholder Approval Calculation

IEX Rule 14.412 sets forth the circumstances in which an Exchange-listed company is required to obtain shareholder approval prior to the issuance of securities in connection with the (1) the acquisition of the stock or assets of another company; (2) a change of control; (3) equity-based compensation of officers, directors, employees, or consultants; and (4) private placements. In some cases, such approval is required, among other potential triggers, if the common stock being issued ''has or will have upon issuance voting power equal to or in excess of 20% of the voting power outstanding before the issuance . . .'' (the ''Shareholder Approval Threshold'').[81] The Exchange believes that the purpose of this aspect of the rule is to ensure that existing shareholders have a voice in transactions that would materially dilute the voting power of their shares.

Ordinarily, determining whether an issuance equals or exceeds the Shareholder Approval Threshold would be a simple calculation: The issuer would multiply the number of shares to be issued by the voting power of such shares and divide by the voting power of the shares outstanding before the issuance. If this number equals or exceeds the Shareholder Approval Threshold, shareholder approval would be required. However, shares listed on LTSE Listings (or that are of the same class of securities that are listed on LTSE Listings) may accrue voting power over time. As a result, even if the voting power of newly issued shares of an LTSE Listings Issuer is less than the Shareholder Approval Threshold at the time of the issuance, it may potentially be greater than the Shareholder Approval Threshold after a certain period of time, depending on how many of the new shares are registered in record name and accrue additional voting power over time, relative to the number of existing shareholders that do so.

IEX Rule 14.412 requires that a company listed on the Exchange receive shareholder approval in advance of the ''potential issuance of common stock'' where the ''common stock has or will have upon issuance voting power'' that would exceed the Shareholder Approval Threshold. The Exchange notes that, by its terms, IEX Rule 14.412 therefore could be read to look only to the voting power of the shares upon issuance, rather than the potential voting power of those shares after some period of time.[82] However, certain interpretations and supplementary material relating to other aspects of IEX Rule 14.412 do look to the potential for changes to the securities being issued, even past the initial issuance.[83] As a result, in light of the potential increased future voting power of new shares to be issued, the Exchange believes that it is appropriate, in calculating the Shareholder Approval Threshold, to require that LTSE Listings Issuers assign a greater level of voting power to the newly issued shares than the Initial Voting Power of those shares, on the presumption that the ultimate voting power of those shares will increase over time.

The Exchange notes, however, that because shareholders that obtain shares in a transaction may or may not elect to hold their shares in record ownership, and may hold them in such manner for varying lengths of time, it is not possible to determine with precision how many shares issued in any transaction would accumulate additional voting power or the extent of voting power those shares will eventually attain. One potential approach would be to assume that all of the new shares in a proposed issuance will be registered in record name and held in that form for ten years, thereby accruing the maximum additional voting power (*i.e.,* ten times the Initial Voting Power).[84] Under that approach, when conducting the shareholder approval calculation, the issuer would multiply the voting power of the shares to be issued (the numerator of this calculation) by ten and would then divide that number by the existing voting power of the shares outstanding (the denominator of this calculation). The Exchange believes that issuers would then be required to obtain shareholder approval frequently, because they would be required to assume a much higher voting power for the shares to be issued (to account for potential future voting power), but would also be required to assume that the voting power of the outstanding shares remains the same. The Exchange believes that this approach would not be appropriate because the Exchange believes that it would be extremely unlikely that all shares of a new issuance will be held in record name by the same shareholder uninterrupted for ten years.[85] In addition, the Exchange believes that it would be even more unlikely for all shares of a new issuance to accrue votes up to the maximum amount while the shares outstanding remain static and do not accrue any additional votes. Given what the Exchange believes is the extremely low probability of this occurrence, the Exchange believes that requiring issuers to make these particular assumptions will result in LTSE Listings Issuers needing to obtain shareholder approval for transactions that would not be materially dilutive to existing shareholders nor would it be consistent with the objective of the rule, as it would effectively impose a Shareholder Approval Threshold of 2% instead of the 20% (if one were to calculate based solely on the Initial Voting Power of the shares at the time of their issuance). The Exchange does not believe that imposing the burden of obtaining shareholder approval (including the

[81] IEX Rule 14.412(a)(1)(A). Shareholder approval may also be required if the number of shares of common stock to be issued is or will be equal to or in excess of 20% of the number of shares of common stock outstanding before the issuance of the stock or securities. *See* IEX Rule 14.412(a)(1)(B).

[82] *See, e.g.,* IEX Rule 14.412(a)(1)(A).

[83] Specifically, for the purposes of determining the number of shares to be issued in an offering of future-priced securities, the Exchange staff will ''look to the maximum potential issuance of common shares.'' *See* Supplementary Material .04 to IEX Rule 14.412. Future-priced securities are securities that are convertible into common stock at a conversion price that is linked to the market price of the underlying common stock at the time of conversion. In such cases, the lower the price of the company's common stock at the time of conversion, the more shares of common stock the holder of the future-priced security would receive.

[84] This approach would be similar to the approach required for calculating the number of shares that may be issued pursuant to an offering of future-priced securities, as discussed *supra* note 83. However, the Exchange believes that this approach would not be appropriate for determining whether the voting power of an issuance by an LTSE Listings Issuer would exceed the Shareholder Approval Threshold. In addition to the reasons described below, the Exchange believes purchasers of convertible securities have a strong economic incentive to exercise their conversion rights and acquire common stock at some point in time. If the price of the underlying common stock has declined at the time of conversion, the number of shares of common stock that will be issued (and thus the dilution of existing shareholders) could increase significantly. While the Exchange believes that LTSE Listings Issuers will attract more long-term focused shareholders, not all shareholders will be long-term or have the incentive, economic or otherwise, to register their shares in record name and accrue additional voting power, and the Exchange therefore believes that, for a variety of reasons, many shareholders will never elect to do so.

[85] As discussed above, *supra* note 11, the average holding period in 2015 was approximately eight months. Although the Exchange expects a longer average holding period for LTSE Listings Issuers, the Exchange believes that assuming a full ten-year holding period for all shareholders of LTSE Listings Issuers would not be reasonable.

monetary costs as well as time and uncertainty) would be justified for transactions that the Exchange believes are unlikely to be materially dilutive to the voting power of existing shareholders.

Proposed Rule 14A.412 would take what the Exchange believes to be a more reasonable and balanced approach that is aligned with the purpose of this requirement, while still taking into account the potential increased future voting power of new shares to be issued.[86] Specifically, for LTSE Listings Issuers that have been listed on LTSE Listings for at least five years, the numerator of the shareholder approval calculation would be determined by multiplying the number of shares to be issued by the product of the Initial Voting Power for such shares and a ''Long-Term Voting Factor,'' rather than just the Initial Voting Power of such shares. The Long-Term Voting Factor is intended to estimate the extent of the increase in voting power that the new shares to be issued are likely to obtain based on the percentage of increased voting power that existing issued shares have already obtained. This percentage would be applied to the new shares to be issued, thus estimating the likely voting power that the new shares would obtain over time.

The Long-Term Voting Factor would be calculated by dividing, as of the Shareholder Approval Calculation Date (defined below), the voting power outstanding attributable to the LTSE-Listings Issuer's shares listed on LTSE Listings by the combined Initial Voting Power of those shares. This number will be equal to one if none of the LTSE Listings Issuer's shareholders have accrued additional voting power and will increase beyond one at a rate proportional to the number of additional votes attributable to LTSE Listings' long-term voting mechanics. In other words, the Long-Term Voting Factor represents the effect of long-term voting on the LTSE Listings Issuer's outstanding voting power as of the Shareholder Approval Calculation Date. For example, if an LTSE Listings Issuer has 1,000,000 shares outstanding on the Shareholder Approval Calculation Date, each with an Initial Voting Power of one vote per share, and as a result of increases in voting power over time, those shares have a total of 3,000,000 votes, the Long-Term Voting Factor would be 3.0. The formula would then assume that new shares to be issued would similarly achieve three votes per share over some period of time in the future. Given that the Exchange is unable to predict how many shareholders will actually elect to hold their shares in record ownership and thereby accrue additional voting power, or how long such shareholders would hold their shares, the Exchange believes that it is reasonable to look to the LTSE Listings Issuer's prior experience and apply that same experience to the new shares to be issued.

For LTSE Listings Issuers that have been listed on LTSE Listings for fewer than five years, the numerator in the shareholder approval calculation would be the greater of (i) the number of shares to be issued multiplied by the product of the Initial Voting Power for such shares and the Long-Term Voting Factor or (ii) the number of shares to be issued multiplied by the Initial Voting Power of such shares further multiplied by two. This effectively applies a minimum Long-Term Voting Factor of two to LTSE Listings Issuers that have been listed on LTSE for fewer than five years, even where the LTSE Listings Issuer has an actual Long-Term Voting Factor of less than two. The Exchange believes that imposing this minimum multiple of two is appropriate because the actual Long-Term Voting Factor that these companies would have experienced during their short period of time of being public companies is likely to be lower than longer-listed issuers and may not be representative of the longer-term growth in voting power that the new shares may ultimately attain.[87]

As stated above, it is difficult to predict with any level of certainty how many shareholders will register their shares in record name and accrue additional voting power; however, the Exchange believes that applying a minimum multiple of two for companies that have been listed on LTSE for less than five years is reasonable and conservatively estimates the relative potential voting power of the new shares to be issued. This belief is informed by the Exchange's understanding of current shareholder turnover data, such as that in 2015 (albeit for non-LTSE Listings Issuers), investors held a stock for an average of about eight months.[88] A minimum Long-Term Voting Factor of two, however, the Exchange believes conservatively assumes a much longer average holding period. By way of example, an LTSE Listings Issuer would only have actually achieved a Long-Term Voting Factor of two, even after five years, if 20% of its outstanding shares were registered in the name of their shareholders on the books of the company in the first month following the issuer's IPO and such shares remained registered to those same investors without any interim transfers throughout the five-year period, and no other shares were added during that period.[89] Both the factor of two and the five-year threshold are being imposed on the basis of the Exchange's best judgment, which the Exchange believes balances the need to recognize that the shares' voting power can increase with the burden faced by companies seeking shareholder approval.

Proposed Rule 14A.412(b) would also clarify how to calculate the denominator in the shareholder approval calculation. IEX Rule 14.412(e)(2) currently provides that the denominator (voting power outstanding) refers to the ''aggregate number of votes which may be cast by holders of those securities outstanding which entitle the holders thereof to vote generally on all matters submitted to the Company's security holders for a vote.'' The calculation would be the same for LTSE Listings Issuers, except that proposed Rule 14A.412(b) would provide that this calculation must be made as of the Shareholder Approval Calculation Date, which would be the date on which an LTSE Listings Issuer enters into a binding agreement to conduct a transaction that may require shareholder approval under IEX Rule 14.412 (*i.e.,* the acquisition of stock of assets of another company or a private placement). The Exchange already expects Exchange-listed issuers to conduct this calculation as of this date;[90] however, because the shares of

[86] The Exchange has included examples demonstrating how an LTSE Listings Issuer would conduct the shareholder approval calculations under proposed Rule 14A.412, as compared to alternative approaches considered, in Exhibit 3.

[87] If the LTSE Listings category is approved, the Exchange will periodically assess whether a five year cut-off for applying a minimum Long-Term Voting Factor and the minimum Long-Term Voting Factor of two continue to be appropriate, or whether either should be modified based on its experience with LTSE Listings Issuers. For example, the Exchange will consider when the rate of growth of the voting power of an LTSE Listings Issuer's shares typically becomes relatively stable, and at what level. The Exchange notes that any such modification would be subject to the provisions of Section 19(b)(1) under the Act and Rule 19b–4 thereunder. *See* 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b–4.

[88] *See* Turnover Ratio of Domestic Shares, *supra* note 11.

[89] If the LTSE Listings category is approved, the Exchange will periodically assess whether the minimum Long-Term Voting Factor of two for LTSE Listings Issuers listed for less than five years should be modified based on its experience with LTSE Listings Issuers. The Exchange notes that any such modification would be subject to the provisions of Section 19(b)(1) under the Act and Rule 19b–4 thereunder. *See* 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b–4.

[90] The Exchange understands that other national securities exchanges similarly expect their listed issuers to conduct the shareholder approval

Continued

an LTSE Listings Issuer may accrue voting power over time, unlike the shares of other Exchange-listed companies, the Exchange believes it is important to explicitly specify in the LTSE Listings Rules the date on which this calculation must be performed.

The provisions described above are designed to clarify how the shareholder approval calculation under IEX Rule 14.412 would be conducted by an LTSE Listings Issuer. All other provisions of IEX Rule 14.412 would continue to apply, including, for example, the financial viability exception in IEX Rule 14.412(f).

(vii) Failure To Meet LTSE Listings Standards

Pursuant to IEX Rule 14.500(a), securities of an Exchange-listed company that do not meet the listing standards set forth in Chapters 14 and 16 of the Exchange's rulebook are subject to potential delisting from the Exchange. IEX Rule Series 14.500 sets forth procedures for the independent review, suspension and delisting of companies that fail to satisfy such standards. Proposed Rule 14A.500(a) would provide that a failure to meet the listing standards set forth in the LTSE Listings Rules would be treated as a failure to meet the listing standards set forth in Chapter 14 of the Exchange's rulebook for purposes of IEX Rule Series 14.500. As a result, the procedures set forth in the IEX Rule Series 14.500 would apply to any LTSE Listings Issuer that fails to comply with the listing standards in the LTSE Listings Rules, in addition to other applicable listing standards in the Exchange's rulebook.

IEX Rule 14.501(d) provides that if a company fails to satisfy the Exchange's listing standards, the type of deficiency at issue will determine whether the company will be immediately suspended or delisted, whether the company will have an opportunity to submit a plan to regain compliance or whether the company is entitled to an automatic cure or compliance period before a delisting determination is issued. Proposed Rule 14A.500(b) would provide that a failure to satisfy one or more of the LTSE Listings Rules will be treated as a deficiency for which a company may submit a plan to regain compliance in accordance with the Exchange's rules. Like all companies listed on the Exchange, LTSE Listings Issuers will be fully subject to IEX rules related to noncompliance and delisting, as set forth in Chapter 14 of the Exchange's rules.

Proposed Rule 14A.500(c) would provide that in the event that an LTSE Listings Issuer becomes subject to delisting from LTSE Listings for failure to satisfy one or more LTSE Listings Rules but is otherwise in compliance with all other applicable listing rules of the Exchange, the Exchange may permit such issuer to remain listed on the Exchange, provided that such issuer will cease to be listed on LTSE Listings and will cease to be an LTSE Listings Issuer.[91] In such cases, the Exchange would assess whether the issuer is in compliance with the Exchange's continued listing criteria (other than continued listing criteria applicable solely to LTSE Listings Issuers); however, the issuer would not need to resubmit a listing application to remain listed on the Exchange.

(viii) Listing Fees for LTSE Listings Issuers

Proposed Rule Series 14A.600 is currently marked ''Reserved.'' The Exchange intends to file a separate proposed rule change with the Commission under Section 19 of the Act that would addresses [sic] listing fees applicable to LTSE Listings Issuers.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act in general,[92] and further the objectives of Section 6(b)(5) of the Act,[93] in particular, in 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, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

As discussed in detail in the Purpose section above, the Exchange believes that there is growing concern among market observers that pressures to meet short-term expectations have resulted in negative consequences for companies, investors and the economy as a whole. The Exchange believes that the LTSE Listings Rules would remove impediments to a free and open market and protect investors and the public interest by providing the marketplace with a differentiated listing venue choice that seeks to encourage greater focus by companies and investors on the long-term. Specifically, the LTSE Listings Rules are intended to better enable companies to focus on long-term value creation, potentially enhancing opportunities for capital formation, and are also intended to foster transparency and effective corporate governance, which would benefit all investors, particularly those with a long-term focus. In addition, because listing on LTSE Listings and becoming subject to the LTSE Listings Rules is a voluntary election, the LTSE Listings Rules are not designed to permit unfair discrimination among issuers.

The following subsections provide additional detail on how the LTSE Listings Rules are designed to further the objectives of Section 6(b) of the Act.

(1) Board of Directors and Committee Requirements

As described in the Purpose section under ''Board of Directors and Committee Requirements,'' the proposed LTSE Listings Rules would impose additional obligations on the boards of directors and board committees of LTSE Listings Issuers. For example, the LTSE Listings Rules would require each LTSE Listings Issuer to establish a board committee dedicated to overseeing the issuer's strategies for creating and sustaining long-term growth (*i.e.,* an LTSP Committee). Among other things, the LTSP Committee would be required to review and approve an LTSE Listings Issuer's LTSP Disclosures, including the disclosure of its Long-Term Growth Strategy, on at least an annual basis. The Exchange believes that these requirements would protect investors and the public interest because it would help LTSE Listings Issuers focus on long-term goals. The LTSE Listings Rules would also require LTSE Listings Issuers to establish an independent committee dedicated to selecting or recommending qualified director nominees (*i.e.,* a nominating/corporate governance committee). In addition, the LTSE Listings Rules would require the LTSP Committee, the nominating/corporate governance committee, the compensation committee and the audit committee to report regularly to the board of directors and would require that the charters of such committees be made available on or through the LTSE Listings Issuer's website. The Exchange believes that these requirements are consistent with the protection of investors and the public interest

calculation under those exchanges' substantially similar rules as of this date.

[91] Regardless of whether or not the Exchange permits an LTSE Listings Issuer to remain listed on the Exchange in such circumstances, the Exchange would expect the issuer to comply with any disclosure obligations relating to the receipt of a notification of deficiency or delisting determination as set forth in IEX Rule 14.501(c) and Item 3.01 of Form 8–K with respect to the termination of its listing on LTSE Listings.

[92] 15 U.S.C. 78f.

[93] 15 U.S.C. 78f(b)(5).

because they are designed to support the governance structure objectives of LTSE Listings.

(2) Long-Term Strategy and Product Disclosures

As described in the Purpose section under ''Long-Term Strategy and Product Disclosures,'' the proposed LTSE Listings Rules would require LTSE Listings Issuers to provide investors with LTSP Disclosures, which are supplemental disclosures regarding an LTSE Listings Issuer's long-term strategy and products. Specifically, the LTSP Disclosures would include disclosures relating to an LTSE Listings Issuer's Long-Term Growth Strategy, Buybacks, Human Capital Investment and research and development. These disclosures would be in addition to the disclosures required under the Act, the Commission's rules thereunder and the Exchange's other rules. The Exchange believes that the LTSP Disclosures would be consistent with the aims of the existing disclosure requirements of the Act—to ensure that investors receive full and accurate information so that they can make informed investment decisions—and are thereby consistent with the protection of investors and the public interest. Specifically, the Exchange believes that the LTSP Disclosure requirements would ensure that investors receive sufficient information to evaluate a company's progress toward meeting long-term goals. Although only LTSE Listings Issuers would be subject to these requirements, these requirements would not unfairly discriminate among issuers as only those companies electing to be subject to the LTSE Listings Rules would be subject to these requirements.

(3) Long-Term Alignment of Executive Compensation

As described in the Purpose section under ''Long-Term Alignment of Executive Compensation,'' the LTSE Listings Rules would require that an LTSE Listings Issuer's compensation committee adopt a set of executive compensation guidelines applicable to Executive Officers that are designed to link executive compensation to the long-term value of the LTSE Listings Issuer. The Exchange believes that these requirements are consistent with the protection of investors and the public interest, consistent with Section 6(b)(5) of the Act, because they would help ensure that Executive Officers are incentivized to take actions that would enhance the long-term growth of an LTSE Listings Issuer, rather than short-term results. In addition, the Exchange believes that requiring a stronger link between a company's long-term performance and its executive compensation is designed to prevent fraudulent and manipulative acts and practices, by incentivizing executives to act in the long-term interest of LTSE Listings Issuers and limiting the extent to which executives could personally profit from efforts to effect short-term performance.

(4) Long-Term Shareholder Voting Structure

As described in the Purpose section under ''Long-Term Shareholder Voting Structure,'' the LTSE Listings Rules would require that LTSE Listings Issuers maintain voting rights provisions in their corporate organizational documents that provide shareholders with the ability, at the shareholders' option, to accrue additional voting power over time. The Exchange believes that these requirements are consistent with the protection of investors and the public interest because they would provide a mechanism by which long-term shareholders can have greater influence in corporate governance. The Exchange believes that long-term shareholders are more likely than short-term investors to exercise their governance rights in a manner that prioritizes long-term growth over short-term results, and thus it is in the public interest and furthers the protection of investors for longer-term investors to have a greater role in corporate governance. In this regard, the Commission has noted that, ''when the interests of long-term investors and short-term traders conflict . . . its clear responsibility is to uphold the interests of long-term investors.'' [94] Further, the Exchange believes that, consistent with Section 6(b)(5) of the Act, the long-term voting rights provisions would not be unfairly discriminatory, as any shareholder of an LTSE Listings Issuer would have equal opportunity to elect to move their shares into registered form and accrue additional voting rights. Further, by requiring that the length of a shareholder's ownership be consistently measured through the shareholder's record ownership on an LTSE Listings Issuer's books, transferred to and from ''street name'' through a DRP, the Exchange believes that the system will foster cooperation and coordination with persons engaged in regulating, clearing, settling, and processing information with respect to, and facilitating transactions in securities, consistent with Section 6(b)(5) of the Act.

(5) Other Long-Term Requirements

As described in the Purpose section under ''Other Long-Term Requirements,'' the LTSE Listings Rules would include certain other rules designed to encourage LTSE Listings Issuers to focus on long-term value creation. For example, the LTSE Listings Rules would provide that LTSE Listings Issuers are generally prohibited from providing Earnings Guidance more frequently than annually. The Exchange believes that this requirement is consistent with the protection of investors and the public interest by enhancing the ability of companies to withstand short-term pressures and focus on long-term growth, and is designed to prevent fraudulent and manipulative acts and practices, such as the risk that a company could take actions to artificially meet prior Earnings Guidance.

The LTSE Listings Rules would also require that each LTSE Listings Issuer develop and publish a policy regarding an LTSE Listings Issuer's impact on the environment and community, and a policy explaining an LTSE Listings Issuer's approach to diversity. The Exchange believes that this requirement is consistent with the protection of investors and the public interest by ensuring that companies consider their impact on various stakeholders and the sustainability of their business.

The LTSE Listings Rules would require LTSE Listings Issuers to have and maintain a publicly accessible website. Documents required to be posted on this website under the LTSE Listings Rules would be required to be made available in a printable version in the English language. The Exchange believes that these requirements are consistent with the protection of investors and the public interest by ensuring that investors and the public have access to the disclosures and other documents required by the LTSE Listings Rules.

The LTSE Listings Rules would require LTSE Listings Issuers to make certain certifications to the Exchange. Specifically, LTSE Listings Issuers would be required to certify, at or before the time of listing, that all applicable listing criteria, including listing criteria under the LTSE Listings Rules, have been satisfied. In addition, the LTSE Listings Rules would require the CEO of each LTSE Listings Issuer to certify annually to the Exchange that the LTSE Listings Issuer is in compliance with proposed Rule Series 14A.400, which would contain the corporate governance

[94] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37500 (June 29, 2005).

requirements of the LTSE Listings Rules, qualifying the certification to the extent necessary. The Exchange believes that these certification requirements are consistent with the protection of investors and the public interest and are designed to prevent fraudulent and manipulative acts and practices. As discussed in the Purpose section, given the unique nature of the LTSE Listings Rules, the Exchange believes that adding an annual certification requirement for LTSE Listings Issuers will assist the CEO and senior management of such issuers in ensuring compliance with LTSE Listings corporate governance requirements on an ongoing basis.

(6) Proposed Rules Clarifying Application of Existing Exchange Rules

As described in the Purpose section under ''Proposed Rules Clarifying Application of Existing Exchange Rules,'' the LTSE Listings Rules would include a number of rules that would clarify the application of existing Exchange rules to LTSE Listings Issuers. In general, these rules would provide that LTSE Listings Issuers must comply with both the LTSE Listings Rules as well as all other applicable rules of the Exchange. However, these rules would also explain any deviations from this general principle. For example, although the Exchange maintains listing rules relevant for various types of securities, including American Depositary Receipts, preferred stock, rights and warrants, among others, the LTSE Listings Rules would clarify that only common equity securities would be eligible for listing on LTSE Listings. Similarly, although the Exchange maintains a number of exemptions from certain corporate governance requirements for certain types of issuers (*e.g.,* Foreign Private Issuers), certain exemptions would not be available for LTSE Listings Issuers. The Exchange believes that these rules are consistent with protecting investors and the public interest because they would provide transparency to issuers and investors on how the Exchange's existing rules would apply to an LTSE Listings Issuer. Although these rules discriminate between issuers listed on LTSE Listings and other issuers listed on the Exchange, as well as between the type of security listed, the Exchange believes that the rules are not unfairly discriminatory, as companies are free to elect whether to list on LTSE Listings and be subject to its additional requirements.

Another example of a proposed rule that would clarify the application of existing Exchange rules to LTSE Listings Issuers is proposed Rule 14A.412, which would clarify how an LTSE Listings Issuer would conduct the shareholder approval calculation in IEX Rule 14.412. The Exchange believes that this proposed Rule would further the objectives of Section 6(b)(5) of the Act because it would ensure that the long-term voting mechanics of the LTSE Listings Rules are taken into account when conducting this calculation. As discussed in the Purpose section, the Exchange believes that the proposed approach appropriately balances the reasonably likely potential dilution to existing shareholders without imposing a disparately burdensome shareholder approval requirement on LTSE Listings Issuers. The fact that shares may accrue voting power over time means that shares may be issued that have voting power that is less than the Shareholder Approval Threshold at the time of issuance, but potentially greater than the Shareholder Approval Threshold after a certain period of time. This would increase the dilution to the shareholders that held shares prior to that issuance. Although such existing shareholders would also have the ability to accrue additional voting power, to protect such shareholders and promote just and equitable principles of trade, proposed Rule 14A.412 would require LTSE Listings Issuers to take into account the likely voting power growth that the potential new shares would obtain over time (*i.e.,* the Long-Term Voting Factor) when determining whether an issuance covered by IEX Rule 14.412 would require shareholder approval.

For purposes of proposed Rule 14A.412, the assumed growth in voting power for the potential new shares is equal to the actual growth in voting power that the existing shares have obtained; however, shares of relatively new LTSE Listings Issuers may not have had time to accrue additional voting power. In other words, the Long-Term Voting Factor may be lower than what it would otherwise be for an LTSE-Listings Issuer that has been listed on LTSE Listings for a longer period of time. As a result, proposed Rule 14A.412 provides that LTSE Listings Issuers that have been listed for fewer than five years must assume a minimum Long-Term Voting Factor of two.[95] The Exchange believes that this provision further protects investors and helps ensure that the shareholder approval calculation in IEX Rule 14.412 appropriately balances the interests of existing shareholders in having a vote on potentially dilutive share issuances with the burden of holding a shareholder meeting under circumstances when material dilution is unlikely. The Exchange believes that this approach is consistent with the policy objectives of IEX Rule 14.412 as discussed in the Purpose section.

Proposed Rule 14A.500(c) would provide that in the event that an LTSE Listings Issuer becomes subject to delisting from LTSE Listings for failure to satisfy one or more LTSE Listings Rules but is otherwise in compliance with all other applicable listing rules of the Exchange, the Exchange may permit such issuer to remain listed on the Exchange, provided that such issuer will cease to be listed on LTSE Listings and will cease to be an LTSE Listings Issuer.[96] The Exchange would assess whether such an issuer is in compliance with the Exchange's continued listing criteria (other than continued listing criteria applicable solely to LTSE Listings Issuers), and this provision would allow such an issuer to remain listed on the Exchange without going through the process of reapplying for an Exchange listing, which the Exchange believes would be disruptive to the issuer and its investors. As a result, the Exchange believes that this proposed rule would further the objectives of Section 6(b)(5) of the Act by, among other things, helping to remove impediments to and perfect the mechanism of a free and open market.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that the proposed rule change will enhance competition between exchange listing markets in furtherance of Section 11A(a)(1)(C)(ii) of the Act[97] and consistent with Section 6(b)(8) of the

[95] As noted in the Purpose section, if the LTSE Listings category is approved, the Exchange will periodically assess whether the minimum Long-Term Voting Factor of two should be modified based on its experience with LTSE Listings Issuers. The Exchange notes that any such modification would be subject to the provisions of Section 19(b)(1) under the Act and Rule 19b–4 thereunder. *See* 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b–4.

[96] The Exchange believes that this provision is similar to rules of other national securities exchanges that permit an issuer receiving a delisting determination to transfer to a separate segment of such exchange, subject to compliance with the continued listing standards of the separate segment. *See* Nasdaq FAQ Identification No. 474 (7/31/2012). Accordingly, the Exchange does not believe that this aspect of the LTSE Listings Rules raises any new or novel issues and is consistent with requirements of Section 6(b)(5) of the Act.

[97] 15 U.S.C. 78k–1(a)(1)(C)(ii).

Act[98] because it will provide issuers with an alternative with a differentiated offering as compared to the other listing rules existing on other national securities exchanges and the Exchange itself. Moreover, as a new listing venue, the Exchange expects to face intense competition from existing exchanges. Consequently, the degree to which a new listing category on the Exchange could impose any burden on intermarket competition is extremely limited, and the Exchange does not believe that such listing category would impose any burden on competing venues that is not necessary or appropriate in furtherance of the purposes of the Act. In addition, there is no barrier to other exchanges adopting similar listing standards. To the extent LTSE Listings is successful in attracting issuers to the list on the Exchange, other exchanges or potential new entrants could respond by adopting their own rules that are designed to foster long-term value creation.

The Exchange also does not believe that the proposed rule change will result in any burden on intramarket competition since becoming subject to the supplemental standards in the LTSE Listings Rules is completely voluntary. Issuers can elect to list on the Exchange without listing on LTSE Listings, or can elect to become subject to the heightened standards of the LTSE Listings Rules. The Commission and Congress have in other contexts recognized that companies may elect to be subject to greater compliance obligations than strictly required, or elect not to rely on exemptions that may otherwise be available. For example, in adopting the Jumpstart Our Business Startups Act,[99] Congress provided that emerging growth companies could, but were not required to, elect to rely on exemptions from various securities law requirements.[100] Similarly, the Commission provides that classes of companies, such as Smaller Reporting Companies, may but are not required to provide particular disclosures.[101] Similarly, other national securities exchanges have adopted categories for listed companies that elect to become subject to higher standards than other companies listed on such national securities exchange.[102]

The Exchange also does not believe that the proposal will impose any burden on competition between LTSE Listings Issuers that is not necessary or appropriate in furtherance of the purposes of the Act because all companies electing to list on LTSE Listings will be subject to the same standards. Furthermore, where appropriate, the LTSE Listings Rules are designed to provide LTSE Listings Issuers with flexibility to implement the minimum standards contained in the LTSE Listings Rules in ways that are best suited for that issuer's business.

Finally, the Exchange does not believe that the transfer agent certification requirement under proposed Rule 14A.413(b)(5) will impose a burden on competition with respect to transfer agents. While not all transfer agents will be able to implement the required software or other systems or processes, any transfer agent can choose to invest the resources necessary to implement such software or other systems or processes. Moreover, as noted above, as a new listing venue, the Exchange expects to face intense competition from existing exchanges. Consequently, the degree to which a new listing category on the Exchange could impose any burden on competition among transfer agents is extremely limited, and the Exchange does not believe that such listing category would impose any burden on transfer agents that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–IEX–2018–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–IEX–2018–06. 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 such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File

[98] 15 U.S.C. 78f(b)(8).

[99] Public Law 112–106, 126 Stat. 306 (2012).

[100] For example, emerging growth companies may, but "need not present more than 2 years of audited financial statements in order for the registration statement of such emerging growth company with respect to an initial public offering of its common equity securities to be effective . . ." *See* Securities Act Section 7(a)(2)(A); 15 U.S.C. 77g(a)(2)(A).

[101] *See, e.g.,* Regulation S–K, Item 10(f); 17 CFR 229.10(f) ("[a] smaller reporting company may comply with either the requirements applicable to smaller reporting companies or the requirements applicable to other companies for each item, unless the requirements for smaller reporting companies specify that smaller reporting companies must comply with the smaller reporting company requirements").

[102] *See generally* Nasdaq Rule 5000 series (containing more stringent listing standards for issuers listed on the "Nasdaq Global Select Market" as compared to those listed on the "Nasdaq Global Market" or the "Nasdaq Capital Market").

Number SR–IEX–2018–06 and should be submitted on or before April 23, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[103]

Jill Peterson,

Assistant Secretary.

[FR Doc. 2018–06568 Filed 3–30–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82952; File No. SR–C2–2018–004]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change Concerning an Affiliation Between the Exchange and Cboe Trading and To Adopt Rules To Permit Inbound Routing by Cboe Trading

March 27, 2018

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 12, 2018, Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2 Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and, for the reasons discussed below, is approving the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt rules related to the inbound router for C2 Options.

The text of the proposed rule change is also available on the Exchange's website (*http://www.c2exchange.com/Legal/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange seeks: (1) To adopt Rule 3.18 to govern the Exchange's receipt of inbound options orders from the Exchange's affiliate broker-dealer, Cboe Trading, Inc. (''Cboe Trading''), on behalf of the Exchange's affiliate options exchanges, Cboe EDGX Exchange, Inc. (''EDGX Options'') and Cboe BZX Exchange, Inc. (''BZX Options) and (2) approval from the Securities and Exchange Commission (the ''Commission'') pursuant to Rule 3.2(f) for affiliate Cboe Trading to become a Trading Permit Holder of the Exchange.

Proposed Rule 3.18 is based on EDGX Options Rule 2.12. Pursuant to proposed Rule 3.18, Cboe Trading's inbound routing services from EDGX Options and BZX Options to the Exchange would be subject to the following conditions and limitations: (1) The Exchange must enter into (a) a plan pursuant to Rule 17d–2 under the Exchange Act with a non-affiliated self-regulatory organization[3] and (b) a regulatory services contract with a non-affiliated SRO to perform regulatory responsibilities for Cboe Trading for unique Exchange rules. (2) The regulatory services contract must require the Exchange to provide the non-affiliated self-regulatory organization with information, in an easily accessible manner, regarding all exception reports, alerts, complaints, trading errors, cancellations, investigations, and enforcement matters (collectively, ''Exceptions'') in which Cboe Trading is identified as a participant that has potentially violated Exchange or Commission rules, and shall require that the non-affiliated self-regulatory organization provide a report to the Exchange quantifying all such exception reports, alerts, complaints, trading errors, cancellations, investigations and enforcement matters on not less than a quarterly basis. (3) The Exchange, on behalf of its parent company, Cboe Global Markets, must establish and maintain procedures and internal controls reasonably designed to ensure that Cboe Trading does not develop or implement changes to its systems on the basis of nonpublic information obtained as a result of its affiliation with the Exchange until such information is available generally to similarly situated Trading Permit Holders of the Exchange.

The Exchange will comply with the above-listed conditions prior to offering inbound routing from Cboe Trading. In meeting the conditions, the Exchange will have mechanisms in place to protect the independence of the Exchange's regulatory responsibility with respect to Cboe Trading, as well as demonstrate that Cboe Trading cannot use any information that it may have because of its affiliation with the Exchange to its advantage.

Exchange Rule 3.2(f) provides that without prior Commission approval, no Trading Permit Holder may be or become affiliated with the Exchange. The Exchange seeks Commission approval for Exchange affiliate Cboe Trading to become a Trading Permit Holder of the Exchange pursuant to Rule 3.2(f).

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[4] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[5] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[6] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the rule change promotes the maintenance of a fair and orderly

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[103] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange will ensure a 17d–2 plan is in place prior to offering inbound routing from Cboe Trading.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] *Id.*

market, the protection of investors and the public interest, and is in the best interests of the Exchange and its Trading Permit Holders as it will allow the routing of orders from affiliated exchanges, BZX Options and EDGX Options, to the Exchange. Moreover, in meeting the requirements of Rule 3.18 (*i.e.,* the 17d–2 plan, the regulatory services contract, and procedures and internal controls) the Exchange believes it will have mechanisms in place that protect the independence of the Exchange's regulatory responsibility with respect to Cboe Trading, as well as demonstrates that Cboe Trading cannot use any information that it may have because of its affiliation with the Exchange to its advantage.

B. Self-Regulatory Organization's Statement on Burden on Competition

C2 does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change will impose any burden on intramarket or intermarket competition that is not necessary or appropriate in furtherance of Act as the proposed rule is based on EDGX Options Rule 2.12 and BZX Options Rule 2.12 [sic], which allow [sic] EDGX Options and BZX Options to receive orders from affiliate Cboe Trading on behalf of affiliate exchanges. Moreover, the requirements of Rule 3.18 (*i.e.,* the 17d–2 plan, the regulatory services contract, and procedures and internal controls) help to prevent an unfair burden on competition and unfair discrimination between customers, issuers, brokers, or dealers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–C2–2018–004 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–C2–2018–004. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–C2–2018–004, and should be submitted on or before April 23, 2018.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[7] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(1) of the Act,[8] which requires, among other things, that a national securities exchange be so organized and have the capacity to carry out the purposes of the Act, and to comply and enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulation thereunder, and the rules of the Exchange. Further, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[9] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Section 6(b)(5) also requires that the rules of an exchange not be designed to permit unfair discrimination among customers, issuers, brokers, or dealers.

Recognizing that the Commission has previously expressed concern regarding the potential for conflicts of interest in instances where a member firm is affiliated with an exchange to which it is routing orders, the Exchange has proposed limitations and conditions to Cboe Trading's affiliation with the Exchange to permit the Exchange to accept routed orders that Cboe Trading would route in its capacity as a facility of C2.

Specifically, as detailed above, the Exchange committed to the following limitations and conditions:

- The Exchange shall enter into a plan pursuant to Rule 17d–2 under the Act with a non-affiliated self-regulatory organization (''SRO'') and ensure that such plan is operative before offering routing services through Cboe Trading. The 17d–2 plan will relieve the Exchange of regulatory responsibilities with respect to Cboe Trading for rules that are common rules between the Exchange and the non-affiliated SRO. In addition, the Exchange shall enter into a regulatory services agreement (''RSA'') with a non-affiliated SRO to perform regulatory responsibilities for Cboe Trading for unique Exchange rules that are not common rules under the 17d–2 plan.
- The RSA shall require the Exchange to provide the non-affiliated SRO with information, in an easily accessible manner, regarding all exception reports, alerts, complaints, trading errors, cancellations, investigations, and enforcement matters (collectively

[7] 15 U.S.C. 78f(b). In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78f(b)(1).

[9] 15 U.S.C. 78f(b)(5).

''Exceptions'') in which Cboe Trading is identified as a participant that has potentially violated Exchange or Commission rules, and shall require that the non-affiliated SRO provide a report, at least quarterly, to the Exchange quantifying all Exceptions in which Cboe Trading is identified as a participant that has potentially violated Exchange or Commission rules.

• The Exchange, on behalf of Cboe Trading, shall establish and maintain procedures and internal controls reasonably designed to ensure that Cboe Trading does not develop or implement changes to its system on the basis of non-public information regarding planned changes to Exchange systems, obtained as a result of its affiliation with the Exchange, until such information is available generally to similarly situated members of the Exchange in connection with the provision of order routing to or from the Exchange.

As the Exchange represents above, the Exchange believes that the above conditions will protect the independence of the Exchange's regulatory responsibility with respect to Cboe Trading and ensure that Cboe Trading cannot use any information that it may have because of its affiliation with the Exchange to its advantage.

In the past, the Commission has expressed concern that the affiliation of an exchange with one of its members raises potential conflicts of interest, and the potential for unfair competitive advantage.[10] To address these concerns, the Exchange has proposed ongoing conditions applicable to Cboe Trading's routing activities in its capacity as a facility of C2, which are enumerated above. The Commission believes that these conditions are designed to mitigate concerns about potential conflicts of interest and unfair competitive advantage. In particular, the Commission believes that a non-affiliated SRO's oversight of Cboe Trading, combined with a non-affiliated SRO's monitoring of Cboe Trading's compliance with the Exchange's rules and quarterly reporting to the Exchange, will help to protect the independence of the Exchange's regulatory responsibilities with respect to Cboe Trading. The Commission also believes that the Exchange's proposal is designed to ensure that the Exchange will not permit Cboe Trading to have any information advantage on account of its affiliation with the Exchange.

Finally, Exchange Rule 3.2(f) provides that, without prior Commission approval, no Trading Permit Holder may be or become affiliated with the Exchange. The Exchange now seeks Commission approval for its affiliate, Cboe Trading, to become a Trading Permit Holder of the Exchange pursuant to Rule 3.2(f) so that its affiliate may provide routing services as a facility of the Exchange. Although the Commission continues to be concerned about potential unfair competition and conflicts of interest between an exchange's self-regulatory obligations and its commercial interest when the exchange is affiliated with one of its members, for the reasons discussed above, the Commission believes that it is consistent with the Act to permit Cboe Trading to become affiliated with the Exchange, in the capacity of a facility of C2, for the purposes of providing routing services for the Exchange subject to the conditions described above.[11]

The Exchange has requested that the Commission find good cause for approving the proposed rule change prior to the 30th day after publication of the notice thereof in the **Federal Register**. The Exchange stated that accelerated approval of its proposal will facilitate the Exchange's plans to migrate C2 Options to Bats technology in May 2018.

The Commission notes that Cboe Trading, formerly known as Bats Trading, Inc.,[12] serves as the routing facility for the Exchange's affiliate options exchanges, EDGX Options and BZX Options and is subject to substantively identical conditions and limitations by those exchanges.[13] The Exchange's current proposal is intended to allow Cboe Trading to perform an identical role for the Exchange as to which it currently performs for EDGX Options and BZX Options, including accepting routed orders sent from EDGX Options and BZX Options to the Exchange.

The Commission believes that good cause exists for accelerated approval of the proposed rule change because it raises no novel issues, as the Exchange is adopting the same conditions and limitations that EDGX Options and BZX Options have adopted for Cboe Trading.[14] Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[15] to approve the proposed rule change prior to the 30th day after the date of publication of the notice of filing thereof in the **Federal Register**.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[16] that the proposed rule change (SR–C2–2018–004) be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Jill Peterson,

Assistant Secretary.

[FR Doc. 2018–06570 Filed 3–30–18; 8:45 am]

BILLING CODE 8011–01–P

[10] *See, e.g.,* Securities Exchange Act Release Nos. 54170 (July 18, 2006), 71 FR 42149 (July 25, 2006) (SR–NASDAQ–2006–006) (order approving Nasdaq's proposal to adopt Nasdaq Rule 2140, restricting affiliations between Nasdaq and its members); 53382 (February 27, 2006), 71 FR 11251 (March 6, 2006) (SR–NYSE–2005–77) (order approving the combination of the New York Stock Exchange, Inc. and Archipelago Holdings, Inc.); 58673 (September 29, 2008), 73 FR 57707 (October 3, 2008) (SR–Amex–2008–62 and SR–NYSE–2008–60) (order approving the combination of NYSE Euronext and the American Stock Exchange LLC); 59135 (December 22, 2008), 73 FR 79954 (December 30, 2008) (SR–ISE–2009–85) (order approving the purchase by ISE Holdings of an ownership interest in DirectEdge Holdings LLC); 59281 (January 22, 2009), 74 FR 5014 (January 28, 2009) (SR–NYSE–2008–120) (order approving a joint venture between NYSE and BIDS Holdings L.P.); 58375 (August 18, 2008), 73 FR 49498 (August 21, 2008) (File No. 10–182) (order granting the exchange registration of BATS Exchange, Inc.); 61698 (March 12, 2010), 75 FR 13151 (March 18, 2010) (File Nos. 10–194 and 10–196) (order granting the exchange registration of EDGX Exchange, Inc. and EDGA Exchange, Inc.); and 62716 (August 13, 2010), 75 FR 51295 (August 19, 2010) (File No. 10–198) (order granting the exchange registration of BATS–Y Exchange, Inc.).

[11] The Commission notes that these limitations and conditions are consistent with those previously approved by the Commission for other exchanges. *See, e.g.,* Securities Exchange Act Release Nos. 64090 (March 17, 2011), 76 FR 16462 (March 23, 2011) (SR–BX–2011–007); 66808 (April 13, 2012), 77 FR 23294 (April 18, 2012) (SR–BATS–2012–013); 66807 (April 13, 2012), 77 FR 23300 (April 18, 2012) (SR–BYX–2012–006); 67256 (June 26, 2012), 77 FR 39277 (July 2, 2012) (SR–BX–2012–030); 69233 (March 25, 2013), 78 FR 19352 (March 29, 2013) (SR–NASDAQ–2013–028); 69232 (March 25, 2013), 78 FR 19342 (March 29, 2013) (SR–BX–2013–013); 69229 (March 25, 2013), 78 FR 19337 (March 29, 2013) (SR-Phlx–2013–15); and 68970 (June 27, 2013), 78 FR 40225 (July 3, 2013) (SR–EDGX–2013–17).

[12] *See* Securities Exchange Act Release No. 81952 (October 26, 2017), 82 FR 50725 (November 1, 2017) (SR-BatsBYX–2017–27).

[13] *See* EDGX Options Rule 2.12 (Cboe Trading, Inc. as Inbound Router) and BZX Options Rule 2.12 (Cboe Trading, Inc. as Inbound Router). *See also* EDGX Options Rule 2.11 (Cboe Trading, Inc. as Outbound Router) and BZX Options Rule 2.11 (Cboe Trading, Inc. as Outbound Router).

[14] The Commission notes that it did not receive any comments on a substantively identical proposal from EDGX Options with respect to inbound routing from Cboe Trading. *See* Securities Exchange Act Release No. 69870 (June 27, 2013), 78 FR 40225 (July 3, 2013) (SR–EDGX–2013–17).

[15] 15 U.S.C. 78s(b)(2).

[16] 15 U.S.C. 78s(b)(2).

[17] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before June 1, 2018.

ADDRESSES: Send all comments to Adrienne Grierson, Deputy Director, Office of Credit Risk Management, Small Business Administration, 409 3rd Street, 8th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Adrienne Grierson, Deputy Director, Office of Credit Risk Management, *lender.oversight@sba.gov,* 202–205–6573, or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov;*

SUPPLEMENTARY INFORMATION: This information collection is reported to SBA's Office Credit Risk Management (OCRM) by SBA's 7(A) Lenders, Certified Development Companies, Microloan Lenders, and Non-Lending Technical Assistance Providers. OCRM uses the information reported to facilitate its oversight and monitoring of these groups, including their overall performance on SBA loans and their compliance with the applicable program requirements.

Solicitation of Public Comments

SBA is requesting comments on (a) Whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collection

Title: SBA Lender Reporting Requirements.

Description of Respondents: SBA 7(A) Lenders, Certified Development Companies, Microloan Lenders, and Non-Lending Technical Assistance Providers.

Form Number: N/A.

Total Estimated Annual Responses: 2,300.

Total Estimated Annual Hour Burden: 21,000.

Curtis Rich,

Management Analyst.

[FR Doc. 2018–06642 Filed 3–30–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day Notice.

SUMMARY: The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA), which requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public of that submission.

DATES: Submit comments on or before May 2, 2018.

ADDRESSES: Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW, 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030 *curtis.rich@sba.gov.*

Copies: A copy of the Form OMB 83–1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION: This information collection is provided by SBA lenders and borrowers to provide basic loan information and certifications regarding the disbursement of loan proceeds. SBA relies on this information during the guaranty purchase review process as a component in determining whether to honor a loan guaranty.

Solicitation of Public Comments

Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collections

Title: Settlement Sheet.

Description of Respondents: SBA Lenders and Borrowers.

Form Number: SBA Form 1050.

Estimated Annual Respondents: 15,000.

Estimated Annual Responses: 15,000.

Estimated Annual Hour Burden: 3,800.

Curtis Rich,

Management Analyst.

[FR Doc. 2018–06641 Filed 3–30–18; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 10318]

Renewal of Cultural Property Advisory Committee Charter

SUMMARY: The Charter of the Department of State's Cultural Property Advisory Committee has been renewed for an additional two years.

The Charter of the Cultural Property Advisory Committee has been renewed for a two-year period. The Committee was established by the Convention on Cultural Property Implementation Act of 1983. The Committee reviews requests from other States Parties to the 1970 UNESCO *Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property* seeking U.S. import restrictions on archaeological or ethnological material. The Committee makes findings and recommendations to the President's designee who, on behalf of the President, determines whether to impose import restrictions. The membership of the Committee consists of private sector experts in archaeology, anthropology, or ethnology; experts in the international sale of cultural property; and representatives of museums and of the general public.

FOR FURTHER INFORMATION CONTACT: Cultural Heritage Center, U.S. Department of State, Bureau of Educational and Cultural Affairs, 2200 C Street NW, Washington, DC 20522.

Telephone: (202) 632–6301; Fax: (202) 632–6300.

Andrew C. Cohen,

Executive Director, Cultural Property Advisory Committee, Department of State.

[FR Doc. 2018–06656 Filed 3–30–18; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 10364]

Town Hall Meeting on Modernizing the Columbia River Treaty Regime

AGENCY: Department of State.

ACTION: Notice of meeting.

SUMMARY: The Department of State (Department) will hold a town hall meeting in Spokane, Washington, to discuss the modernization of the Columbia River Treaty (CRT) regime.

DATES: The meeting will be held on April 25, 2018, from 5:00 p.m. to approximately 7:00 p.m., Pacific Time.

ADDRESSES: The meeting will be held in the Isabella Room of the Historic Davenport Hotel, 10 South Post Street, Spokane, Washington 99201.

FOR FURTHER INFORMATION CONTACT: Susan May, *ColumbiaRiverTreaty@state.gov,* 202–647–2228.

SUPPLEMENTARY INFORMATION: This Town Hall will initiate the Department's public engagement on the modernization of the CRT regime. The meeting is open to the public, up to the capacity of the room. Requests for reasonable accommodation should be made to the email listed above, on or before April 18, 2018. The Department will consider requests made after that date, but might not be able to accommodate them. Information regarding the proposed agenda, and other information about the meeting, can be found at on *www.state.gov* or by emailing the email address listed above.

Cynthia A. Kierscht,

Director, Office of Canadian Affairs, Department of State.

[FR Doc. 2018–06612 Filed 3–30–18; 8:45 am]

BILLING CODE 4710–29–P

SURFACE TRANSPORTATION BOARD

Release of Waybill Data

The Surface Transportation Board has received a request from the Southern California Association of Governments (WB18–11—3/27/18) for permission to use data from the Board's 2016 Masked Carload Waybill Sample. A copy of this request may be obtained from the Office of Economics.

The waybill sample contains confidential railroad and shipper data; therefore, if any parties object to these requests, they should file their objections with the Director of the Board's Office of Economics within 14 calendar days of the date of this notice. The rules for release of waybill data are codified at 49 CFR 1244.9.

Contact: Alexander Dusenberry, (202) 245–0319.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2018–06606 Filed 3–30–18; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Fourteenth RTCA SC–230 Airborne Weather Detection Systems Plenary

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Fourteenth RTCA SC–230 Airborne Weather Detection Systems Plenary.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Fourteenth RTCA SC–230 Airborne Weather Detection Systems Plenary.

DATES: The meeting will be held May 02–03, 2018 9:00 a.m.–5:00 p.m.

ADDRESSES: The meeting will be held at: RTCA Headquarters, 1150 18th Street NW, Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Karan Hofmann at *khofmann@rtca.org* or 202–330–0680, or The RTCA Secretariat, 1150 18th Street NW, Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or website at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Fourteenth RTCA SC–230 Airborne Weather Detection Systems Plenary. The agenda will include the following:

Wednesday, May 2, 2018—9:00 a.m.–5:00 p.m.

1. Welcome and Administrative Remarks
2. Introductions
3. Agenda Review
4. Meeting Minutes Review and Approval of Last Plenary
5. Review and Work Resolution of Final Review and Comment (FRAC) Inputs for DO–220A Change 1 and DO–213A Change 1

Thursday, May 3, 2018—9:00 a.m.–5:00 p.m.

1. Continue Review and Work Resolution of FRAC Inputs For DO–220A Change 1 and DO–213A Change 1
2. Decision to Approve Release of DO–220A Change 1 and DO–213A Change 1 for Presentation to the Program Management Committee
3. Discuss and Approve Revision to Terms of Reference
4. Action Item Review
5. Any Other Business
6. Date and Place of Next Meeting
7. Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC on March 28, 2018.

Michelle Swearingen,

Systems and Equipment Standards Branch, AIR–6B0, Policy and Innovation Division, AIR–600, Federal Aviation Administration.

[FR Doc. 2018–06600 Filed 3–30–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Research, Engineering and Development Advisory Committee Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of meeting.

SUMMARY: The FAA is issuing this notice to advise the public of the Research, Engineering & Development Advisory Committee meeting.

DATES: The meeting will be held on April 11, 2018—9:30 a.m. to 4:30 p.m.

ADDRESSES: The meeting will be held at the Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: Chinita A. Roundtree-Coleman at (609) 485–7149 or website at *chinita.roundtree-coleman@faa.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App. 2), notice is hereby

given of a meeting of the Research, Engineering and Development (RE&D) Advisory Committee. The meeting agenda will include receiving from the Committee guidance for FAA's research and development investments in the areas of air traffic services, airports, aircraft safety, human factors and environment and energy. Attendance is open to the interested public but seating is limited. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to attend the meeting, present statements, or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the Committee at any time.

Issued in Washington, DC, on March 27, 2018.

Chinita A. Roundtree-Coleman,

Computer Specialist.

[FR Doc. 2018–06586 Filed 3–30–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by the California Department of Transportation (Caltrans), pursuant to 23 U.S.C. 327.

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans. The actions relate to a proposed highway project, State Route 132 West Freeway/Expressway Project from post miles 11.0 to 15.0 and 15.7 to 17.5 in the County of Stanislaus in the City of Modesto, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions. A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before August 30, 2018. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Haesun Lim, Acting Branch Chief, Central Sierra Environmental Analysis Branch, 855 M Street, Suite Significant Impact (FONSI) for the project, approved on March 9, 2018, and in other documents in the FHWA project records. The EA, FONSI, and other project records are available by contacting Caltrans at the addresses provided above. The Caltrans EA and FONSI can be viewed and downloaded from the project website at *http://www.dot.ca.gov/d10/x-project-sr132west.html,* or viewed at the Stanislaus County Library (1500 I Street, Modesto, CA 95354).

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. National Environmental Policy Act (NEPA)
2. Fixing America's Surface Transportation Act (Fast Act)
3. Clean Air Act
4. Federal-Aid Highway Act
5. Clean Water Act
6. Historic Sites Act
7. Section 106 of the National Historic Preservation Act
8. Archeological Resources Protection Act
9. Archeological and Historic Preservation Act
10. Antiquities Act
11. Endangered Species Act
12. Migratory Bird Treaty Act
13. Fish and Wildlife Coordination Act
14. Magnuson-Stevens Fishery Conservation and Management Act
15. Section 4(f) of the Department of Transportation Act
16. Civil Rights Act, Title VI
17. Farmland Protection Policy Act
18. Uniform Relocation Assistance and Real Property Acquisition Policies Act
19. Rehabilitation Act
20. Americans with Disabilities Act
21. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
22. Resource Conservation and Recovery Act (RCRA)
23. Safe Drinking Water Act
24. Occupational Safety and Health Act
25. Atomic Energy Act
26. Toxic Substances Control Act
27. Federal Insecticide, Fungicide and Rodenticide Act
28. E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management
29. E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations
30. E.O. 12088, Federal Compliance with Pollution Control Standards

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1).

Kenneth Born,

Team Leader, Planning and Air Quality, Federal Highway Administration, Sacramento, California.

[FR Doc. 2018–06639 Filed 3–30–18; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2008–0063]

Petition for Waiver of Compliance

Under part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that on March 23, 2018, the Memphis Area Transit Authority (MATA) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at Title 49 CFR. FRA assigned the petition Docket Number FRA–2008–0063.

In its petition, MATA seeks to extend the terms and conditions of its Shared Use waiver, originally granted by FRA's Railroad Safety Board (Board) on October 31, 2008, and extended in 2013. MATA seeks a permanent waiver of compliance from some sections of Title 49 of the CFR for operation of its vintage Riverfront Streetcar line, which features ''limited connections'' to the general railroad system, including a 1.5-mile shared corridor with the Canadian National Railway (CN) and Amtrak. This shared corridor includes a diamond at-grade rail crossing of the CN/Amtrak track by the Streetcar and 11 shared highway-rail grade crossings. All shared highway-rail at-grade crossings have signalized crossing protection. Also, the diamond at-grade rail crossing is fully interlocked and signaled. All maintenance of the right-of-way is performed by CN forces. MATA ceased operation of its streetcars in 2014 after two fires onboard its rolling stock. MATA hopes to reopen the Riverfront Streetcar line in summer 2018 with overhauled/rebuilt streetcars.

MATA again seeks partial relief from 49 CFR part 225, *Railroad Accidents/Incidents: Reports Classification and Investigations,* regarding employee injuries, because it already reports them to the Federal Transit Administration and the Occupational Safety and Health Administration.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by May 17, 2018 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov.*

Robert C. Lauby,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2018–06629 Filed 3–30–18; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Bureau of Transportation Statistics

[Docket ID Number DOT–OST–2014–0031]

Agency Information Collection; Activity Under OMB Review; Report of Financial and Operating Statistics for Small Aircraft Operators

AGENCY: Office of the Assistant Secretary for Research and Technology (OST–R), Bureau of Transportation Statistics (BTS), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for extension of currently approved collection. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on January 23, 2018 (83 FR 15, Page 3257).

No comments were received.

DATES: Written comments should be submitted by May 2, 2018.

FOR FURTHER INFORMATION CONTACT: Marianne Seguin, Office of Airline Information, RTS–42, Room E32–105, OST–R, BTS, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, Telephone Number (202) 366–1547, Fax Number (202) 366–3383 or EMAIL *Marianne.Seguin@dot.gov.*

Comments: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street NW, Washington, DC 20503, Attention: OST Desk Officer.

SUPPLEMENTARY INFORMATION:

OMB Approval No. 2138–0009.

Title: Report of Financial and Operating Statistics for Small Aircraft Operators.

Form No.: BTS Form 298–C.

Type of Review: Extension of a currently approved collection for the financial data.

Respondents: Small certificated (29) and commuter air carriers (35).

Schedule F1

Number of Respondents: 64.
Number of Annual Responses: 256.
Total Burden per Response: 4 hours.
Total Annual Burden: 1,024 hours.

Schedule F2

Number of Respondents: 29.
Number of Annual Responses: 116.
Total Burden per Response: 12 hours.
Total Annual Burden: 1,392 hours.

Needs and Uses: Program uses for Form 298–C financial data are as follows:

Mail Rates

The Department of Transportation sets and updates the Intra-Alaska Bush mail rates based on carrier aircraft operating expense, traffic, and operational data. Form 298–C cost data, especially fuel costs, terminal expenses, and line haul expenses are used in arriving at rate levels. DOT revises the established rates based on the percentage of unit cost changes in the carriers' operations. These updating procedures have resulted in the carriers receiving rates of compensation that more closely parallel their costs of providing mail service and contribute to the carriers' economic well-being.

Essential Air Service

DOT often has to select a carrier to provide a community's essential air service. The selection criteria include historic presence in the community, reliability of service, financial stability and cost structure of the air carrier.

Carrier Fitness

Fitness determinations are made for both new entrants and established U.S. domestic carriers proposing a substantial change in operations. A portion of these applications consists of an operating plan for the first year (14 CFR part 204) and an associated projection of revenues and expenses. The carrier's operating costs, included in these projections, are compared against the cost data in Form 298–C for a carrier or carriers with the same aircraft type and similar operating characteristics. Such a review validates the reasonableness of the carrier's operating plan.

The quarterly financial submissions by commuter and small certificated air carriers are used in determining each carrier's continuing fitness to operate. Section 41738 of Title 49 of the United States Code requires DOT to find all commuter and small certificated air carriers fit, willing, and able to conduct passenger service as a prerequisite to providing such service to an eligible essential air service point. In making a

fitness determination, DOT reviews three areas of a carrier's operation: (1) The qualifications of its management team, (2) its disposition to comply with laws and regulations, and (3) its financial posture. DOT must determine whether or not a carrier has sufficient financial resources to conduct its operations without imposing undue risk on the traveling public. Moreover, once a carrier begins conducting flight operations, DOT is required to monitor its continuing fitness.

Senior DOT officials must be kept fully informed and advised of all current and developing economic issues affecting the airline industry. In preparing financial condition reports or status reports on a particular airline, financial and traffic data are analyzed. Briefing papers prepared for senior DOT officials may use the same information.

The Confidential Information Protection and Statistical Efficiency Act of 2002 (44 U.S.C. 3501 note), requires a statistical agency to clearly identify information it collects for non-statistical purposes. BTS hereby notifies the respondents and the public that BTS uses the information it collects under this OMB approval for non-statistical purposes including, but not limited to, publication of both Respondent's identity and its data, submission of the information to agencies outside BTS for review, analysis and possible use in regulatory and other administrative matters.

Issued in Washington, DC, on March 27, 2018.

William Chadwick, Jr.,

Director, Office of Airline Information, Bureau of Transportation Statistics.

[FR Doc. 2018–06615 Filed 3–30–18; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Guidance on Stress Testing for Banking Organizations With More Than $10 Billion in Total Consolidated Assets

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning renewal of its information collection titled, ''Guidance on Stress Testing for Banking Organizations with more than $10 Billion in Total Consolidated Assets.''

DATES: Comments must be submitted on or before June 1, 2018.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0312, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0312'' in your comment. In general, the OCC will publish them on *www.reginfo.gov* without change, including any business or personal information that you provide, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection [1] by any of the following methods:

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Click on the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0312'' or ''Guidance on Stress Testing for Banking Organization with More than $10 Billion in Total Consolidated Assets.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.
- *Viewing Comments Personally:* You may personally inspect and photocopy comments at the OCC, 400 7th Street, SW, Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, (202) 649–5490 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the proposed collection of information set forth in this document.

Title: Guidance on Stress Testing for Banking Organization with More than $10 Billion in Total Consolidated Assets.

OMB Control No.: 1557–0312.

Description: Each banking organization should have the capacity to

[1] Following the close of the 60-Day comment period for this notice, the OCC will publish a notice for 30 days of comment for this collection.

understand its risks and the potential impact of stressful events and circumstances on its financial condition.[2] On May 17, 2012, the OCC, along with the Federal Deposit Insurance Corporation (FDIC) and the Board of Governors of the Federal Reserve (FRB), published guidance on the use of stress testing as a means to better understand the range of a banking organization's potential risk exposures.[3] The OCC is now seeking to renew the information collection associated with that guidance.

The guidance provides an overview of how a banking organization should structure its stress testing activities to ensure those activities fit into the banking organization's overall risk management. The purpose of the guidance is to outline broad principles for a satisfactory stress testing framework and describe the manner in which stress testing should be used. While the guidance is not intended to provide detailed instructions for conducting stress testing for any particular risk or business area, it does describe several types of stress testing activities and how they may be most appropriately used by banking organizations. The guidance also does not explicitly address the stress testing requirements imposed upon certain companies by section 165(i) of the Dodd-Frank Wall Street Reform and Consumer Protection Act.[4]

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 62.

Estimated annual burden: 16,120 hours.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collections of information are necessary for the proper performance of the OCC's functions, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the information collections, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: March 26, 2018.

Karen Solomon,

Acting Senior Deputy Comptroller and Chief Counsel.

[FR Doc. 2018–06573 Filed 3–30–18; 8:45 am]

BILLING CODE 4810–33–P

[2] For purposes of this guidance, the term ''banking organization'' means national banks and federal branches and agencies supervised by the OCC; state member banks, bank holding companies, and all other institutions for which the FRB is the primary federal supervisor; and state nonmember insured banks and other institutions supervised by the FDIC.

[3] 77 FR 29458 (May 17, 2012).

[4] Public Law 111–203, 124 Stat. 1376. Section 165(i) of the Dodd-Frank Act is codified at 12 U.S.C. 5365(i)(2).

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Procedures To Enhance the Accuracy and Integrity of Information Furnished to Consumer Reporting Agencies Under Section 312 of the Fair and Accurate Credit Transactions Act

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995.

An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number.

The OCC is soliciting comment concerning the renewal of its information collection titled, ''Procedures to Enhance the Accuracy and Integrity of Information Furnished to Consumer Reporting Agencies under Section 312 of the Fair and Accurate Credit Transactions Act.''

DATES: Comments must be received by June 1, 2018.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0238, 400 7th Street SW, Suite 3E–218, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC, 400 7th Street SW, Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street, SW, Suite 3E–218, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests and requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of part 44 requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the proposed extension of this collection of information.

Title: Procedures to Enhance the Accuracy and Integrity of Information Furnished to Consumer Reporting Agencies under Section 312 of the Fair and Accurate Credit Transactions Act (FACT Act).

OMB Control No.: 1557–0238.

Type of Review: Regular.

Description: Section 312 of the Fair and Accurate Credit Transactions Act of 2003 (FACT Act) required the issuance of guidelines for use by furnishers regarding the accuracy and integrity of the information about consumers that they furnish to consumer reporting agencies and to prescribe regulations requiring furnishers to establish reasonable policies and procedures for implementing the guidelines. Section 312 also required the issuance of regulations identifying the circumstances under which a furnisher must reinvestigate disputes about the accuracy of information contained in a consumer report based on a direct request from a consumer.

Twelve CFR 1022.42(a) requires furnishers to establish and implement reasonable written policies and procedures regarding the accuracy and integrity of consumer information that they provide to a consumer reporting agency (CRA).

Section 1022.43(a) requires a furnisher to conduct a reasonable investigation of a dispute initiated directly by a consumer in certain circumstances. Furnishers are required to have procedures to ensure that disputes received directly from consumers are handled in a substantially similar manner to those complaints received through CRAs.

Section 1022.43(f)(2) incorporates the statutory requirement that a furnisher must notify a consumer by mail or other means (if authorized by the consumer) not later than five business days after making a determination that a dispute is frivolous or irrelevant. Section 1022.43(f) incorporates the statute's content requirements for the notices.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 1,133 respondents.

Estimated Total Annual Burden: 185,603 hours.

Comments submitted in response to this notice will be summarized, included in the request for OMB approval, and become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: March 26, 2018.

Karen Solomon,

Acting Senior Deputy Comptroller and Chief Counsel.

[FR Doc. 2018–06580 Filed 3–30–18; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Bad Debt Reserves of Banks.

DATES: Written comments should be received on or before June 1, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Bad Debt Reserves of Banks.

OMB Number: 1545–1290.

Regulation Project Number: TD 8513.

Abstract: Section 585 (c) of the Internal Revenue Code requires large banks to change from reserve method of accounting to the specific charge off method of accounting for bad debts. Section 1.585–8 of the regulation contains reporting requirements in cases in which large banks elect (1) to include in income an amount greater than that prescribed by the Code; (2) to use the elective cut-off method of accounting: Or (3) to revoke any elections previously made.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 2,500.

Estimated Time per Respondent: 15 min.

Estimated Total Annual Burden Hours: 625.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 27, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–06672 Filed 3–30–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning application for registration for certain excise tax activities.

DATES: Written comments should be received on or before June 1, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis, at (202) 317–5751 or Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: 637 Registration Program.

OMB Number: 1545–1835.

Form Number: 637.

Abstract: The authority for the requirement for registration is found in Internal Revenue Code sections 4101 (Fuel Taxes), 4222 (Retailers and Manufacturers Excise Taxes), 4682 (Ozone-depleting Chemicals Tax), and the regulations. Form 637, Application for Registration (For Certain Excise Tax Activities) is used to apply for excise tax registration for activities under sections 4101, 4222, and 4682. Common activities for which persons are registered include that of a refiner, terminal operator, position holder, throughputter, ultimate vendor, first retail seller of certain heavy vehicles, manufacturer of sport fishing equipment, and to file a claim. The information will be used to make an informed decision on whether the applicant/registrant qualifies for registration.

Current Actions: There are no changes being made to the burden associated with the collection tools at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 4,840.

Estimated Time per Respondent: 6 hours, 30 minutes.

Estimated Total Annual Burden Hours: 30,499.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 26, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–06665 Filed 3–30–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms 12339, 12339–B, 12339–C, and 13775

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Forms 12339, Internal Revenue Service Advisory Council Membership Application; 12339–B, Information Reporting Program Advisory Committee Membership Application, 12339–C, Advisory Committee on Tax Exempt and Government Entities—Membership Application, and Form 13775, Tax Check Waiver.

DATES: Written comments should be received on or before June 1, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Sara Covington at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or at (202) 317–6038 or through the internet at *sara.l.covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Internal Revenue Service Advisory Council—Membership Application, Information Reporting Program Advisory Committee—Membership Application, and Advisory Committee on Tax Exempt and Government Entities—Membership Application.

OMB Number: 1545–1791.

Form Numbers: 12339, 12339–B & 12339–C.

Abstract: Form 12339 must be completed by those individuals interested in applying for IRSAC. Form 12339–B must be completed by those interested in applying for IRPAC. Form 12339–C was created to better solicit and maintain all of the applicant information for those interested in becoming members of these Advisory Councils. Each form is submitted in conjunction with Form 13775, Tax Check Waiver.

Estimated Number of Respondents: 500.

Estimated Time per Response: 50 minutes.

Estimated Total Annual Burden Hours: 417.

Title: Tax Check Waiver.

OMB Number: 1545–1791.

Form Number: 13775.

Abstract: Form 13775 authorizes the Government Liaison Disclosure analysts to provide the tax compliance check results to the appropriate IRS officials.

Estimated Number of Respondents: 50.

Estimated Time per Response: 1 hr, 30 minutes.

Estimated Total Annual Burden Hours: 75.

Current Actions: There are no changes to the forms (12339, 12339–B, 12339–C and 13775) in this collection.

Type of Review: Extension of a previously approved collection.

Affected Public: Individuals or households, and businesses or other for-profit organizations.

The following paragraph applies to all of the collections of information covered by this notice: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 27, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–06675 Filed 3–30–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Branded Prescription Drug Fee.

DATES: Written comments should be received on or before June 1, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this regulation should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Branded Prescription Drug Fee.

Regulation Project Number: 1545–2209.

Abstract: This document contains regulations that provide guidance on the annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 45.

Estimated Average Time per Respondent: 40 hours.

Estimated Total Annual Burden Hours: 1,800.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless the collection displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 27, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–06664 Filed 3–30–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Guidance on Reporting Interest Paid to Nonresident Aliens.

DATES: Written comments should be received on or before June 1, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this regulation should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Guidance on Reporting Interest Paid to Nonresident Aliens.

OMB Number: 1545–1725.

Regulation Project Number: TD 9584.

Abstract: This document contains final regulations that provide guidance on the reporting requirements for interest on deposits maintained at the

U.S. office of certain financial institutions and paid to nonresident alien individuals. These proposed regulations affect persons making payments of interest with respect to such a deposit.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents: 2,000.

Estimated Time per Response: 15 minutes.

Estimated Total Burden Hours: 500 hours.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 27, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–06666 Filed 3–30–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8892

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 8892, Application for Automatic Extension of Time to File Form 709 and/or Payment of Gift/Generation—Skipping Transfer Tax.

DATES: Written comments should be received on or before June 1, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Sandra Lowery at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or at (202) 317–5754 or through the internet, at *Sandra.J.Lowery@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Application for Automatic Extension of Time to File Form 709 and/or Payment of Gift/Generation-Skipping Transfer Tax.

OMB Number: 1545–1913.

Form Number: Form 8892.

Abstract: Form 8892 was created to serve a dual purpose. First, the form enables the taxpayers to request an extension of time to file Form 709 when they are not filing an individual income tax extension. Second, it serves as a payment voucher for taxpayers who are filing an individual income tax extension (by Form 4868) and will have a gift tax balance due on Form 709.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 10,000.

Estimated Time per Respondent: 43 minutes.

Estimated Total Annual Burden Hours: 7,200.

The following paragraph applies to all of the collections of information covered by this notice: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 27, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–06670 Filed 3–30–18; 8:45 am]

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Part II

Department of Agriculture

Agricultural Marketing Service

7 CFR Part 1051

Milk in California; Proposal To Establish a Federal Milk Marketing Order; Proposed Rule

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1051

[Doc. No. AO–15–0071; AMS–DA–14–0095]

Milk in California; Proposal To Establish a Federal Milk Marketing Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule; order for referendum; notice of public meeting.

SUMMARY: The Agricultural Marketing Service (AMS) proposes the issuance of a Federal Milk Marketing Order (FMMO) regulating the handling of milk in California. This proposed rule proposes adoption of a California FMMO incorporating the entire state of California and would adopt the same dairy product classification and pricing provisions used throughout the current FMMO system. The proposed California FMMO provides for the recognition of producer quota as administered by the California Department of Food and Agriculture. This proposed FMMO is subject to producer approval by referendum.

DATES: The Agricultural Marketing Service (AMS) will conduct a public meeting at 9:00 a.m. on April 10, 2018, to explain and answer questions relating to how the proposed California FMMO contained in this proposed rule, if adopted, would operate and review the producer referendum process that will be followed to obtain producer approval of the proposed rule.

ADDRESSES: The public meeting will be held at the Clovis Veterans Memorial District Building, 808 Fourth Street, Clovis, California 93612. Meeting information can be found at *www.ams.usda.gov/caorder.*

FOR FURTHER INFORMATION CONTACT: Erin Taylor, Acting Director, Order Formulation and Enforcement Division, USDA/AMS/Dairy Program, STOP 0231, Room 2969–S, 1400 Independence Ave. SW, Washington, DC 20250–0231, (202) 720–7311, email address: *erin.taylor@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This proposed rule, in accordance to 7 CFR part 900.13a, is the Secretary's final decision in this proceeding and proposes the issuance of a marketing order as defined in 7 CFR part 900.2(j). AMS finds that a FMMO for California would provide more orderly marketing conditions in the marketing area, warranting promulgation of a California FMMO. The record is replete with discussion from most parties on whether disorderly marketing conditions exist, or are even needed, to warrant promulgation of a California FMMO. FMMOs are authorized by the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674 and 7253) (AMAA). The declared policy of the AMAA makes no mention of ''disorder,'' and AMS finds that disorderly marketing conditions are not a requirement for an order to be promulgated. The standard for FMMO promulgation is to ''. . . establish and maintain such orderly marketing conditions . . . ,'' (7 U.S.C. 602(4)) and AMS finds that the proposed California FMMO meets that standard.

AMS has considered all record evidence presented at the hearing. Pursuant to a February 14, 2018 Memorandum from Secretary of Agriculture Sonny Perdue, Judicial Officer William Jensen conducted an independent *de novo* review of the hearing record. The Judicial Officer issued an Order on March 9, 2018 whereby he ratified all decisions and rulings made by Administrative Law Judge (ALJ) Jill Clifton during the hearing. The Judicial Officer ratified ALJ Clifton's Certification of the Transcript, except that he revised the list of exhibits that ALJ Clifton identified as not having been admitted into evidence by adding ''Exhibit 108-Exhibit D'' to that list. AMS has also considered the arguments and proposed findings submitted in post-hearing briefs, officially noticed documents, and comments and exceptions filed in response to the recommended decision to formulate this proposed FMMO. The regulatory provisions proposed herein reflect California marketing conditions, while adhering to fundamental FMMO principles that have historically helped to maintain orderly marketing conditions, ensured a sufficient supply of pure and wholesome milk, and been in the public interest.

A FMMO is a regulation issued by the Secretary of Agriculture that places certain requirements on the handling of milk in the area it covers. Each FMMO is established under the authority of the AMAA. A FMMO requires handlers of milk for a marketing area to pay minimum class prices according to how the milk is used. These prices are established under each FMMO after a public hearing where evidence is received on the supply and demand conditions for milk in the market. A FMMO requires that payments for milk be pooled and paid to individual farmers or cooperative associations of farmers on the basis of a uniform or average price. Thus, all eligible dairy farmers (producers) share in the marketwide use-values of milk by regulated handlers.

AMS proposes the establishment of a FMMO in 7 CFR part 1051 to regulate the handling of milk in California. Where appropriate, AMS proposes the adoption of uniform provisions found in 7 CFR part 1000 that are have been adopted into the 10 current FMMOS established in chapter X. These uniform provisions include, but are not limited to, product classification, end-product price formulas, Class I differential structure, and the producer-handler definition.[1] This decision recognizes the unique market structure of the California dairy industry through tailored performance-based standards to determine eligibility for pool participation.

As in all current FMMOs, California handlers regulated by a California FMMO would be responsible for accurate reporting of all milk movements and uses, and would be required to make timely payments to producers. The California FMMO would be administered by the United States Department of Agriculture (USDA) through a Market Administrator, who would provide essential marketing services, such as laboratory testing, reporting verification, information collection and publication, and producer payment enforcement.

A unique feature of the proposed order is a provision for the recognition of the quota value specified in the California quota program currently administered by the California Department of Food and Agriculture (CDFA). AMS finds that the California quota program should remain a function of CDFA in whatever manner CDFA deems appropriate. Should CDFA continue to use producer monies to fund the quota program, AMS finds that the proper recognition of quota values within a California FMMO, as provided for in the Agriculture Act of 2014 (2014 Farm Bill) (Pub. L. 113–79, sec. 1410(d)), is to permit an authorized deduction from payment to producers, in an amount determined and announced by CDFA.

In conjunction with this proposed FMMO, AMS conducted a Regulatory Economic Impact Analysis to determine the potential impact of regulating California milk handlers under a FMMO on the milk supply, product demand and prices, milk allocation in California and throughout the United States, and impacts to consumers. As part of the

[1] References to Class I, Class II, Class III and Class IV refer to products classified in those classes based on uniform FMMO provisions.

analysis, a regional econometric model was used to project deviations from the USDA Agricultural Baseline Projections to 2026 [2] under the provisions of the proposed California FMMO. The full text of the Regulatory Economic Impact Analysis Report and accompanying documentation may be accessed at *www.regulations.gov* or *www.ams.usda.gov/caorder.*

Prior documents in this proceeding:

Notice of Hearing: Issued July 27, 2015; published August 6, 2015 (80 FR 47210);

Notice To Reconvene Hearing: Issued September 25, 2015; published September 30, 2015 (80 FR 58636);

Recommended Decision and Opportunity To File Written Exceptions: Issued February 6, 2017; published February 14, 2017 (82 FR 10634);

Documents for Official Notice: Issued August 8, 2017; published August 14, 2017 (82 FR 37827); and

Submission for OMB Review: Information Collection—Producer Ballots: Issued September 27, 2017; published October 2, 2017 (82 FR 45795);

Delay of Rulemaking: Issued February 1, 2018; published February 6, 2018 (83 FR 5215);

Ratification of Record: Issued March 14, 2018; published March 19, 2018 (83 FR 11903).

This proposed rule is governed by the provisions of Sections 556 and 557 of Title 5 of the United States Code and is therefore excluded from the requirements of Executive Order 12866.

This proposed rule is not expected to be an Executive Order 13771 regulatory action because this proposed rule is not a significant regulatory action under Executive Order 12866.

The provisions of this proposed rule have been reviewed under Executive Order 12988, Civil Justice Reform. They are not intended to have a retroactive effect. If adopted, the proposed FMMO would not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

The AMAA provides that administrative proceedings must be exhausted before parties may file suit in court. Under 7 U.S.C. 608c(15)(A) of the AMAA, any handler subject to an order may request modification or exemption from such order by filing with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with the law. A handler is afforded the opportunity for a hearing on the petition. After a hearing, USDA would rule on the petition. The AMAA provides that the district court of the United States in any district in which the handler is an inhabitant, or has its principal place of business, has jurisdiction in equity to review USDA's ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of the entry of the ruling.

Civil Rights Impact Analysis

AMS has reviewed this proposed rule in accordance with Departmental Regulation 4300–4—Civil Rights Impact Analysis (CRIA), to identify and address potential impacts the proposal might have on any protected groups of people. After a careful review of the proposed rule's intent and provisions, AMS has determined that this proposed rule, if adopted, would not limit or reduce the ability of individuals in any protected classes to participate in the proposed FMMO, or to enjoy the anticipated benefits of the proposed program. Any impacts on dairy farmers and processors arising from implementation of this proposed rule are not expected to be disproportionate for members of any protected group on a prohibited basis.

An anonymous commenter took exception to AMS's determination with respect to civil rights impact of the proposed rule. The commenter took exception with AMS's conclusion that because the proposed California FMMO would provide for orderly marketing conditions, its implementation would not result in disparate impacts on protected classes, especially consumers. The civil rights analysis did not consider consumers because consumers are not a protected class. Other observations suggested by the commenter regarding consumerism and homelessness are outside the scope of the CRIA.

Regulatory Flexibility Analysis

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be unduly or disproportionately burdened. Small dairy farm businesses have been defined by the Small Business Administration (SBA) (13 CFR 121.601) as those businesses having annual gross receipts of less than $750,000. SBA's definition of small agricultural service firms, which includes handlers that would be regulated under this proposed FMO, varies depending on the product manufactured. Small fluid milk and ice cream manufacturers are defined as having 1,000 or fewer employees. Small butter and dry or condensed dairy product manufacturers are defined as having 750 or fewer employees. Small cheese manufacturers are defined as having 1,250 or fewer employees.

For the purpose of determining which California dairy farms are ''small businesses,'' the $750,000 per year criterion was used to establish a production guideline that equates to approximately 315,000 pounds of milk per month. Although this guideline does not factor in additional monies that may be received by dairy farmers, it is a standard encompassing most small dairy farms. For the purpose of determining a handler's size, if the plant is part of a larger company operating multiple plants that collectively exceed the employee limit for that type of manufacturing, the plant is considered a large business even if the local plant has fewer than the defined number of employees.

Interested persons were invited to present evidence at the hearing on the probable regulatory and informational impact of the proposed California FMMO on small businesses. Specific evidence on the number of large and small dairy farms in California (above and below the threshold of $750,000 in annual sales) was not presented at the hearing. However, data compiled by CDFA [3] suggests that between 5 and 15 percent of California dairy farms would be considered small business entities. No comparable data for dairy product manufacturers was available.

Record evidence indicates that implementing the proposed California FMMO would not impose a disproportionate burden on small businesses. Currently, the California dairy industry is regulated by a California State Order (CSO) that is administered and enforced by CDFA. While the CSO and FMMOs have differences that are discussed elsewhere

[2] Official Notice is taken of: U.S. Department of Agriculture, Office of the Chief Economist, World Agricultural Outlook Board, Interagency Agricultural Projections Committee, 2016, *Long-term Projections Report OCE–2016–1.*

[3] Official Notice is taken of: CDFA, *California Dairy Review,* Volume 19, Issue 9, September 2015. *https://www.cdfa.ca.gov/dairy/pdf/CDR/2015/CDR_SEPT_15.pdf.*

in this document, they both maintain similar classified pricing and marketwide pooling functions. Therefore, it is not expected that the proposed regulatory change will have a significant impact on California small businesses.

The record evidence indicates that while the program is likely to impose some costs on the regulated parties, those costs would be outweighed by the benefits expected to accrue to the California dairy industry. In conjunction with the publication of the recommended decision (82 FR 10634), AMS released a Regulatory Economic Impact Analysis (REIA) to study the possible impacts of the proposed California FMMO. AMS received five comments related to the REIA. The substance of those comments and AMS's response are provided in the documentation that accompanies an updated REIA, which was prepared to reflect the provisions proposed in this FMMO. The updated analysis may be viewed in conjunction with this proposed FMMO (Docket No. AMS–DA–14–0095) at *www.regulations.gov.*

California Dairy Market Background

The record shows that the California dairy industry accounts for approximately 20 percent of the nation's milk supply. While its 39 million residents are concentrated in the state's coastal areas, the majority of California's dairy farms are located in the interior valleys, frequently at some distance from milk processing plants and consumer population centers.

CDFA has defined and established distinct regulations for Northern and Southern California dairy regions.[4] According to data published by CDFA,[5] over 94 percent of the state's approximately 40.4 billion pounds of milk for 2016 was produced in the Northern California region. The five leading milk production counties in 2016 were Tulare, Merced, Kings, Stanislaus, and Kern, together accounting for approximately 72.4 percent of the state's milk.

According to CDFA, there were 1,392 dairy farms in California in 2016. Of those, 1,297 were located in Northern California, and 95 were in Southern California. The statewide average number of cows per dairy was 1,249; in Northern California, the average herd size was 1,265 cows, and in Southern California, 1,026 cows. Average milk production for the state's 1.74 million cows was 23,265 pounds in 2016.

According to record evidence, 132 handlers reported milk receipts to CDFA for at least one month during 2015. A CDFA February 2015 list of California dairy product processing plants by type of product produced[6] shows that 35 California plants processed Class 1 products; 75 plants processed Class 2 and 3 products; 18 plants processed Class 4a products; and 64 plants processed Class 4b products.[7] Some plants processed products in more than one class.

CDFA reported[8] that approximately 98 percent of California's 2016 milk production was market grade (Grade A), and the rest was manufacturing grade (Grade B). Thirteen percent of the milk pooled under the CSO was utilized by California processors as Class 1 (fluid milk). Eight and three-tenths percent was utilized for Classes 2 and 3 (soft and frozen dairy products), 32.3 percent was utilized for Class 4a (butter and dried milk powders), and 46.4 percent was utilized for Class 4b (cheese).

According to CDFA, total Class 1 sales in California were approximately 642 million gallons in 2016. Record evidence shows that annual California Class 1 sales outside the state averaged 22 million gallons for the five years preceding 2015.

The record shows that for the five-year period from 2010 through 2014, an average of 230 million pounds of California bulk milk products were transferred to out-of-state plants for processing each year. During the same period, an average of 633 million pounds of milk from outside the state was received and reported by California pool plants each year.

Impact on Small Businesses

AMS proposes to establish a FMMO in California similar to the 10 existing FMMOs in the national system. The California dairy industry is currently regulated under the CSO, which is similar to the proposed FMMO in most respects. California handlers currently report milk receipts and utilization to CDFA, which calculates handler prices based on component values derived from finished product sales surveys. Likewise, FMMO handlers report milk receipts and utilization to the Market Administrators, who calculate handlers' pool obligations according to price formulas that incorporate component prices based on end product sales values. Under both programs, the value of handlers' milk is pooled, and pool revenues are shared by all the pooled producers. Thus, transitioning to the FMMO is expected to have only a minimal impact on the reporting and regulatory responsibilities for large or small handlers, who are already complying with similar CSO regulations.

Pricing

Under the proposed California FMMO, uniform FMMO end-product price formulas would replace the CDFA price formulas currently used to calculate handler milk prices. FMMO end-product price formulas incorporate component prices derived from national end-product sales surveys conducted by AMS. Use of price formulas based on national product sales would permit California producers to receive prices for pooled milk reflective of the national market for commodity products for which their milk is utilized. Consistent with the current FMMOs, California FMMO Class I prices would be computed using the higher of the Class III or IV advance prices announced the previous month, and would be adjusted by the Class I differential for the county where the plant is located.[9]

Regulated minimum prices, especially for milk used in cheese manufacturing, are likely to be higher than what handlers would pay under the CSO. However, pooling regulations under the proposed FMMO would allow handlers to elect not to pool milk used in manufacturing. This option would be available to both large and small manufacturing handlers.

Dairy farmers whose milk is pooled on the proposed California FMMO would receive a pro rata share of the pool revenues through the California FMMO uniform blend price. The California FMMO would not provide for the quota and non-quota milk pricing tiers found under the CSO. Under the proposed California FMMO, regulated handlers would be allowed to deduct monies, in an amount determined and announced by CDFA, from blend prices paid to California dairy farmers for

[4] Official Notice is taken of: CDFA, *Stabilization and Marketing Plan for Market Milk, as Amended, for the Northern California Marketing Area,* August 2015. *https://www.cdfa.ca.gov/dairy/pdf/hearings/2015/NOCAL_STAB_PLAN61.pdf.*

[5] Official Notice is taken of: CDFA, *California Dairy Statistics Annual,* 2016. *https://www.cdfa.ca.gov/dairy/pdf/Annual/2016/2016_Statistics_Annual.pdf.*

[6] Official Notice is taken of: CDFA, Milk and Dairy Food Safety Branch, *Milk Plant Listings. https://www.cdfa.ca.gov/ahfss/Milk_and_Dairy_Food_Safety/index.html#Plants.*

[7] References to Class 1, Class 2, Class 3, Class 4a and Class 4b refer to products classified in those categories based on the CSO.

[8] CDFA, *California Dairy Statistics Annual,* 2016.

[9] FMMOs have four classifications of milk: Class I—fluid milk products; Class II—fluid cream products, soft ''spoonable'' cheeses, ice cream, and yogurt; Class III—hard cheeses and spreadable cheese such as cream cheese; Class IV—butter and dried milk products.

pooled milk and send those monies to CDFA to administer the quota program.

These changes are expected to affect producers and handlers of all sizes, but are not expected to be disproportionate for small entities.

Producer-Handlers

The record shows that there are four producer-handlers [10] in California whose Class 1 milk production is all or partially exempt from CSO pricing and pooling by virtue of their ''exempt quota'' holdings, representing approximately 21 million pounds of milk each month. It is likely that these four entities would become fully regulated by the proposed California FMMO and accountable to the marketwide pool for all of their Class I sales in the marketing area. By accounting to the pool for all their Class I sales in the marketing area, the value of the marketwide pool is expected to increase, benefiting most other large and small producers. The proposed California FMMO makes no provision for exempting large producer-handlers from pricing and pooling regulations under the order.

The evidentiary record shows that several smaller California producer-handlers, whose production volume exceeds the threshold to receive an exemption from the CSO's pricing and pooling regulations, would likely qualify as producer-handlers under the proposed California FMMO.[11]

Interstate Commerce

The evidentiary record indicates that milk in interstate commerce, which the CSO does not have authority to regulate, would be regulated under the proposed California FMMO. Currently, California handlers who purchase milk produced outside the state do not account to the CSO marketwide pool for that milk. Record evidence shows approximately 425 million pounds of milk from outside the state was processed into Class 1 products at California processing plants during 2014.

Under the proposed FMMO, all Class I milk processed and distributed in the marketing area would be subject to FMMO pricing and pooling regulations, regardless of its origin. Thus, revenues from Class 1 sales that are not currently regulated would accrue to the California FMMO pool and would be shared with all producers who are pooled on the California FMMO, including out-of-state producers. If California handlers elect to continue processing out-of-state milk into Class I products, under the provisions of the proposed California FMMO they would be required to pay the order's classified minimum price for that milk. Those additional revenues would be pooled and would benefit large and small producers who participate in the pool. Both large and small out-of-state producers who ship milk to pool plants in California would receive the California FMMO uniform blend price for their milk.

Classification and Fortification

Dairy product classification under the CSO and the proposed FMMO is similar, but not identical. The table below compares CSO and FMMO product classes.

CSO Class	Equivalent FMMO Class
Class 1	Class I.
Class 2 and 3	Class II.
Class 4b	Class III.
Class 4a	Class IV.

Under the proposed California FMMO, the classification of certain California products would change to align with standard FMMO classifications:

- Reassigning buttermilk from CSO Class 2 to FMMO Class I
- Reassigning half and half from CSO Class 1 to FMMO Class II
- Reassigning eggnog from CSO Class 2 to FMMO Class I
- There are numerous instances where the CSO classifies a product based on product type and where the product is sold.[12] The proposed California FMMO would classify all products based solely on product type.

Under the proposed FMMO, California handlers would no longer receive credits for fluid milk fortification. Instead, accounting for fortification would be uniform with other FMMOs, as the fluid milk equivalent of the milk solids used to fortify fluid milk products would be classified as Class IV, and the increased volume of Class I product due to fortification would be classified as Class I. The FMMO system accounts for fortification differently than does the CSO. The record does not indicate the net impact of this change. However, the impact is not expected to disproportionately affect small entities.

Transportation Credits

The proposed California FMMO does not contain a transportation credit program to encourage milk shipments to Class 1, 2, and 3 plants, as is currently provided for in the CSO. AMS proposes that producer payments be adjusted to reflect the applicable producer location adjustment for the handler location where the milk is received, thus providing the incentive to producers to supply Class I plants. Producers are responsible for finding a market for their milk and consequently bear the cost of transporting their milk to a plant. The record of this proceeding does not support reducing the producers' value of the marketwide pool by authorizing transportation credits to handlers. This change is not expected to disproportionately impact small business entities.

Summary

AMS continues to find that adoption of the proposed California FMMO would promote more orderly marketing of milk in interstate commerce. Classified milk prices under the order would reflect national prices for manufactured products and local prices for fluid milk products, fostering greater equality for California producers and handlers in the markets where they compete. Under the proposed FMMO, handlers would be assured a uniform cost for raw milk, and producers would receive uniform payments for raw milk, regardless of its use. Small dairy farmers and handlers are not expected to be disproportionately impacted by the transition from CSO to FMMO regulations.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the ballot materials that will be used in conducting the referendum have been submitted to and approved by OMB (0581–0300). The forms to be used to administer the proposed California FMMO have also been reviewed by OMB (0581–0032) and would be approved should the California FMMO producer referendum pass.

Any additional information collection and recordkeeping requirements that may be imposed under the proposed order would be submitted to OMB for public comment and approval.

Secretary's Decision

Notice is hereby given of the filing with the Hearing Clerk of this final decision with respect to the proposed marketing agreement and order

[10] Producer-handlers are dairy farmers who process and distribute their own farm milk into dairy products.

[11] The CSO exempts producer-handlers with sales averaging less than 500 gallons of milk per day on an annual basis and who distribute 95 percent of their production to retail or wholesale outlets.

[12] Official Notice is taken of: CDFA, *Classification of Dairy Products. https://www.cdfa.ca.gov/dairy/pdf/PRDCLASS.pdf.*

regulating the handling of milk in California.

This final decision is issued pursuant to the provisions of the AMAA and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR part 900). The proposed marketing agreement and order are authorized under 7 U.S.C. 608c.

The proposed marketing agreement and order are based on the record of a public hearing held September 22 through November 18, 2015, in Clovis, California. The hearing was held to receive evidence on four proposals submitted by dairy farmers, handlers, and other interested parties. Notice of this hearing was published in the **Federal Register** on August 6, 2015 (80 FR 47210).

Ninety-eight witnesses testified over the course of the 40-day hearing. Witnesses provided a broad overview of the history and complexity of the California dairy industry, and submitted 194 exhibits containing supporting data, analyses, and historical information.

Upon the basis of evidence introduced at the hearing and the record thereof, the Administrator of AMS on February 6, 2017, filed with the Hearing Clerk, USDA, a recommended decision and Opportunity to File Written Exceptions thereto by May 15, 2017. Twenty-nine comments or exceptions were filed. That document also announced AMS's intent to request approval of new information collection requirements to implement the program. Written comments on the proposed information collection requirements were due April 17, 2017. Two comments were filed. AMS issued a notice regarding Documents for Official Notice, inviting comments on whether the Department should take official notice of numerous listed documents submitted for consideration by proponents. The notice was issued on August 8, 2017, and published on August 14, 2017. Comments on the official notice request were due August 29, 2017. Three supportive comments were received and are discussed later in this decision. Lastly, AMS announced its intent to request approval of a new information collection for ballot material to be used in a producer referendum in a document issued on April 17, 2017, and published on April 21, 2017. Comments on the ballot material information collection were due June 20, 2017. One supportive comment was received. A Submission for OMB Review seeking OMB approval of the ballot material was issued on September 27, 2017, and published on October 2, 2017 (82 FR 45795).

The material issues presented on the record of hearing are as follows:

1. Whether the handling of milk in the proposed marketing area is in the current of interstate commerce, or directly burdens, obstructs, or affects interstate commerce in milk or its products;

2. Whether economic and marketing conditions in California show a need for a Federal marketing order that would tend to effectuate the declared policy of the Act;

3. If an order is issued, what its provisions should be with respect to:

a. Handlers to be regulated and milk to be priced and pooled under the order;

b. Classification of milk, and assignment of receipts to classes of utilization;

c. Pricing of milk;

d. Distribution of proceeds to producers; and

e. Administrative provisions.

Findings and Conclusions

The findings and conclusions on the material issues are based on the record of the hearing and the comments and exceptions filed with regard to the recommended decision. Discussions are organized by topic, recognizing inevitable overlap in some areas. Topics are addressed in the following order:

1. Regulatory Comparison
2. Overview of Proposals
3. Justification for a California FMMO
4. California Quota Program Recognition
5. Definitions and Uniform Provisions
6. Classification
7. Pricing
8. Pooling
9. Transportation Credits
10. Miscellaneous and Administrative Provisions
11. Ruling on Office Notice Documents
12. Rulings on Proposed Findings, Conclusions, and Exceptions

1. Regulatory Comparison

The purpose of the following section is to provide a general description and comparison of the major features of the California state dairy regulatory framework and the FMMO system as provided in the evidentiary record. A more detailed discussion of each issue is provided in the appropriate section of this decision.

California State Order:

Currently, milk marketing in California is regulated by the CDFA. The CSO is codified in the *Pooling Plan for Market Milk,* as amended, and in two *Stabilization and Marketing Plan(s) for Market Milk,* as amended, for the Northern and Southern California marketing areas.[13]

Quota

The California quota program is a state-administered producer program that entitles the quota holder to $0.195 per pound of solids-not-fat above the CSO base and overbase price of milk.[14] The quota premium is funded by a deduction from the CSO marketwide pool before the CSO overbase price is calculated. The quota program requires quota holders to deliver milk to a pool plant at least once every 60 days. Quota can be bought and sold, and according to record evidence, approximately 58 percent of California dairy farms owned some volume of quota in 2015.

Classification

The CSO provides for the pricing of five classified use values of milk. In general, Class 1 is milk used in fluid milk products; Class 2 is milk used in heavy cream, cottage cheese, yogurt, and sterilized products; Class 3 is milk used in ice cream and frozen products; Class 4a is milk used in butter and dry milk products, such as nonfat dry milk; and Class 4b is milk used in cheese—other than cottage cheese—and whey products.

Pricing

The CSO utilizes an end-product pricing system to determine classified prices for raw milk produced and manufactured in the State of California. Class 1, 4a, and 4b prices are announced monthly. Class 2 and 3 prices are announced bi-monthly. Prices for all five milk classes are component-based. Three components of milk are used to determine prices: butterfat (fat); solids-not-fat (SNF), which includes protein and lactose; and a fluid carrier (used in only the Class 1 price).

The CSO determines milk component prices based on commodity market prices obtained from the Chicago Mercantile Exchange (CME), the AMS Dairy Market News Western Dry Whey—Mostly (WDW-Mostly) price series, and the announced nonfat dry milk (NFDM) California Weighted Average Price (CWAP), which is determined by CDFA through weekly surveys of California manufacturing plants.

The price for milk used in cheese manufacturing (CSO Class 4b) is a

[13] Official Notice is taken of: Chapter 2, Part 3, Division 21 and Chapter 3, Part 3, Division 21 of the California Food and Agriculture Code.

[14] The hearing record reveals that the $0.195 per pound solids-non-fat equates to a $1.70 per cwt of milk quota premium. Additionally, under current CSO provisions, base and overbase prices are equal.

central issue in this proceeding. The Class 4b price is announced monthly and utilizes average commodity market prices for block Cheddar cheese, butter, and dry skim whey to determine the Class 4b component values. The average CME prices for butter and 40-pound Cheddar blocks are adjusted by f.o.b. price adjusters, which are designed to represent the difference between the CME price and the price California manufacturers actually receive. The CME butter price is also reduced by $0.10 per pound to derive the value of whey butter as it relates to cheese processing. The value of dry skim whey is determined through a sliding scale that provides a per hundredweight (cwt) value based on a series of announced WDW-Mostly per pound value ranges. The sliding scale determines dry whey's contribution to the Class 4b price, with a floor of $0.25 per cwt and a ceiling of $0.75 per cwt when the WDW-Mostly price equals or exceeds $0.60 per pound.

The CSO pricing system has a number of features worth highlighting. First, under the CSO, handlers must pay at least minimum classified prices for all Grade A milk purchased from California dairy farmers, regardless of whether the milk is pooled on the CSO. Additionally, Class 1 processors may claim credits against their pool obligations to offset the cost of fortifying fluid milk to meet the State-mandated nonfat solids content standards.

The classified use values of all the milk pooled on the CSO are aggregated, and producers are paid on the fat and SNF component levels in their raw milk. Producers are paid on the basis of their allocated quota (if applicable), base, and overbase production for the month. While the CSO pricing formulas have changed over time, in their current form the base and overbase prices are the same. Generally, the quota price is the overbase price plus the $1.70 per cwt quota premium.

Pooling

Almost all California-produced milk received by California pool plants is pooled on the CSO, with some exceptions. Grade B milk is neither pooled nor subject to minimum prices. Manufacturing plants that do not make any Class 1 or 2 products can opt out of the pool; however, they are still required to pay announced CSO classified minimum prices for Grade A milk received. The requirement that quota holders must deliver milk to a pool plant at least once every 60 days tends to limit the amount of Grade A milk not pooled on the CSO. The decision not to pool milk in California carries with it a stipulation that the plant may not repool for 12 months after opting not to pool, and after repooling, a plant cannot opt out of pooling for 12 months.

Entities recognized as producer-handlers under the CSO may be exempt from pooling some or all of their milk. Producer-handlers are dairy farmers who also process and distribute their dairy products. Fully exempt (''Option 66'') producer-handlers have minimal production volumes and are exempt from the pricing and pooling provisions of the CSO. Producer-handlers who own exempt quota (''Option 70'') do not account to the CSO marketwide pool for the volume of Class 1 milk covered by their exempt quota.

The State of California cannot regulate interstate commerce; therefore, milk from out-of-state producers cannot be regulated by the CSO. While the record reflects that California handlers typically pay for out-of-state milk at a price reflective of the receiving plant's utilization, those prices are not regulated or enforced by the CSO.

Transportation Credits

The CSO provides transportation credits to producers for farm-to-plant Class 1, 2, and 3 milk movements between designated supply zones and plants with more than 50 percent Class 1, 2, and/or 3 utilization in designated demand zones. The CSO also provides for transportation allowances to handlers for plant-to-plant milk movements.

Federal Milk Marketing Orders

A FMMO is a regulation issued by the Secretary of Agriculture (Secretary) that places certain requirements on the handling of milk in a defined geographic marketing area. FMMOs are authorized by the AMAA. The declared policy of the AMAA is to ''. . . establish and maintain such orderly marketing conditions for agricultural commodities in interstate commerce . . .'' (7 U.S.C. 602(1)). The principal means of meeting the objectives of the FMMO program are through the use of classified milk pricing and the marketwide pooling of returns.

Classification

Whereas the CSO designates five classes of milk utilization, FMMOs provide for four classes of milk utilization. FMMO Class I is milk used in fluid milk products. Class II is milk used to produce fluid cream products, soft ''spoonable'' products like cottage cheese, ice cream, sour cream, and yogurt, and other products such as kefir, baking mixes, infant formula and meal replacements, certain prepared foods, and ingredients in other prepared food products. Class III is milk used to produce spreadable cheeses like cream cheese, and hard cheeses, like Cheddar, that can be crumbled, grated, or shredded. Class IV is milk used to produce butter, evaporated, or sweetened condensed milk in consumer-style packages, and dry milk products.

Pricing

Like the CSO, the FMMO program currently uses end-product price formulas based on the wholesale prices of finished products to determine the minimum classified prices handlers pay for raw milk in the four classes of utilization. However, the FMMO pricing system has some notable differences. While the CSO announces some classified prices on a bi-monthly basis, FMMOs announce prices for all four milk classes monthly. FMMOs use four components of milk to determine prices: Butterfat, protein, nonfat solids, and other solids.

Like the CSO, the FMMO determines component prices based on commodity prices. However, AMS administers the Dairy Product Mandatory Reporting Program (DPMRP) to survey weekly wholesale prices of four manufactured dairy products (cheese, butter, NFDM and dry whey), and releases weekly average survey prices in the National Dairy Product Sales Report (NDPSR).[15] The FMMO product-price formulas use these surveyed prices to determine the component values in raw milk.

As referenced previously, a central issue of this proceeding is the pricing of milk used for cheese manufacturing (FMMO Class III). The FMMO pricing system determines the Class III value from DPMRP surveyed butter, cheese, and dry whey prices. The FMMO does not utilize a sliding scale to determine the value of whey that contributes to the Class III price.

Unlike the CSO, FMMOs do not provide for a tiered system of producer payments. A uniform blend price is computed for each FMMO reflecting the use of all milk in each marketwide pool. A blend price is paid for all milk that is pooled on the FMMO, adjusted for location. In six of the FMMOs, producers are paid for the pounds of butterfat, pounds of protein, pounds of other solids, and cwt of milk pooled. The cwt price is known as the producer price differential (PPD) and reflects the

[15] Official Notice is taken of: The Notice of Equivalent Price Series: 77 FR 22282. The National Dairy Product Sales Report was deemed as equivalent to the price series previously released by the National Agricultural Statistics Service.

producer's pro rata share of the value of Class I, Class II, and Class IV uses in the pool relative to Class III value. In the other four FMMOs, producers are paid on a butterfat and skim basis.

Pooling

Inclusion in the FMMO marketwide pool carries with it an obligation to be available to serve the fluid market with necessary milk supplies throughout the year. In the FMMO system, participation in the pool is mandatory for distributing plants that process Grade A milk into Class I products sold in a FMMO marketing area. Handlers of manufacturing milk (Class II, III, or IV) have the option of pooling, and pool eligibility is based on performance standards specific to each FMMO.

FMMOs recognize the unique business structures of producer-handlers and exempt them from the pricing and pooling regulations of the orders based on size. Producer-handler exemptions under FMMOs are limited to those vertically-integrated entities that produce and distribute no more than three million pounds of packaged fluid milk products each month.

Unlike the CSO, FMMOs are authorized to regulate the interstate commerce connected with milk marketing. Thus, there is no differentiated regulatory treatment for milk produced outside of a FMMO marketing area boundary. All eligible milk is pooled and priced in the same manner, regardless of its source.

Transportation Credits

The Appalachian and Southeast FMMOs provide for transportation credits to offset a handler's cost of hauling supplemental milk to Class I markets. During deficit months, handlers can apply for transportation credits to offset the cost of supplemental milk deliveries from outside the marketing area to meet the Class I demand of FMMO handlers. The most significant difference from the CSO here is that the FMMO transportation credits described are not paid from the marketwide pool. Instead, they are paid from separate funds obtained through monthly assessments on handlers' Class I producer milk. The exception is the Upper Midwest FMMO, which provides transportation credits on plant-to-plant milk movements paid from the marketwide pool.

2. Overview of Proposals

Four proposals were published in the Hearing Notice of this proceeding. Dairy Farmers of America, Inc., Land O'Lakes, Inc., and California Dairies, Inc. jointly submitted Proposal 1. Dairy Farmers of America, Inc. (DFA), is a national dairy-farmer owned cooperative with approximately 14,000 members and several processing facilities located throughout the United States, with products marketed both nationally and internationally. Within California, DFA represents 260 members and operates three processing facilities. Land O'Lakes (LOL) is a national farmer-owned cooperative with over 2,200 dairy-farmer members. LOL has processing facilities in the Upper Midwest, the eastern United States, and the State of California, with products marketed nationally and internationally. Within California, LOL represents 200 dairy-farmer members and operates three processing facilities. California Dairies, Inc. (CDI), is a California based dairy-farmer owned cooperative with 390 dairy-farmer members, six processing facilities in California, and national and international product sales. Combined, DFA, LOL, and CDI (Cooperatives) market approximately 75 percent of the milk produced in California.

Proposal 1 seeks to establish a California FMMO that incorporates the same dairy product classification and pricing provisions as those used throughout the FMMO system. Proposal 1 also includes unique pooling provisions, described as ''inclusive'' throughout the proceeding, that would pool the majority of the milk produced in California each month while also allowing for the pooling of milk produced outside of the marketing area if it meets specific pooling provisions. The proposal includes fortification and transportation credits similar to those currently provided by the CSO. Lastly, Proposal 1 provides for payment of the California quota program quota values from the marketwide pool before the FMMO blend price is computed each month.

Proposal 2 was submitted on behalf of the Dairy Institute of California (Institute). The Institute is a California trade association representing proprietary fluid milk processors, cheese manufacturers, and cultured and frozen dairy products manufacturers in 38 plants throughout California. Institute plants process 70 percent of the fluid milk products, 85 percent of the cultured and frozen dairy products, and 90 percent of the cheese manufactured in the state. The Institute's first position is that a California FMMO should not be promulgated. However, should USDA find justification for promulgation, the Institute supports Proposal 2. Proposal 2 incorporates the same dairy product classification provisions used throughout the FMMO system, as well as pooling provisions that are consistent with those found in other FMMOs. The Proposal 2 pooling provisions require the pooling of Class I milk, but the pooling of milk used in manufactured products is optional. Proposal 2 includes fortification and transportation credits similar to those currently provided by the CSO. It also includes an additional shrinkage allowance for extended shelf life (ESL) products above that provided in the FMMO system. Lastly, Proposal 2 recognizes quota value by allowing producers to opt out of the quota program, thus receiving a FMMO blend price reflective of the market's utilization. Under Proposal 2, producers who remain in the quota program would have their blend price monies transferred to CDFA and redistributed according to their quota and non-quota holdings.

Proposal 3 was submitted on behalf of the California Producer Handlers Association (CPHA). CPHA is an association of four producer-handlers: Foster Farms Dairy, Inc. (Foster); Hollandia Dairy, Inc.; Producers Dairy Foods, Inc. (Producers);and Rockview Dairies, Inc. (Rockview). CPHA members own their respective dairy farms and process that farm milk, as well as the milk of other dairy farms, for delivery to consumers. CPHA members own exempt quota, which entitles them to exemption from CSO pricing and pooling provisions for the volume of Class 1 milk covered by their exempt quota. Proposal 3 seeks recognition and continuation of CPHA members' exempt quota status under a California FMMO.

Proposal 4 was submitted on behalf of Ponderosa Dairy (Ponderosa). Ponderosa is a Nevada dairy farm that supplies raw milk to California fluid milk processing plants. Ponderosa contends that disorderly marketing conditions do not exist in California that would warrant promulgation of a FMMO. However, if USDA finds justification for a California FMMO, Proposal 4 seeks to allow California handlers to elect partially-regulated plant status with regard to milk they receive from out-of-state producers. Such allowance would enable handlers to not pool out-of-state milk, as long as they could demonstrate that they paid out-of-state producers an amount equal to or higher than the market blend price.

3. Justification for a California FMMO

This section reviews and summarizes the testimony, hearing evidence, and comments and exceptions filed regarding the recommended decision addressing whether or not promulgation of a California FMMO is justified. After careful consideration and review, this final decision affirms the finding that

the proposed California FMMO would provide for more orderly marketing conditions for the handling of milk in the State of California, as provided for and authorized by the AMAA. The Secretary has found upon the record that the proposed order and all of its terms and provisions will tend to effectuate the declared policy of the AMAA 608 c(4).

Summary of Testimony

A Cooperative witness testified regarding current California marketing conditions and the need for establishing a California FMMO. According to the witness, California is the largest milk-producing state, producing more than 20 percent of the nation's milk. The witness stated that the pooled volume of a California FMMO would be the largest of all FMMOs, averaging slightly below 3.4 billion pounds per month; the Class I volume would represent the third largest, following the Northeast and Mideast FMMOs.

The Cooperative witness testified that the primary reason California farmers are seeking the establishment of a FMMO is to receive prices reflective of the national commodity values for all milk uses. The witness opined that orderly marketing is no longer attainable through the CSO because the prices California dairy farmers receive do not reflect the full value of their raw milk. The witness estimated that this pricing difference has reduced California dairy farm income by $1.5 billion since 2010. The witness maintained that Proposal 1 allows California dairy farms to receive an equitable price for their milk, while also tailoring FMMO provisions to the California dairy industry. The Cooperatives' post-hearing brief reflected this position.

The Cooperative witness testified that there are significant price differences, depending on whether a producer's milk is regulated by the CSO or a FMMO. To illustrate this difference, the witness compared California farm milk prices to those received by producers in the states that comprise the Upper Midwest and Pacific Northwest marketing areas.[16] The witness selected these areas for comparison due to the similar milk utilization in the Upper Midwest FMMO and the geographic proximity of the Pacific Northwest FMMO. The witness estimated that between August 2012 and May 2015, California dairy farmers received on average $1.85 per cwt less (ranging from $0.43–$4.27 per cwt lower) than producers pooled on the Upper Midwest and Pacific Northwest FMMOs. The witness used the data to emphasize a wide difference in prices for farmers in similarly situated areas. The witness opined that a California FMMO, as advanced in Proposal 1, would ensure California dairy farmers receive equitable prices, more in line with those received by their FMMO counterparts.

The Cooperative witness emphasized that while both the CSO and the FMMOs use end-product pricing formulas to determine class prices, the two regulatory systems use different commodity series, effective dates, yield factors, and make allowances, which result in substantially different prices, as highlighted above. The witness explained that while the two regulatory systems have always had price differences, historically CSO and FMMO prices were relatively close. According to the witness, prices began to diverge significantly in 2007 when the CSO established a fixed whey factor in its formula for milk used to produce cheese. From that point forward, the witness said, price differences have become significant and have led to market disruptions both in the fluid and manufacturing markets.

The Cooperative witness summarized USDA's justification from the FMMO Order Reform decision for adopting a national Class I price surface that assigns a Class I differential for every county in the country, including counties in California. The witness said that the separate CSO Class 1 price surface undermines the integrity of the nationally coordinated Class I price surface and has become a source of disorder in California. To demonstrate the disorder, the witness compared FMMO Class I and CSO Class 1 prices for both in-state and out-of-state purchases. The witness said that because of the CSO and FMMO differences in both classified price formulas and Class I/1 price surfaces, the Class 1 price paid by California handlers is almost always lower than what it otherwise would be if FMMO Class I prices were applicable for those same purchases.

The Cooperative witness presented a similar comparison between CSO Class 1 prices and Class I prices in FMMO areas that were likely competitors. The witness said that under FMMO regulations, the difference in Class I prices between two FMMO areas is attributed to the difference in the Class I differential at the two locations. For example, the witness explained, the Class I price difference between two plants, one located in a $2.10 zone and another in the $2.00 zone, would be $0.10 per cwt. However, when the witness compared Class 1 prices in California and a competing FMMO area, the price difference was always greater than the difference in differentials. For example, the FMMO differential in the Los Angeles/San Diego market is $2.10, while the differential in neighboring Phoenix is $2.35, a difference of $0.25. However, said the witness, when comparing the actual CSO Class 1 price in Los Angeles/San Diego with the FMMO Class I price in Phoenix from August 2012 to July 2015, the difference averaged $0.62. The witness concluded that these observed price differences undermine a nationally-coordinated pricing structure and contribute to disorderly marketing, where fluid milk handlers pay different minimum prices depending on where they are regulated.

The Cooperative witness also provided testimony on the CSO and FMMO price disparities for manufacturing milk. The witness testified that FMMO Class II, III, and IV prices reflect national prices for products manufactured in these classes. If Proposal 1 is adopted, the witness said, California handlers would pay the same uniform prices as their FMMO competitors in the national marketplace. The witness noted past FMMO decisions that discussed the national supply and demand for manufactured dairy products and the need for national uniform manufacturing prices. The witness stressed that California producers should also receive these national prices like their FMMO counterparts.

The Cooperative witness elaborated on the differences between CSO and FMMO manufacturing class prices. When comparing FMMO Class II to CSO Class 2 and Class 3 prices, the witness cited differences in the commodity series used as price references, the time periods of data used, and the length of time prices are applicable to explain the sometimes large differences in prices under the two regulatory systems. As a result, the witness said, Class 2 products are sometimes sold on a spot basis to exploit short-term price differences.

The Cooperative witness presented a comparison of CSO Class 4a and FMMO Class IV prices from January 2000 to July 2015, revealing that over the entire time period the Class 4a price averaged $0.29 per cwt less than the Class IV price. The witness added that over this 15-year period, the CSO Class 4a price on an annual average basis was never above the FMMO Class IV price.

The Cooperative witness also provided testimony on the price disparity between CSO Class 4b and FMMO Class III price formulas. Data from January 2000 to July 2015 revealed

[16] Wisconsin, Minnesota, and Illinois; Oregon, Washington and Northern Idaho, respectively.

that the CSO Class 4b price was lower than the Class III price in 161 of the 187 months examined. The witness computed the average difference over that 15-year time period to be $0.91 per cwt, with the largest difference of $3.24 per cwt occurring in November 2014. The witness attributed the observed price differences to differences in the valuation of dry whey between the CSO 4b and the FMMO Class III formulas. The witness said that in 2007, the whey factor in the CSO Class 4b formula became a tiered, bracketed system with a floor of $0.25 and a ceiling of $0.75, which is reached when the WDW-Mostly price is greater than or equal to $0.60 per pound. The witness added that the whey value contained in the FMMO Class III price comes from the AMS NDPSR, and reflects the mandatory reporting of dry whey sales throughout the country. The witness estimated that from August 2012 through July 2015, the Dairy Market News (DMN) whey value contributed $0.68 per cwt to the CSO 4b price, while the NDPSR whey value contributed $2.39 per cwt to the FMMO Class III price. The witness concluded that the whey cap contained in the CSO 4b price results in lower contributions to the marketwide pool than what is observed in the national marketplace and reflected in FMMO prices.

The Cooperative witness reiterated the consequences of having two different regulatory pricing schemes which has led to severe differences between the regulated markets. The witness opined that the regulatory differences allow California handlers who purchase raw milk and manufacture products for sale in the national marketplace to pay substantially different regulated minimum prices than handlers regulated by the FMMO system. The witness estimated that because of the regulatory price differences, from August 2012 to July 2015, California farms received, on average, $1.89 per cwt less than similarly-situated FMMO farms. The witness concluded that this results in California farms being in a worse competitive position than similarly situated FMMO farms. The witness labeled this as disorderly and said that this condition should be remedied through the adoption of Proposal 1.

The Cooperative witness also entered data estimating the value of regulating interstate commerce through the establishment of a California FMMO. The witness cited January 2009 through July 2015 CDFA data that indicated a monthly average of 54.5 million pounds of milk originating outside the state was processed by California processing plants, and another monthly average 36 million pounds of milk was produced inside California and sold to plants located outside of the state. The witness explained that this milk is able to evade CSO minimum-price regulations because of the state's inability to regulate interstate commerce. Consequently, the witness said, out-of-state farms delivering milk to California plants can receive plant blend prices, which can be higher than the market's overbase price received by in-state producers delivering to the same plant. The witness elaborated that the problem is compounded because processors receiving these unregulated supplies are not required to pay minimum classified prices and can instead pay a lower price than their competitors pay for regulated milk. By regulating these interstate transactions through the establishment of a California FMMO, the witness stressed, the California market would be more orderly.

The Cooperatives' post-hearing brief also highlighted the CSO's inability to regulate out-of-area milk as a market dysfunction. The Cooperatives wrote that out-of-area sales financially harm California dairy farms because the Class 1 revenues from those sales do not contribute to the CSO marketwide pool that is shared with all the farms in the market.

A consultant witness, appearing on behalf of the Cooperatives, testified in support of Proposal 1. The witness was of the opinion that the primary purpose of FMMOs is to enhance producer prices, which is provided in the AMAA through its flexibility to regulate milk and/or milk products, not just fluid milk. As evidence of this flexibility, the witness discussed the Evaporated Milk Marketing Agreement, in existence until 1947, under which manufacturing milk was regulated. The witness said it was reasonable to conclude from this example that the regulation of all California plants that purchase milk from California farms, as contained in Proposal 1, would fall within the scope of the AMAA.

The consultant witness elaborated that extending minimum price regulation to all classes of milk in California is necessary to avoid the market-disrupting practice of handlers opting to not pool eligible milk because of price, often referred to as depooling. The witness said that many FMMOs have adopted provisions to reduce instances of depooling. Currently under the CSO, the witness said, while plants can choose to not participate in the marketwide pool, they gain no price advantage because they are still required to pay minimum classified prices. The witness was of the opinion that the impact of depooling would be greater in a California FMMO because of how California quota premiums are paid. The witness testified that uniform prices calculated after deducting quota premiums would be less than they otherwise would be if large volumes of milk were not pooled. Additionally, the witness addressed the requirement of uniform producer payments. The witness was of the opinion that under Proposal 1, once quota premiums were paid, as required by California law, remaining pool revenues would be distributed uniformly to producers for non-quota milk, as required by the AMAA.

The consultant witness addressed the issue of whether Proposal 1 would implement classified prices that were too high. The witness opined that the classified price formulas contained in Proposal 1 would not establish manufacturing milk prices that are too high because FMMO regulated handlers in other areas are already paying those prices. The witness entered data showing that cheese production has increased in the western states (not including California and Idaho) by 92 percent from 2000 to 2014, while California cheese production has increased only 64 percent. The witness concluded that minimum FMMO prices have not been detrimental to FMMO-regulated plants, and offered the fact that over-order premiums are currently paid to FMMO producers to support that claim. The witness stated that regulations providing for orderly marketing conditions should also provide stability (regulations should not alter market transactions) and efficiency (regulations should stimulate a competitive economic environment), and concluded that both are embodied in Proposal 1.

Twenty-seven California dairy farmers testified in support of Proposal 1. Sixteen belong to one of the three proponent Cooperatives: Nine LOL members, three DFA members, and four CDI members. An additional 11 dairy farmers not associated with the Cooperatives provided testimony supporting the adoption of Proposal 1.

Although each dairy farmer provided unique testimony, several difficulties challenging the California dairy industry were addressed repeatedly. Producer testimony described financial hardships due to the CSO producer prices they receive consistently being below the amount needed to cover the cost of production. One farmer witness cited CDFA cost of production data from the first quarter of 2015 for the North

Valley of California, and estimated that 90 percent of surveyed farms had negative net incomes. Farmer witnesses stated that a FMMO would provide an opportunity for dairy farms to cover their cost of production and work toward reducing debts incurred from historically low mailbox prices.

A number of producers testified that historically they had many competitive advantages (low cost of land, grain, hay and water) enabling them to produce milk at a significantly lower cost than farms located in the rest of the county. All of the witnesses testified that the hardships of high land, feed, and/or water costs, as compared to those in other dairy states, have eroded their competitive advantage. Citing no competitive advantage, coupled with the difference between the FMMO and CSO pricing formulas, dairy farmers testified they are receiving a lower mailbox price than their FMMO counterparts. Testimony stressed that these realities are forcing many California dairy farms out of business.

Many producers expressed that their inability to cover the cost of production is tied to how whey is valued in the CSO Class 4b formula. Thirteen of the 27 producers testified regarding the impact of the whey valuation on mailbox prices. The witnesses stressed that the CSO historically responded to producers' needs by encouraging manufacturing plant investment that would provide an outlet for milk to be processed at a regulated price considered fair. According to the witnesses, this regulatory balance shifted in 2007 because of a CDFA rulemaking that adopted a sliding scale capping the value of the dry whey factor in the Class 4b formula. Witnesses stated that the 2007 hearing marked the start of the widening discrepancy between mailbox prices for California dairy farmers and those received by other dairy farmers across the nation. Witnesses also said that the reduced mailbox prices continue to undervalue milk throughout the State. The producers were of the opinion that a California FMMO would bring California's valuation of dry whey in line with the rest of the country. With comparable whey values, producers testified their mailbox price would become more representative of the true market value of their milk.

Three testifying producers owned farms in both California and in FMMO regulated areas. These producers testified to the difference in production costs and mailbox prices received by their farms over the last decade or more. Their testimonies specifically highlighted the industry differences between California and Wisconsin. The producers said the production advantages California dairy farmers once enjoyed (inexpensive land, feed, and a different regulatory environment) no longer exist, and as a result, California dairy farms are closing or moving out of state at an increasing rate.

Seven producers testified that the use of futures contracting and hedging as risk management tools are hindered by the differences in the CSO and FMMO price formulas. They explained that current risk management tools are based on FMMO prices, and the fact that CSO prices are different make those tools less effective for California producers.

Eight producers provided evidence about reductions in the California dairy industry since 2007. According to the witnesses, many farms have elected to reduce their herd size or cease dairy farming. A witness provided September 2014 to September 2015 data showing that the Cooperatives have experienced a 6.6 percent reduction in milk production volume. The witness stated that the reduction seen by the Cooperatives is supported by CDFA data showing a 3.5 percent reduction in California milk production. The witness noted that while milk production in California is decreasing, it is increasing in the rest of the country. The witnesses believed the discrepancy between California and national milk production trends is due to the inability of California farms to compete on a level playing field with farms in the FMMO system. Many also expressed concern with the impact on related businesses due to the closing of many California dairy farms.

According to six producer witnesses, many farms have opted to weather the milk price volatility by diversifying their operations and investing in tree-crop production. Several witnesses testified that lenders encourage tree-crop production over dairy farming, due to the reduction of risk and the large margins attainable in tree-crop farming. Producers expressed a belief that the adoption of a California FMMO would lead to a more stable dairy industry supported by lenders.

Overall, California producer witnesses stated they are currently subject to a regulatory system that does not provide producer milk prices representative of the full value of their raw milk in the market. The producers believe adoption of a California FMMO represents an opportunity to remedy this regulatory disadvantage and to compete on a level playing field with the rest of the country.

A Western United Dairymen (WUD) representative testified in support of Proposal 1. WUD is a trade organization representing approximately 50 percent of California dairy farmers, whose farm sizes range from 17 to 10,000 cows. According to the WUD witness, the difference between CSO Class 4b and FMMO Class III prices demonstrates that the CSO is not providing California dairy farms with a milk price reflective of the national marketplace for manufactured dairy products. The witness attributed the pricing differences to how dry whey is accounted for in the two price formulas. The witness said the value difference has become increasingly larger since the CSO adopted a fixed whey factor in 2007, and then subsequently replaced it with a sliding scale whey factor in 2011. The witness said that from August 2014 to July 2015 the CSO Class 4b whey value averaged $1.50 per cwt less than the FMMO Class III whey value. As a result, the witness said, there are different regulated minimum milk prices for the milk products that compete in a national market. This regulated milk price difference, the witness stressed, results in market decisions based on government regulations instead of market fundamentals. Furthermore, the witness said, the resulting lower CSO class prices put California dairy farmers at a competitive disadvantage compared to their FMMO counterparts. The witness concluded that this situation is disorderly and reiterated WUD's support for Proposal 1 as a more appropriate method to determine the value of whey.

A witness representing the California Dairy Campaign (CDC) testified in support of Proposal 1. CDC is a dairy producer organization with members located throughout California. The CDC witness said that over the last 10 years, more than 600 California dairy farms have permanently closed or moved to other states. The witness attributed this to milk prices that have been consistently lower than the cost of producing milk in California, and noted that water and feed availability due to the ongoing drought is the primary reason for increased production costs. The witness highlighted the consolidation and concentration of the California dairy manufacturing sector that causes dairy producers to be price takers in the market, thus making equitable regulated minimum prices vital to the long-term viability of California dairy farms.

The CDC witness testified that the failure of the CSO to align with FMMO prices, particularly between CSO Class 4b and FMMO Class III, has resulted in a more than $1.5 billion loss to

California producers since 2010. The witness also said that risk-management tools, particularly the USDA Margin Production Program (MPP), are not as effective for California dairy farms because the national all-milk price used to determine MPP payments is significantly higher than California producer mailbox prices under CSO regulation.

The witness highlighted CDC's support of specific provisions contained in Proposal 1, including the adoption of FMMO end-product pricing formulas, unique pooling provisions that address the needs of the California market, regulation of out-of-state milk, uniform producer-handler provisions, fluid milk fortification allowances, and the continuation of the California quota program. The witness opined that Proposal 1 addresses California's unique market conditions and is the only path to restoring California producer price equity and the health of the California dairy industry.

CDC's post-hearing brief stated that CDC has supported adoption of a California FMMO for over 20 years. The brief highlighted 2015 CDFA data showing California cost of production at $19.30 per cwt, while the average farm income was $15.94 per cwt. The brief stated the belief that minimum prices are put in place to ensure dairy farmers are able to share in some minimal level of profitability. CDC estimated that in 2015, a 1,000-cow California dairy farm was paid approximately $1.4 million less than equal-sized farms whose milk was pooled on a FMMO. A witness representing Milk Producers Council (MPC) testified in support of Proposal 1. MPC is a nonprofit trade association with 120 California dairy-farmer members, accounting for approximately 10 percent of the California milking herd. The witness agreed with testimony given by the Cooperatives outlining California's disorderly marketing conditions. The witness said that California dairy farmers have repeatedly, though unsuccessfully, sought relief through CDFA to bring CSO classified prices more in line with FMMO classified prices. This is why California dairy farmers are now seeking to join the FMMO system, the witness added.

The MPC witness testified that Proposal 1 would establish orderly marketing conditions in California, resulting in a level playing field for producers and processors. The witness stressed that not only would Proposal 1 provide price alignment between California and FMMOs, but a California FMMO would regulate interstate commerce—something the CSO cannot do. Proposal 1 would also maintain the current California quota program, a vital financial tool for many California dairy farmers, the witness stated. The witness said that while the quota program has no impact on the minimum prices handlers pay, it does aid in providing a local milk supply for some plants that would otherwise have to source milk from farther distances. The witness explained that in some instances, quota is an investment farms located in higher cost areas of the state make to remain financially viable and be able to provide a local milk supply to plants that would otherwise have to seek a supply from farther distances.

A witness representing the National Farmers Union (NFU) testified in support of Proposal 1. NFU is a national grassroots farmer organization with over 200,000 members across the nation, including dairy farmers located in California. The witness testified that NFU supports the inclusion of California in the FMMO system so California dairy farms can receive prices similar to those received by dairy farms located throughout the country. The witness testified that California's low-milk prices and high-feed costs have resulted in strained margins and ultimately the closure of over 400 dairy farms in the last five years.

The NFU witness testified that the pay price differences between dairy farms whose milk is pooled under the CSO and FMMOs are primarily due to the difference in the Class 4b and Class III prices and have resulted in disorderly marketing conditions and a revenue loss to California dairy farms of more than $1.5 billion since 2010. The witness added that pay-price differences have reduced the ability of California dairy farms to utilize risk management tools, and put them at a disadvantage when competing for resources such as feed, land, cattle and labor.

A witness appearing on behalf of the Institute testified that while the Institute offered Proposal 2 as an alternative to the Cooperatives' proposal, their first position is that disorderly marketing conditions do not exist in California to warrant the promulgation of a FMMO. The witness stated that the California dairy industry is currently regulated by the CSO, whose purpose, much like a FMMO, is to provide for orderly marketing conditions. The witness emphasized their opinion that orderly marketing conditions are currently achieved through CSO classified pricing and marketwide pooling.

The Institute witness reviewed CSO history and regulatory evolution, and highlighted regulatory changes demonstrating how the CSO has consistently adapted to changing market conditions. Some, but not all, of these regulatory changes are highlighted below.

The Institute witness explained that California sought state solutions to disorderly marketing conditions through the Young Act of 1935. When FMMOs were authorized in 1937, California opted to remain under the purview of the CSO.

The Institute witness explained that the CSO adopted marketwide pooling through the Gonsalves Milk Pooling Act. Before that time, handlers operated individual handler pools, giving Class 1 handlers strong bargaining power as producers sought Class 1 contracts.

According to the witness, this led to handler practices that eroded producer revenues. The witness testified that the California quota program, also authorized by the Gonsalves Milk Pooling Act, was a way for Southern California dairy farmers, who at the time had a higher percentage of Class 1 contracts, to preserve some of the Class 1 earnings they would otherwise be required to share with all producers through marketwide pooling. At the time, the witness said, producers were assigned a production base, and producer quota was allocated based on historical Class 1 sales. Milk marketed in excess of a producer's base and quota allocations was termed overbase milk. The witness explained that during this time the state's population was growing, and quota was deemed necessary to ensure the market's Class 1 needs would always be met.

The Institute witness said that when the quota program was established, there was a growing number of dairy farmers who also owned fluid milk bottling operations. They typically processed all the milk they produced, and were referred to as producer-handlers. These operations feared that the income benefits they gained from processing their own milk would disappear with the establishment of mandatory pooling. To relieve this concern, the witness said smaller producer-handlers were exempted from pooling in return for not receiving a quota allocation. The witness explained larger producer-handlers had the option of not receiving a quota premium, and deducting those quota pounds from their Class 1 obligations to the pool, an amount referred to as exempt quota.

The Institute witness testified that the CSO was modified numerous times in the late 1970's and early 1980's to ensure that Class 1 needs of the market would always be met. First, call provisions were established requiring manufacturing plants participating in

the pool to maintain a percentage of quota milk available to Class 1 plants. Second, a system of transportation credits and allowances was established to cover part of the cost of moving milk from surplus areas to deficit areas for Class 1 use. According to the witness, CDFA regularly updates these milk movement incentives to reflect current costs.

In the early 1990's, CDFA amended how the quota premium was derived. At the time, quota funds were derived from Class 1, 2, and 3 prices, while overbase prices were derived from Class 4a and 4b prices. Consequently, the witness noted, the difference between quota and overbase prices varied greatly by month. The witness said the historic value of quota, in comparison to the overbase value, was evaluated to derive a fixed quota price of $0.195 per pound of quota solids nonfat.

The Institute witness also reviewed several instances since 2000 where CSO provisions were amended to reflect changing market conditions and changing FMMO regulations. These instances included adopting the ''higher of'' concept for pricing Class 1 milk, incorporating a dry whey factor in the price formulas, and changing the make allowances contained in the product price formulas—all changes the witness said were necessary to maintain orderly marketing conditions in California.

The Institute witness maintained that current California marketing conditions are orderly, and therefore the establishment of a FMMO is not justified. The witness stated the CSO program focuses on orderly marketing conditions to ensure Class 1 needs are met, while providing reasonable returns to those dairy farms who supply the Class 1 market. The witness stressed the regulated price differences between CSO Class 4a/4b prices and FMMO Class III/IV prices do not amount to disorder, and in fact, those differences are needed to maintain orderly marketing in the state.

The Institute witness testified that in the CSO-regulated environment, where all milk is subject to minimum price regulation, it is important that manufacturing prices are not set above market-clearing levels. The witness elaborated that the largest market, and therefore the highest value, for finished dairy products is in the eastern United States where most of the population resides. Therefore, the witness said, in order for California dairy products to be transported and compete in the eastern markets, they must have a lower value in the West. The witness was of the opinion that FMMO Class III and Class IV prices are not appropriate local, market-clearing prices for California.

The Institute witness also opined that current differences between CSO Class 2 and 3 prices and FMMO Class II prices are not disorderly. The witness explained that Class 2 and 3 prices are set relative to the Class 4a price, and it is important that these prices are not set so high as to encourage dairy ingredient substitution with Class 4a products. The witness argued the Cooperatives provided no evidence that the class price differences between the CSO and FMMO systems are disorderly.

The Institute witness also testified regarding the difference between CSO Class 1 and FMMO Class I prices. While CSO Class 1 prices are somewhat lower than those in neighboring FMMO areas, the witness said, they are not causing disorderly marketing conditions. The witness explained that if lower priced California milk is sold into FMMO areas, there are provisions for FMMO partial regulation to ensure the California Class 1 plants do not have a regulatory price advantage over the FMMO plants.

The Institute witness testified that recent declines in California milk production and increases in dairy farm consolidation are not evidence of disorderly marketing conditions. The witness elaborated that dairy-farm consolidation is a natural market evolution resulting from differences in producers' cost structure, risk tolerance, and access to capital. This is no different than consolidation trends seen in other regions of the country, added the witness. The witness also testified that, while dairy farmer margins have been volatile in recent years, California milk production costs have remained below the United States average. According to USDA Economic Research Service data, the witness said 2010–2014 California milk production costs were well below the national average, by a yearly average of $4.19 per cwt. Regardless of milk production and consolidation trends, the witness stated that California has adequate milk supplies to meet fluid demand, and milk movements to meet processing and manufacturing demands are largely efficient.

The Institute witness explained that its members represent approximately 65 percent of the fluid milk processing in California, and none have expressed difficulty obtaining milk supplies or any type of disorderly marketing condition. The witness expressed concern that any changes in the regulatory environment would likely increase the cost of fluid milk. This cost would be passed onto consumers, thereby creating a barrier for fluid milk sales, said the witness.

The Institute witness opined the CSO has an effective pricing and pooling system that has evolved over time to address changing market conditions, and disorderly marketing conditions do not exist to warrant a California FMMO. However, should the Department recommend a California FMMO, the witness said the provisions outlined in Proposal 2 should be adopted.

The post-hearing brief submitted on behalf of the Institute reiterated its opinion that the Department must find disorderly marketing conditions to justify intervention. Disorderly marketing conditions under the AMAA, the Institute wrote, refers to the fluid milk supply and not the market for manufactured milk. The brief stated that California has, on average, an 11 to 12 percent Class 1 utilization and more than enough reserve milk to meet fluid demand.

The Institute's brief outlined a six-point test that it argued needs to be met in order to justify a California FMMO. The Institute stated the current CSO already meets all six of the requirements and thus Federal intervention is not justified.

The Institute's brief also addressed the 1996 and 2014 Farm Bills as they pertain to the consideration of a California FMMO. The Institute stressed that in neither case did Congress amend the AMAA, and therefore the Department is authorized, but not required, to incorporate the California quota program. According to the Institute, whatever decision the Department makes, it must uphold the AMAA's uniform payments and trade barrier provisions. The Institute stated that Proposal 1's incorporation of the California quota program does not uphold either of these provisions.

The Institute's post-hearing brief argued that the differences in Class III and Class 4b prices, highlighted by the Cooperatives, do not provide justification for a California FMMO. According to the brief, the AMAA requires marketing orders to have regional application that recognizes differences in production and market conditions.

A witness appearing on behalf of Hilmar Cheese Company (Hilmar) testified that the Department has consistently found that evidence of disorderly marketing conditions must exist in order to justify Federal intervention through the promulgation or amendment of a FMMO. Hilmar is a dairy manufacturer with facilities in California and Texas selling dairy products both domestically and internationally. According to the witness, Hilmar's California cheese and

whey manufacturing facility is the largest cheese manufacturing facility in the State, processing 12 percent of the total California milk supply, which is purchased from 200 dairy farms, most of whom are not affiliated with any cooperative.

The Hilmar witness cited previous Department decisions, including the 1981 Southwestern Idaho/Eastern Oregon and the 1990 Carolina promulgations, as examples of what market conditions should be present in order for the Department to act. The witness was of the opinion that the Cooperatives did not provide evidence of actual disorderly marketing conditions in California warranting Federal intervention.

In its post-hearing brief, Hilmar stated that FMMOs are designed to be a marketing tool to address problems associated with the inherent instability in milk marketing. Hilmar reiterated its opposition to a California FMMO, stating that the Department has consistently denied proposals seeking price enhancement, as they believe is the case in this proceeding. Hilmar stated that the record does not support the notion that there is an inadequate supply of milk for fluid use in California, and therefore a California FMMO is not justified.

A witness appearing on behalf of HP Hood, LLC, a milk processor with facilities in California and other states, testified that disorderly marketing conditions are not present in California and therefore a FMMO is not warranted. The witness said the CSO is an efficient program that has been routinely updated to reflect changing market conditions. The witness stated that HP Hood has not had any difficulty securing an adequate supply of raw milk for its California processing plants, nor is HP Hood aware of instances where raw milk had to be transported long distances in order to meet California demand.

The HP Hood witness suggested the Department consider the potential adverse impacts of recommending a California FMMO on other FMMOs, as well as potential increases in milk costs to consumers that may stem from adoption of the higher uniform minimum milk prices included in Proposal 1. The witness specifically opposed the inclusive pooling portion of Proposal 1 and explained how the ability for milk handlers to pool or not pool is how orderly marketing has been maintained in the existing FMMOs. The witness urged the adoption of Proposal 2, should the Department find that a California FMMO is warranted.

A witness appeared on behalf of Saputo Cheese USA, Inc. (Saputo), a proprietary international dairy and grocery products manufacturer and marketer with seven dairy product-manufacturing facilities in California. Saputo opposes the promulgation of a California FMMO, but should the Department find a FMMO warranted, it supports adoption of Proposal 2. The witness testified that disorderly marketing conditions are not present in California to warrant FMMO promulgation. The witness explained how CDFA has been responsive to dairy industry concerns, has held many hearings in the past, and administers the CSO in a manner that facilitates orderly marketing as well as, or better than, the FMMO system.

The Saputo witness summarized many of the similarities and differences between the CSO and FMMO systems. The witness was of the opinion that the CSO mandatory pooling rules increased milk production to surplus levels and encouraged the construction of bulk, storable dairy product manufacturing facilities. In conjunction with these rules, the witness explained, CSO regulated minimum prices are set at levels that are not too high to encourage significant additional increases in supply.

The Saputo witness described the California cheese production landscape. The witness, relying on CDFA data, said that from January through March of 2015, 57 cheese plants processed 45 percent of California's milk. The witness noted that out of the 57 cheese plants, 3 of the plants processed more than 25 percent of the state's entire milk supply. The witness stated that if the increase in the hypothetical California FMMO Class III price included in the USDA Preliminary Economic Analysis of $1.84 per cwt occurred, under a system of mandatory pooling, the aforementioned 3 cheese plants would face combined increased annual raw milk costs of nearly $196.5 million. The witness testified that such raw milk cost increases would be disorderly and threaten the viability of California manufacturing facilities.

A witness appearing on behalf of Farmdale Creamery (Farmdale) testified in support of Proposal 2. Farmdale is a proprietary dairy processing company located in San Bernardino, CA, that manufactures cheese, sour cream, dried whey protein concentrate, and buttermilk. The witness was of the opinion that disorderly marketing conditions are not present in California, since there is no shortage of milk to meet fluid milk needs. The Farmdale witness opined that the CSO maintains an orderly market by responding to changing market conditions when warranted.

Should the Department find a California FMMO justified, the witness supported adoption of Proposal 2 and opposed the mandatory pooling provisions contained in Proposal 1.

The witness also testified about financial losses incurred by Farmdale since 2005, when the CSO whey value was sometimes higher than what they could obtain from the market. The witness added that their on-again, off-again financial losses demonstrate the inability of current regulatory pricing systems to track and value the whey markets.

A witness appeared on behalf of Pacific Gold Creamery (Pacific Gold) in opposition to the adoption of a California FMMO, although the witness supported the provisions contained in Proposal 2 should a FMMO be recommended. Pacific Gold operates a dairy farmer-owned specialty cheese plant in California. The witness testified that across existing FMMOs and unregulated areas, dairy product manufacturers regularly pay below FMMO minimum prices. The witness presented and explained USDA-prepared FMMO data regarding volumes of milk pooled and not pooled across existing FMMOs.

The Pacific Gold witness explained how their business produces ricotta from the whey stream of their cheese manufacturing, and how ricotta sales supplement the income of the cheese operation. The witness was of the opinion that the FMMO Class III price, and the accompanying higher whey value contained in Proposal 1, would be devastating to small and mid-size facilities. The witness also testified how an increase in California minimum-regulated prices would jeopardize exports, saying that U.S. domestic cheese prices are already relatively higher than global prices.

A post-hearing brief was submitted on behalf of Trihope Dairy Farms (Trihope). Trihope is a dairy farm located in, and pooled on, the Southeast FMMO. Trihope stated that disorderly marketing conditions do not exist in California to warrant promulgation of a FMMO. Trihope was of the opinion that California dairy farmers are seeking higher prices through a new regulatory body, which is not a justification for USDA to proceed. According to Trihope, the AMAA was designed to solve marketing problems in unregulated areas, not to address price disparities between Federal and State regulation.

Trihope expressed concern about the potential impact a California FMMO would have on the entire system. Trihope specifically noted the impacts to the southeastern marketing areas contained in the USDA Preliminary Economic Impact Analysis. According to their brief, Trihope estimates losses from 2017 to 2024 of approximately $313,091. Trihope wrote that California's marketing issues of high California milk production and limited plant capacity would not be solved by a FMMO.

A post-hearing brief submitted by Select Milk Producers, Inc. (Select) expressed support for the adoption of a California FMMO. Select is a national dairy-farmer cooperative that markets over 6.5 billion pounds of milk annually, and whose members' milk is regularly pooled on the Appalachian, Mideast, Southeast and Southwest FMMOs. Select also supplies plants located in many other FMMOs, but it does not supply any California plants. Select opined that having California's milk supply priced similarly to the rest of the FMMOs would remedy the competitive disadvantages faced by companies competing in the national marketplace, and would allow for more efficient milk movements. Select expressed support for maintaining a uniform national pricing system and opposed the Institute's alternative whey-pricing proposal. Select expressed support for the Cooperatives' inclusive pooling provisions on the basis that the provisions would apply only to California, due to its unique marketing conditions. Select stated the California quota program should be addressed outside of this rulemaking proceeding. Select was of the opinion that adoption of a California FMMO would lead to more orderly milk marketing throughout the entire FMMO system, and thus uphold the intent of the AMAA.

A post-hearing brief submitted on behalf of the Northwest Dairy Association (NDA) expressed support for Proposal 1. NDA is a dairy farmer-owned cooperative that markets the milk of its 460 members and operates numerous fluid milk and manufacturing plants located in Washington, Oregon, Idaho, and Montana. NDA was of the opinion that adoption of Proposal 1 would create more orderly marketing conditions and strengthen the entire FMMO system. As California represents the largest milk supply in the United States, NDA wrote, it is important for the integrity of the FMMO program to include the additional 20 percent of United States milk represented by California. NDA stated that California producers should not be disadvantaged with lower Class III and IV prices than what their western FMMO producer counterparts receive.

Findings

The record contains a voluminous amount of testimony, evidence, and opinions as to whether or not a California FMMO is justified. The Cooperatives and their supporters argue that a California FMMO was authorized by Congress in the 2014 Farm Bill. They contend that this proceeding is not about whether or not a FMMO should be established, but rather to determine what the California FMMO provisions should be. The Cooperatives are of the opinion that the existence of disorderly marketing conditions is not required by the AMAA to justify order promulgation. They stressed in their post-hearing briefs that a FMMO needs to establish and maintain orderly marketing conditions, and that would be accomplished through the adoption of their proposal. However, should the Department find that disorderly marketing conditions must be present, the Cooperatives provided evidence of what they believe are ongoing disorderly marketing conditions in California.

In general, the record reflects that the California producer community supports joining the FMMO system. Producers are of the opinion that the prices they currently receive under the CSO do not reflect the appropriate value for their milk and its components. Particularly, producers believe that the price they receive for milk used for cheese manufacturing does not value the dry whey component at a level commensurate with what manufacturers receive for whey in the marketplace.

In contrast, the Institute and its members consistently argued throughout the hearing, in their post-hearing briefs, and in comments to the recommended decision that the existence of disorderly marketing conditions is required by the AMAA, and that such conditions do not exist in California. They provided testimony explaining how the CSO is a flexible system that is routinely evaluated through the CDFA hearing process and changes are made as market conditions warrant. The Institute and its members were united in the opinion that the Cooperatives are solely seeking to receive higher prices for their milk, and that such higher prices are not justified for California.

As discussed earlier, the declared policy of the AMAA is to ''. . . establish and maintain such orderly marketing conditions for agricultural commodities in interstate commerce . . .'' FMMOs accomplish this through the classified pricing of milk products and marketwide pooling of those classified use values. Through these mechanisms, orderly marketing conditions are provided so that handlers are assured uniform minimum raw milk costs and producers receive minimum uniform payments for their raw milk, regardless of its use.

While in recent history FMMOs have been consolidated, amended and expanded, it has been decades since a new order has been promulgated. The records of those promulgation proceedings include descriptions of the market conditions at the time, and how a FMMO would provide order in the market. However, those decisions did not, nor does this final decision find, that disorderly marketing conditions must exist or are a condition of order promulgation. Order promulgation and amendatory proceedings have reiterated that a FMMO must adhere to the declared policy of the AMAA, where there is no express or implicit declaration of a requirement for a finding of disorderly marketing conditions.

This final decision continues to find, based on the evidentiary record, a FMMO for California would provide more orderly marketing conditions in the marketing area, and therefore promulgation of a California FMMO is warranted. The record is replete with discussion from most parties on whether disorderly marketing conditions exist, or are even needed, to warrant promulgation of a California FMMO. The declared policy of the AMAA makes no mention of ''disorder,'' and this final decision continues to find that disorderly marketing conditions are not a requirement for an order to be promulgated. The standard for FMMO promulgation is to ''. . . establish and maintain such orderly marketing conditions . . . ,'' and this decision continues to find that the proposed California FMMO meets that standard by providing uniform minimum raw milk costs to handlers and minimum uniform payments to producers for their raw milk, regardless of its use.

Comments filed on behalf of the Cooperatives supported the Department's finding that a California FMMO would effectuate the declared policy of the AMAA and was therefore warranted. The Cooperatives supported the determination that disorderly market conditions were not a requirement for FMMO promulgation. Furthermore, the Cooperatives wrote, the recommended decision properly found that the intent of the AMAA was not to preclude a group of state-

regulated producers from petitioning for a FMMO. The Cooperatives expressed that the recommended California FMMO, with some modifications they offered, would provide for more orderly marketing conditions by assuring producers that the prices they receive more appropriately represent the full value of all the classified use values of raw milk in the market. Additionally, wrote the Cooperatives, the proposed California FMMO would provide more orderly marketing conditions by ensuring that prices paid by handlers would be reflective of the national market for manufactured dairy products in which California products compete.

Comments filed on behalf of Select supported the finding that disorderly marketing conditions are not a requirement for order promulgation and that a California FMMO would provide more orderly marketing conditions.

Additionally WUD, CDC, MPC, and National All-Jersey (NAJ), whose comments focused primarily on the specific provisions recommended, offered general support for establishing a California FMMO.

The Institute took exception to the Department's finding that disorderly marketing conditions are not a requirement for order promulgation. They argued that a FMMO can only be promulgated if the regulations ''establish'' order, and they contend that the Department's finding that an order can be established if it creates ''more'' order unjustly broadens the authority of the AMAA. The Institute wrote that to establish orderly marketing conditions, market disorder must first exist. Therefore, because the Department did not find disorder in the California marketplace, the promulgation of a California FMMO is not justified.

The Institute further argued that the California FMMO promulgation standard articulated in the recommended decision was in contrast to prior agency decisions that cited disorder as a reason for promulgation or amendment. Lastly, the Institute argued that FMMO Supplemental Rules of Practice refer to disorder as a condition for submitting an amendatory proposal, so such standard should not be ignored in the California FMMO proceeding. The Institute concluded that the Department does not have the legal authority to change its interpretation of the declared policy of the AMAA, and therefore California lacks the market disorder needed to justify promulgation of a FMMO.

Separate comments filed by Leprino Foods (Leprino) and Dean Foods supported the arguments by the Institute regarding order promulgation.

Comments filed by the International Dairy Foods Association (IDFA) did not offer an opinion on whether a California FMMO should be promulgated, but did take exception with the Department's finding that disorderly marketing is not a requirement for FMMO promulgation. IDFA opined that if orderly marketing conditions already exist, the Department has no basis to promulgate an order. Like the Institute, IDFA argued that there should be no differentiation in the threshold for Federal government intervention between amendatory and promulgation proceedings. IDFA contended that the FMMO Supplemental Rules of Practice were adopted through notice and comment rulemaking by which the Department adopted the disorderly marketing conditions requirement, and the different threshold for promulgation described in the recommended decision is not appropriate. Additionally, IDFA reviewed multiple amendatory FMMO decisions that cited disorderly marketing conditions as a justification for regulatory change. IDFA concluded that imposing Federal regulations in a market that exhibits no signs of market disorder carries the risk of disrupting the currently existing orderly marketing conditions. Comments filed by Hilmar also took exception with the Department's finding that disorderly marketing conditions are not a requirement for FMMO promulgation. Hilmar wrote that the objective of the AMAA is to establish and maintain orderly marketing conditions and that the Department ignored past FMMO proceedings that cited disorderly marketing conditions as a justification for regulatory change. Hilmar contended that the Department did not explain why the California FMMO proceeding was held to a different standard.

Another commenter also argued that disorderly marketing conditions should be a requirement for FMMO promulgation. The commenter elaborated that in order for a FMMO to align with the public interest, the public should have access to milk at a reasonable cost, and further study is needed to determine the impact to all stakeholders. The commenter wrote that it was not in the public interest to establish a FMMO in a market where disorderly market conditions have not been found.

Additional opposition to the Department's finding that disorderly marketing conditions are not a requirement for FMMO promulgation was also expressed in comments filed by Pacific Gold and HP Hood.

Comments filed by CPHA were specific to exempt quota; however CPHA stressed that it would be unable to offer support or opposition to a California FMMO until CDFA has released its plan for operating the California quota program.

The Department recognizes that many commenters took exception to the finding that disorderly marketing is not a requirement for FMMO promulgation. Similar to arguments made at the hearing and in post-hearing briefs, the commenters provided numerous rulemaking examples where market disorder was found. However, none demonstrated that market disorder was a requirement for FMMO promulgation. This final decision continues to find that the declared policy of the AMAA to ''establish and maintain orderly marketing conditions'' does not require market disorder to be the justification for promulgation of an order.

Numerous commenters noted that the Supplemental Rules of Practice in 7 CFR 900.20–900.33 stipulate that petitioners provide examples of market disorder to justify requesting an amendatory proceeding. Commenters took exception to the fact that the Department was not now requiring evidence of market disorder to justify this promulgation proceeding. The 2008 Farm Bill required the Department to establish these Supplemental Rules specifically to address only amendatory proceedings. The rules outline submission requirements for FMMO amendatory proposals and specify timeframes the Department must adhere to during the amendatory rulemaking process. Congress could have extended the reach of the Supplemental Rules to include both amendatory and promulgation FMMO proceedings, but did not.

The record indicates that there are both handler and producer price differences between the CSO and the FMMO systems. The record contains data regarding the difference in classified use values paid by handlers regulated by the CSO and FMMOs. As will be discussed later, this decision proposes the adoption of the classified price formulas that currently exist in the FMMO system. A California FMMO, under the provisions contained in this final decision, would ensure that the prices handlers pay to purchase pooled California milk would be similar to prices paid for milk pooled on other FMMOs. As commodity dairy products compete in the national market, current FMMOs uniformly price the raw milk used in those products. This pricing system ensures that competing handlers have uniform minimum raw milk costs, and consequently none has a regulatory price advantage. The record demonstrates that California

manufactured dairy products compete in the national market. However, the CSO-regulated prices for raw milk paid by California manufacturers are different than those paid by manufacturers under FMMOs. This final decision continues to find the proposed California FMMO would provide classified milk prices that would be more uniform with those paid by competing handlers, and more reflective of the national market for manufactured milk products and the local market for fluid milk products, as is the policy for the 10 current FMMOs. This final decision finds these prices would provide more orderly market conditions for California.

This final decision continues to find that the classified prices proposed for a California FMMO will provide producers with a minimum producer blend price more reflective of the national market for manufactured products and the utilization of the local California market. Taken together, handler and producer prices reflective of the national market in which manufactured dairy products are sold will ensure orderly marketing conditions in California.

While the current CSO provides classified pricing and marketwide pooling similar to a FMMO, the hearing record reflects that California dairy producers have been unsuccessful in obtaining a minimum regulated price they believe is reflective of the full value of their raw milk. Some parties argued on the record, and in their comments on the recommended decision, that because the CSO already provides for classified pricing and marketwide pooling, disorderly marketing conditions do not exist in California, and therefore there is no justification for promulgating a California FMMO. As discussed earlier, disorderly marketing conditions are not a precedent or requirement for order promulgation. Furthermore, this final decision continues to find that it is not the intent of the AMAA to preclude a group of producers from petitioning for a FMMO simply because they are otherwise regulated by a state order that provides for classified pricing and marketwide pooling. Such a restriction would place an undue barrier on those producers as they would not have the opportunity to petition for FMMO regulation simply because they are currently regulated by a state.

Additionally, unlike the CSO, a California FMMO would have the authority to regulate interstate commerce. The record reveals that there is milk, both raw and packaged, being sold into and out of California over which the CSO has no regulatory jurisdiction. The revenues from those unregulated Class I sales are not shared with all the producers supplying the California market. A FMMO would ensure that those classified use values would be shared with all producers who supply the California market. The ability of a California FMMO to capture interstate sales, through either full or partial regulation, would protect the integrity of the entire regulatory framework. Furthermore, out-of-state producers supplying that milk would be paid the order's blend price, which is reflective of the market's total classified use value.

In their post-hearing brief, the Institute made reference to a ''six-point test'' that must be met in order for a FMMO to be promulgated. While the Institute correctly lists various factors that have been used in some order promulgations, the articulated AMAA standard that must be met for order promulgation is that the order will ''. . . establish and maintain such orderly marketing conditions. . . .''

Other parties in post-hearing briefs contended that the 2014 Farm Bill mandated that a California FMMO be promulgated. The Farm Bill merely authorized a California FMMO that recognizes quota value as determined appropriate through a rulemaking proceeding. It is important to note that California producers could have petitioned for a FMMO at any time. However, Congress did not provide for the recognition of quota before the 1996 Farm Bill, and later, the 2014 Farm Bill. This decision finds that a California FMMO is justified, as it would meet the objective of the AMAA to ''. . . maintain such orderly marketing conditions. . . .'' The provisions proposed herein are tailored to the California market, adhere to the uniform handler and producer pricing provisions of the AMAA, and recognize quota as authorized by the 2014 Farm Bill and as deemed appropriate by an objective analysis of this hearing record.

Some hearing participants indicated that a goal of FMMOs, and therefore of a California FMMO, is to enhance producer prices. Other participants from outside of California, in testimony and post-hearing briefs, expressed the opinion that a California FMMO could not be promulgated if it would have adverse impacts on other FMMOs, and that the Department must act to mitigate those adverse impacts before such promulgation.

FMMOs are a marketing tool that, among other things, establish a marketing framework and enforce market-based minimum prices to handlers and uniform payments to producers reflective of all classified use values in the market. The record reflects that at the time of the hearing, California represented over 20 percent of the United States milk supply. If a California FMMO is established, over 80 percent of the United States milk supply would fall under the same regulatory framework. This decision finds that a California FMMO would provide more orderly marketing conditions in California. Through inclusion of California in the FMMO regulatory framework, the prices received by all producers participating in the FMMO system would be more reflective of the national marketplace for dairy products. This would send uniform market signals to producers that would allow them to make their individual business decisions.

Comments filed by the Maine Dairy Industry Association (MDIA) supported the establishment of the proposed California FMMO, but reiterated their opinion that the Department must mitigate potential adverse producer impacts in other FMMOs. Specifically, MDIA commented that the Department should address four specific adverse impacts: Impact on producer welfare and orderly marketing; impact on Class I utilization; impact from projected regional changes in milk production; and impact from projected depooling in various FMMOs.

It is to be expected that incorporating an additional 20 percent of the U.S. milk supply into a FMMO—milk that is currently state regulated—would have an impact in other regions of the country. The REIA released in conjunction with this final decision estimates the potential impact of regulating California milk handlers under a FMMO and its results show impacts in all regions throughout the United States. This final decision continues to find that promulgation of a California FMMO would enable 80 percent of the United States milk supply to fall under the same regulatory framework. Consolidation under this Federal milk marketing framework would ensure that prices received by all producers participating in the FMMO system would be more reflective of the national marketplace for dairy products. This final decision finds that changes to other FMMOs to counter projected impacts are not warranted and would only serve to send incorrect market signals to those producers who need to make individual business decisions based on accurate information.

4. California Quota Program Recognition

This section reviews and highlights the hearing evidence, post hearing briefs, and comments or exceptions submitted in response to the recommended decision regarding the appropriate recognition of the California quota program, including exempt quota, in a California FMMO. The California quota program is a state-administered program that entitles the quota holder to an additional $0.195 per pound of SNF over the CSO overbase price. Currently, the money to pay the quota premium is deducted from the CSO marketwide pool before the CSO overbase price is calculated. This decision continues to find that the quota program should remain entirely within the jurisdiction of CDFA, and that its proper recognition under the proposed California FMMO would be through an authorized deduction from payments due to producers.

Summary of Testimony

A Cooperative witness testified regarding the development of the California quota program and its continued significance to California dairy farmers. The witness explained the California quota system is a tiered pricing system, developed in the late 1960s, that pays producers on three price calculations referred to as quota, base, and overbase. In its current form, ownership of quota entitles producer-owners to a higher price for milk covered by quota, and a lower base/overbase price on their nonquota milk production. Approximately 58 percent of all California farmers own quota at varying levels, which in aggregate represents approximately 2.2 million pounds of SNF on a daily basis. The witness testified that, currently, quota premium payments are approximately $12.5 to $13 million per month, and this money is taken out of the CSO marketwide pool before the base/overbase price is calculated. The witness stressed that the quota program is an important revenue source for California dairy farms and that the value of quota should not be diminished with the adoption of a California FMMO.

The Cooperative witness reviewed the authorization of the California milk pooling and quota programs by the 1967 Gonsalves Milk Pooling Act (Gonsalves Act). Originally, the witness explained, producers were assigned quota holdings as they related to the producers' historical milk production and individual deliveries to the Class 1 market. The witness said that in the beginning, quota premiums were not a set value, but instead were determined by allocating quota holdings to the highest value milk (Class 1). Then base and overbase production were allocated to the remaining classes in descending order of classified value. In essence, the witness explained, quota holders were paid the Class 1 price for their quota holdings, and then a separate lower value for their non-quota holdings. According to the witness, when CDFA sought to enhance producer prices, additional revenue was typically assigned to Class 1 and subsequently quota holders, and overbase prices were not impacted. The witness said that as milk production grew without corresponding increases in quota holdings, producers were faced with lower milk prices on their non-quota production. Therefore, the Gonsalves Act was amended, effective January 1, 1994, setting the quota premium at $0.195 per pound of SNF (equivalent to $1.70 per cwt). The result, said the witness, was that overbase production did not subsidize quota milk, and quota holders could receive a reasonable return on their quota holdings.

The witness also discussed adjustments made to the total CSO marketwide pool value in conjunction with the quota program. According to the witness, when pooling was originally established, the provisions contained producer location differentials designed to encourage quota milk to be delivered to Class 1 plants. However, as overbase milk production began to grow, location differentials applicable only to quota milk did not ensure that the market's Class 1 needs would always be met, the witness stated. Consequently, in 1983 transportation allowances (on milk movements from ranches to plants) were established in lieu of location differentials. At the same time, the witness said, regional quota adjusters (RQAs), while providing no direct incentive to move Class 1 milk, were established to address producer equity issues that arose with the elimination of location differentials. The witness described RQAs as reductions (ranging from $0.00 to $0.27 per cwt) to the producer's quota premium, depending on their farm location and plant of receipt. In essence, the witness said, quota premiums have a location value: The further the dairy farm is located from the receiving plant, the lower the quota premium.

The Cooperative witness stated that quota can only be held on Grade A milk produced in California, and a quota holder must deliver milk to a pool handler at least every 60 days. The witness also noted the fact that quota is bought and sold on a monthly basis, which underscores its continued importance to California dairy farms. The witness estimated that at a price of $525 per pound of SNF, the California quota program has a value of $1.2 billion to California dairy farms.

The witness was of the opinion, which was reiterated in the Cooperatives' post-hearing briefs, that under current California and Federal statutory authorities, a California FMMO can be established and the California quota program maintained. The witness said that the main objective of Proposal 1 is to preserve the quota program to the maximum extent possible, and that proponents believe this is consistent with the Congressional intent of the Agricultural Act of 2014 (2014 Farm Bill), which authorized a California FMMO that recognizes the quota program.

The witness concluded by outlining what the proponents believe is the necessary framework of a proposed working relationship between CDFA and the Department, and said that the provisions contained in Proposal 1 are needed to effectively maintain the quota program. The witness explained that Proposal 1 allows the quota premium to be removed from the marketwide pool before a FMMO blend price is computed. Producers would then receive the blend price for their nonquota holdings and the FMMO blend price plus the quota premium (adjusted for RQAs) for their quota holdings. According to the witness, USDA would enforce all producer payments, including quota payments, and jurisdiction over quota administration, calculations, record keeping, and regulatory changes would remain with CDFA.

In their post-hearing brief, the Cooperatives asserted that their proposal is the only one that properly recognizes the quota program as intended by Congress. The Cooperatives rebutted the Institute's claim that adoption of Proposal 1 would create a trade barrier to milk produced outside the state because that milk would be ineligible for the quota program. The Cooperatives offered a modification that would create an out-of-state adjustor to ensure out-of-state producers do not receive a lower price than their in-state counterparts who can earn California quota premium payments.

The Cooperatives further argued that Proposal 1 upholds the AMAA's uniform pricing provisions, as all quota milk would be paid uniformly, all non-quota milk would be paid uniformly, and all milk located outside of the proposed marketing area would be

unaffected by the quota program. The Cooperatives' brief stated that the ability of a FMMO to regulate interstate commerce would provide a more level playing field among all handlers with sales in California.

A consultant witness, appearing on behalf of the proponents of Proposal 1, testified regarding the economic importance of the California quota program, and provided a brief history of its evolution. At current market prices, the witness estimated the value of the California quota program at $1.164 billion—a significant economic asset for dairy farms and the communities they support, especially in counties where a high percentage of milk production is covered by quota. The witness noted that not only is quota a solid financial investment for dairy farms, but it is a tangible asset used by dairy farms to obtain additional financing from banks and lenders.

The witness utilized an economic impact analysis model to estimate the total economic impact of the California quota program. The witness estimated that total annual economic value of quota is associated with a $27.9 million increase in California GDP, creation of 1,269 jobs, an $11 million increase in local tax revenue, and a $16.7 million increase in Federal tax revenue. The witness clarified that the analysis did not consider the economic impact of the quota program on non-quota holders, but stressed that any change to the quota program would create regulatory uncertainty and diminish the economic value of quota. The witness opined that Proposal 2 does not recognize the economic value of quota and would result in the devaluation of the asset, which would financially harm California quota holders. The witness concluded that Proposal 1 was the only proposal that would preserve and maintain the California quota program.

Twelve dairy farmers testified that a California FMMO must provide for the continuation of the California quota program. The farmers stressed the importance of the program as an asset for dairy farms throughout the state. The witnesses explained that farms utilize quota not only for the monthly quota premium they receive, but also as an asset on farm balance sheets for lending purposes. The witnesses expressed concern that any devaluation of their quota asset would be financially harmful to their businesses. Of the 27 dairy farmers who testified, eight said they owned quota, and both quota and non-quota holders expressed support for the quota program.

A witness testifying on behalf of WUD also elaborated on the importance of maintaining the quota program and the need for strict pooling provisions to ensure the quota premium could continue to be paid. The witness said quota is considered an asset and if its value is diminished, it could create cash flow and lending difficulties for dairy farms. The witness was of the opinion that if a California order was adopted with pooling provisions similar to those found in other FMMOs, the quota value would likely be diminished, which would violate the California statute. A witness appearing on behalf of the Institute testified regarding Proposal 2's recognition of the California quota program. Like the Cooperative witness, the Institute witness provided a historical overview of the quota program's authorization and evolution. The witness stated that the quota program served as a way to compensate producers who shipped most of their milk to Class 1 plants through the contract system in place prior to marketwide pooling. At the time, the witness said, the industry believed prices to producers would become more uniform and quota allocation would be equalized among producers as Class 1 utilization grew.

The Institute witness outlined the problems the Institute believes arise from Proposal 1's method for quota recognition. The witness was of the opinion, which also was stressed in the Institute's post-hearing brief, that the Cooperatives have rendered an overly broad interpretation of the 2014 Farm Bill, and in doing so, proposed provisions that violate the AMAA. The witness said that before quota can be recognized, a California FMMO must first determine and pay a traditional FMMO blend price to out-of-state dairy farms who cannot own quota. The witness said that subtracting the quota value from the marketwide pool first, before computing a non-quota blend price, as suggested in Proposal 1, would result in non-uniform payments to producers and violate the AMAA.

The Institute witness explained the mechanics of quota recognition in Proposal 2, which were modeled after the former Oregon-Washington FMMO. The witness said that out-of-state producers would receive a traditional FMMO blend price for their milk pooled on the California FMMO. In-state producers would have the option to receive the CDFA calculated quota and non-quota prices, or they could irrevocably opt out of the quota program and receive the traditional FMMO blend price. The witness explained that producers opting to be paid on a quota/non quota basis would have their aggregate FMMO blend price monies transferred to CDFA for reblending and distribution to that producer subset. The witness opined that by giving in-state producers the payment choice, the uniform payment provision of the AMAA would be satisfied. The Institute witness said that Proposal 2 sought to recognize quota value as authorized by the 2014 Farm Bill while simultaneously upholding the purpose and provisions of the AMAA. These opinions were reiterated in the Institute's post-hearing brief.

The Institute witness highlighted California producer support for the quota program, and was of the opinion that USDA's Preliminary Economic Impact Analysis prediction that the program would quickly erode under Proposal 2 was overstated.

Proposal 3, submitted by the CPHA, seeks to have exempt quota—as part of the California quota program—be recognized and preserved, should a California FMMO be recommended. CPHA also proposed that the terms of consanguinity, as currently applied to producer-handlers under CDFA regulations, be removed to allow indefinite perpetuation of exempt quota. CPHA withdrew the second part of their proposal at the hearing.

A consultant witness for CPHA provided testimony regarding the history of the Gonsalves Act and detailed how exempt quota was included as part of the State's milk marketing program from its inception. According to the witness, the CSO marketwide pooling system and quota program were developed as an alternative to a FMMO. The witness said the quota program was originally designed so that farmers who historically served fluid milk processors would continue to receive a higher price for the portion of their milk that had previously been under Class 1 contract; under the CSO marketwide pooling system, all of the Class 1 revenue would be shared with the market's producers. Over time, the witness said, it was thought that quota holdings would be equalized among dairy farmers. Those who had not previously held contracts with fluid milk processors were expected to be assigned rights to new quota created as the fluid milk market expanded.

The consultant witness explained that dairy farmers who processed their own milk into fluid milk products were issued exempt quota, rather than regular quota, under the new CSO system. The exempt quota was allotted to these vertically integrated entities, known as producer-handlers, in recognition of how their milk was marketed. The witness said that there were originally

49 exempt quota holders, but only 4 remain. The witness said that the amount of exempt quota was legislatively capped in 1995.

The consultant witness clarified that exempt quota was issued as certificates of ownership to the producer entity. The witness explained that the handler side of the business is still required to report all of its milk receipts to the CSO, and in turn, the handler entity receives a credit against its financial obligation to the pool for the volume of exempt quota owned by the producer entity. The handler entity then accounts to the CSO marketwide pool for Class 1 sales in excess of the exempt quota volume, said the witness. The producer entity side receives the Class 1 price from the handler side for the exempt quota volume of milk they produce, and then they receive a combination of the quota and overbase prices from the marketwide pool, depending on their regular quota holdings.

A witness from Producers, testifying on behalf of CPHA, said that all four members of CPHA own exempt quota, are referred to as ''Option 70'' producer-handlers, are fully regulated, and report to the CSO marketwide pool for all their Class 1 sales. The witness contrasted this to ''Option 66'' producer-handlers, who are fully exempt from the CSO and do not participate in the quota program. Of the original 49 ''Option 70'' producer-handlers, the witness said only the four CPHA members remain, and all have maintained essentially the same business structures since the quota program was established.

According to the Producers witness, CPHA members hold both exempt quota and regular quota, but most of the milk produced by CPHA members is accounted for as overbase production. Using 2015 CDFA data, the Producers witness calculated that ''Option 70'' producer-handler milk represents approximately 0.6 percent of all California production. The witness estimated that exempt quota represents 17.4 percent of ''Option 70'' producer-handler production and 4.6 percent of all California Class 1 sales. The witness said that all of the milk produced and sold by CPHA members, including volumes covered by exempt quota, is reported to the CSO marketwide pool.

The Producers witness said that the Gonsalves Act primarily addressed industry problems that did not impact producer-handlers because all the milk from their dairy operations flowed to their own Class 1 plants and the markets they had developed. The witness was of the opinion that the exempt quota feature was included as part of the quota program to recognize the vertically integrated producer-handler's unique business structure.

Additional CPHA witnesses representing Foster and Rockview joined the Producers witness in describing their acquisition and maintenance of exempt quota over the years. Each mentioned they had to make strategic business decisions or sacrifices in order to preserve their exempt quota status.

The CPHA witnesses attempted to quantify the value of exempt quota, explaining that exempt quota is carried as an asset on their farms' books and can be sold as or converted to regular quota. The CPHA witnesses measured the value of exempt quota as the difference between the CSO Class 1 and the quota prices. Using historical CDFA data, the Producers and Rockview witnesses calculated the average exempt quota value over the previous 20 years to be approximately $1.14 and $1.20 per cwt, respectively.

Using CDFA data for the preceding five years, a second Foster witness calculated the value of exempt quota in terms of regular quota for both northern and southern California. The witness estimated that every pound of exempt quota in northern California and southern California is worth 1.96 pounds and 2.12 pounds of regular quota, respectively. Valuing regular quota at $525 per pound of SNF, but not adjusting for RQAs, the witness estimated the value of exempt quota as $1,029 per pound of SNF in northern California, and $1,113 per pound of SNF in southern California. Citing CDFA production data, the witness calculated the value of the collective 40,244.51 pounds of SNF exempt quota in northern California as $41,411,600 and the 17,669.59 pounds of SNF exempt quota in southern California as $19,666,253.

The Rockview witness added that converting exempt quota to regular quota would make those volumes eligible for CSO transportation credits that are not currently available for exempt quota milk.

A Cooperative witness also testified with regard to the evolution of exempt quota for ''Option 70'' producer-handlers. The witness estimated that the four CPHA members market approximately five percent of all California Class 1 sales. The witness explained that exempt quota entitles the producer-handler to waive any pool obligation on those holdings. The witness described the value of exempt quota as the difference between the Class 1 and quota prices. The witness estimated that from 1970 through 2014, the additional value of exempt quota was approximately $0.58 per cwt in southern California. The witness estimated the monthly impact to the marketwide pool of recognizing exempt quota in this manner at less than one-half of one cent per cwt. The witness testified that the Cooperatives did not oppose adoption of Proposal 3.

A witness representing the Institute was of the opinion that exempt quota was offered to large producer-handlers for political expediency. According to the witness, as the Gonsalves Act and the particulars of marketwide pooling were being developed in the 1960s, larger producer-handlers worried they would lose advantages enjoyed under the then-prevailing system. The witness explained that to head off producer-handler opposition to marketwide pooling, concessions were made to smaller producer-handlers who were exempted entirely from pooling and received no quota allocation. Larger entities were given the option to forgo the quota premium and instead exempt those pounds from their Class 1 pool obligations.

The Institute witness testified that exempt quota holds no real market value, as it cannot be bought and sold. The witness acknowledged that determining an equivalency between exempt quota and regular quota might be one method to assign a value to exempt quota. The Institute witness opined that exempt quota holders have already recovered the cost of their exempt quota, which they were last able to purchase 20 years previous.

A witness from Dean Foods testified that the competitive advantage producer-handlers gain from their exempt quota can be spread out over their total volume of Class 1 sales. Dean Foods is a national fluid milk manufacturer that operates three Class I plants and one Class II plant in California. The witness argued that CPHA witnesses diluted the impact of exempt quota on Class 1 sales by comparing exempt quota volumes to total California milk production. The witness contended that it was more accurate to compare total ''Option 70'' producer-handler Class 1 production to total California Class 1 sales. The witness calculated that the total volume of the four producer-handlers, including their exempt quota volumes, accounted for 24 percent of total California Class 1 volume, including milk from out of state. The witness testified that 31 handlers process the other 76 percent of California Class 1 milk.

Additional fluid milk processor witnesses representing Clover Stornetta Farms and Farmdale Creamery, along with another Dean Foods witness, all

testified that their companies face significant disadvantages compared to producer-handlers with exempt quota because, unlike exempt quota holders, their companies must account to the CSO pool at classified prices every month for all the milk they utilize. Some witnesses claimed they have lost sales to ''Option 70'' producer-handlers due to these regulatory disadvantages.

The Producers witness countered opposition testimony that exempt quota provides a competitive advantage enabling producer-handlers to bid customers away from fully-regulated handlers. The witness said that Producers pays the Class 1 price to the farm side of the business for the exempt quota milk they use, and pays the quota or overbase price for the rest of the farm's milk it processes.

In its post-hearing brief, the Institute argued against recognition of exempt quota under a California FMMO. According to the Institute's brief, the recognition of exempt quota in a California FMMO would violate the AMAA's uniform pricing provisions. The Institute explained that by recognizing exempt quota, exempt-quota-holding producer entities would not share the value of all their Class 1 sales with their fellow dairy farmers, and handler entities would not be required to pay uniform minimum prices for their raw milk supplies.

The Institute brief further argued that the 2014 Farm Bill language authorizing a California FMMO that recognizes quota value does not mean California's entire quota system should be preserved and maintained, nor that certain Class 1 handlers should be permitted to have a regulatory competitive advantage over other Class 1 handlers. The Institute brief also argued that permitting a differentiated status for only those few entities who currently own exempt quota would be inequitable to new market entrants.

In response, CPHA's reply brief asserted that CPHA handler entities currently pay Class 1 prices for all their raw milk, exempt quota provides no financial advantage over other fully-regulated handlers, and there are no market disruptions attributable to exempt quota. The reply brief stressed that CPHA producer entities, not their handler counterparts, hold exempt quota. The reply brief also asserted that the record contains no evidence that exempt quota holders enjoy raw milk price advantages. CPHA contended that all handlers pay the same classified price for raw milk in California, despite misperceptions to the contrary. CPHA pointed out that competitors have won and lost accounts for milk sales for a variety of reasons not necessarily attributed to exempt quota ownership.

According to CPHA's reply brief, Congress's use of the term ''quota system,'' and its omission of specific reference to exempt quota in the 2014 Farm Bill language, is consistent with its directive that the Secretary should hold a hearing to consider, and is authorized to recognize, all aspects of California's quota program under a California FMMO.

CPHA's reply brief clarified the intent of Proposal 3 to allow for the preservation of exempt quota status for those few producer-handlers who own it. CPHA argued its members are not seeking exemption from all pricing and pooling obligations under a California FMMO, but merely recognition of their ownership of exempt quota and the related volumes of production it represents.

A post hearing brief submitted by Trihope expressed concerns regarding the recognition of the California quota program within the FMMO framework. Trihope was of the opinion that any recognition of quota would violate the AMAA's uniform payments provision. Trihope also wrote that authorizing quota payments would give a revenue advantage to California dairy farms and create a trade barrier for out-of-state farms seeking to be pooled on the California FMMO.

Findings

The record contains detailed information about the establishment and evolution of the quota program administered by the State of California. The record reflects that the Gonsalves Act legislatively authorized both the California quota program and marketwide pooling within the structure of the CSO. Until that point, dairy farms were paid through individual handler pools that reflected a plant's use values for their milk—there was no marketwide pooling function that allowed all producers to share in the benefits from Class 1 sales and the burden of balancing the market to ensure an adequate supply of milk to meet Class 1 demand. Many witnesses alluded to the political compromise reached to compensate dairy farmers who held Class 1 supply contracts from the financial loss they would incur by pooling and sharing their Class 1 revenue with all dairy farmers in California. While the original quota allotment was based on existing Class 1 contracts, it was thought at the time that quota would equalize among producers as Class 1 utilization increased and future quota allotments were issued; however, this did not occur.

Many witnesses spoke of the importance they believe the California quota program has for the state's dairy industry. Producers spoke of the investments they made in purchasing quota allotments, and of the continued financial benefit quota provides through the monthly quota premium they receive. Even producers who own little or no quota spoke of the importance of continuing the program for their fellow dairy farmers.

The 2014 Farm Bill authorized the promulgation of a California FMMO, and specified that the order ''shall have the right to reblend and distribute order receipts to recognize quota value.'' The hearing record is replete with testimony on the proper interpretation of those final three words, ''recognize quota value.'' The Cooperatives conveyed, and stressed in their post-hearing brief submissions, that the 2014 Farm Bill mandates the quota program must be recognized, and only the method of recognition is to be decided through this rulemaking proceeding. The Cooperatives were of the opinion that the proper recognition of quota value is through the deduction of quota monies from the marketwide pool before a California blend price is calculated, as is current practice for the CSO.[17] The Cooperatives stressed repeatedly that should any conflict be found between the provisions of the 2014 Farm Bill and the AMAA, the 2014 Farm Bill language should be given more credence, as it is the most recent Congressional action.

Institute witnesses and post-hearing briefs stressed that quota recognition must be harmonized with the AMAA, in particular its uniform payments and trade-barrier provisions. Should any conflict arise, the Institute contends that because the Farm Bill did not amend the AMAA, the AMAA as the authorizing legislation should take precedent. The Institute's approach to recognizing quota value is to first allow producers the one-time decision to opt out of the quota program. Those producers who opt out of the quota program would be paid a FMMO blend price calculated without a deduction for quota. Those producers who remain in the quota program would have their FMMO blend price monies sent, in aggregate, to CDFA for reblending and redistribution according to their quota and nonquota milk marketings. The Institute is of the opinion that because dairy producers opting out of the quota program would not have their payments affected by

[17] This position was slightly modified in their post-hearing brief to also adjust prices for out-of-state producers so that their price was not impacted by quota payments.

quota, recognizing quota under a California FMMO would not violate the uniform pricing and trade-barrier provisions of the AMAA.

As discussed earlier, when promulgating or amending any FMMO, the Department must always evaluate whether the proposed action is authorized by the AMAA. The AMAA not only clearly defines its policy goal, which this decision has already discussed, but it also defines specific provisions that must be contained in the FMMO framework. The two most relevant to the discussion on quota recognition are the provision for uniform payments handlers make to producers, and the provision to prevent trade barriers. The uniform payment provisions require all handlers regulated by a FMMO to pay the same classified use value for their raw milk, and all producers whose milk is pooled on a FMMO to receive the same price for their milk regardless of how it is utilized. In this respect, similarly situated handlers are assured that they are paying the same raw milk costs as their competitors, and producers are indifferent as to where or how their milk is utilized, as they receive the same price regardless.

The trade barrier provision specifies that no FMMO may in any manner limit the marketing of milk or milk products within the marketing area. In this regard, FMMOs cannot adopt provisions that would create any economic barrier limiting the marketing of milk within marketing area boundaries.

To determine how to properly recognize quota value, Congress provided additional guidance to the 2014 Farm Bill language through the 2014 Conference Report.[18] In the report, Congress specified that the Department has discretion to determine how best to recognize quota value in whatever manner is appropriate on the basis of a rulemaking proceeding. Consistent with the Conference Report, this decision evaluated record evidence pertaining to how the current California quota program operates, how it can best be recognized within FMMO provisions tailored to the California market, and how all the FMMO provisions work in conjunction with each other to adhere to all AMAA provisions.

The California quota program, like the CSO, is administered by CDFA. The record reflects that 58 percent of California dairy farmers own quota. In its current form, the quota program entitles a quota holder to an additional $0.195 per pound SNF (equivalent to $1.70 per cwt) over the market's overbase price on the quota milk they market each month. Similar to their FMMO counterparts, California handlers pay classified use values for their milk, and those values make up the CSO marketwide pool. Each month, CDFA deducts quota monies from the CSO marketwide pool before a marketwide blend price, otherwise known as the overbase price, is calculated. CDFA then announces the quota and overbase prices[19] to be paid to California dairy farmers. As a result, in general, nonquota milk receives the market's overbase price, and quota milk receives the overbase price plus an additional $1.70 per cwt. CDFA enforces payments of both quota and overbase prices. Record data shows that the deduction from the CSO marketwide pool to pay quota premiums is approximately $12.5 to $13 million per month. Numerous witnesses estimated, at quota market prices at the time of the hearing, the asset value of quota at $1.2 billion.

The record reflects that the California quota program is funded by California producers. All handlers regulated through the CSO pay minimum classified use values, and it is only once those values have been pooled that the quota value is deducted from the pool. Data on the record indicates that all California dairy farmers, including quota holders, receive $0.37 per cwt less, on average, for all of their milk marketings in order to fund the $0.195 per pound of quota SNF payment to quota holders.

This decision continues to find the California quota program could be maintained, administered, and enforced by CDFA and that a California FMMO should operate as a stand-alone program. As is currently done in all FMMOs, handlers would pay classified use values into the pool, and all producers, both in-state and out-of-state, would receive a FMMO blend price reflective of the market's use values. It is through this structure that a California FMMO could ensure the uniform payment and trade barrier provisions of the AMAA are upheld.

Should CDFA determine it can continue to operate the California quota program through the use of producer monies, as is the current practice, the proposed California FMMO could recognize quota values through an authorized deduction by handlers from the payments due to producers for those dairy farmers determined by CDFA to be participants in the state-administered California quota program. The amount of the deduction would be determined and announced by CDFA.

Currently, FMMOs allow for authorized deductions, such as the Dairy Promotion and Research Program assessment, from a producer's milk check. The proposed California FMMO would similarly authorize a deduction for the state-administered California quota program. The California FMMO would allow regulated handlers to deduct monies, in an amount determined and announced by CDFA, from blend prices paid to California dairy farmers for pooled milk, and send those monies to CDFA to administer the quota program. CDFA would in turn enforce quota payments to quota holders.

In essence, this decision proposes that the California quota program could continue to operate in essentially the same manner as it currently does. The record reflects that the California quota program already assesses California producers to pay quota values to quota holders. While producers may not see this as an itemized deduction on their milk checks, their overbase price is lower than it otherwise would be if there was no quota program. This is a result of deducting the quota value from the pool prior to calculating the overbase price.

The California FMMO would authorize deductions from those California producers whose milk is pooled on the order. As this decision will later explain, the proposed California FMMO would have performance-based pooling standards that allow for manufacturing milk to not be pooled. CDFA would be responsible for the collection of California producer monies for milk not pooled because a California FMMO would only apply to producer milk as defined by the order. USDA and CDFA could cooperate by sharing data through a memorandum of understanding to facilitate CDFA administration of the quota program.

The Department received 13 comments supporting the recommendation to continue the California quota program under the authority and direction of CDFA, with FMMO cooperation for relevant information sharing. Comments expressing support for the proposed recognition of California quota program in the recommended California FMMO were received from the Cooperatives, the Institute, CPHA, HP Hood, Select, Producers, WUD, MPC, Pacific Gold,

[18] Official Notice is taken of: the Agricultural Agreement of 2014 Conference Report. *https://www.congress.gov/congressional-report/113th-congress/house-report/333/1.*

[19] The record reflects that CDFA also announces a base price that is equal to the overbase price. For simplicity, this decision will refer only to the overbase price.

NAJ, The Kroger Company (Kroger), CDC, and other individuals. Several commenters stated that the proposed recognition resolved concerns raised during the hearing regarding inclusive pooling, uniform pricing and interstate trade barriers.

Comments filed on behalf of the Institute stated that the Department's solution acknowledges the ''recognize quota'' language of the 2014 Farm Bill without violating the AMAA's requirements for uniform pricing. The Institute was also of the opinion that permitting CDFA to operate a standalone quota program through authorized deductions from producer payments allows the Department to avoid any potential interstate commerce issues relating to quota.

Comments filed on behalf of the Cooperatives also supported the Department's proposed recognition of the California quota program, as well as CDFA's continued administration of quota as a standalone program. The Cooperatives stated that the Department's decision properly recognized quota values and protected the financial investment of the California quota holders. The Cooperatives stated their support is contingent upon CDFA continuing the quota program as proposed by the Department, and added that if CDFA were unable or unwilling to maintain the program without diminishing quota value, the Cooperatives would withdraw their support of the Department's decision. The Cooperatives proposed that specific references to the applicable California statute and regulations that pertain to the California quota program be added to the proposed California FMMO.

Comments submitted on behalf of WUD supported the Department's treatment of the quota program, but requested that the producer referendum be postponed until CDFA determines how it will operate the program.

CDFA submitted a comment confirming its ability to establish a standalone, producer-funded quota program as proposed by the Department, and stated its aim to reach a conclusion prior to a California FMMO producer referendum. In its filed comments, CDFA indicated that it would work toward a solution with the intent of concluding its process before a California FMMO producer referendum was held so California producers would have the pertinent information needed to make an informed decision.

The Department continues to find the proper recognition of quota under the proposed California FMMO is to allow for authorized deductions from producer payments in accordance with the California quota program, as determined and administered by CDFA. As the Department finds this rulemaking proceeding is separate from CDFA's handling of the quota program, language referencing the CDFA regulations for administering quota is not included in the proposed California FMMO. Standalone language in the proposed California FMMO references the California quota program.

Regarding the treatment of exempt quota as addressed in Proposal 3, this decision continues to find that exempt quota is part of the California quota program and therefore its proper recognition should be determined by CDFA. The record demonstrates that exempt quota was initially granted when the California quota program was established, and like regular quota, the provisions have been adjusted numerous times through both California legislative and rulemaking actions. This decision continues to find the continuation of exempt quota, in whatever manner appropriate, should be determined by CDFA.

The record reflects that under the proposed FMMO, the four California producer-handlers who own exempt quota would likely become fully-regulated handlers because their sales exceed three million pounds per month. These fully-regulated handlers would be required to account to the marketwide pool for all of their Class I utilization and pay uniform FMMO minimum classified prices for all milk they pool. The CPHA witnesses testified that exempt quota is held on the producer side of their businesses. CDFA could best determine how those producers holding exempt quota should be compensated for their exempt quota holdings. Such compensation cannot be made by reducing the minimum Class I obligation of FMMO fully-regulated handlers without undermining the uniform handler payment provision of the AMAA.

Comments submitted on behalf of the CPHA expressed provisional support for the proposed treatment of quota, assuming all aspects of the current program, including exempt quota, would be maintained by CDFA. CPHA asked the Department to reopen the comment period pertaining to the quota program until CDFA releases a final statement detailing their plan to administer the quota program in its entirety. CPHA stated that until such time their comments on the recommended decision would be incomplete.

This decision does not find justification for reopening the public comment period. CDFA has publically outlined the steps it intends to take to preserve, plan for, and operate the California quota program. CDFA has publically stated it intends to complete a producer referendum and release the results before a FMMO producer referendum is held. California producers will be able to consider that information when voting on the proposed California FMMO.

Throughout the hearing, and in post-hearing briefs and comments filed in response to the recommended decision, dairy farmers and their Cooperative representatives stressed that while a California FMMO would provide them a more equitable price for their milk, entry into the FMMO system must not diminish or disturb, in any form, California quota values. This final decision continues to find that the package of FMMO provisions in this decision would create more orderly marketing of milk in California, adhere to all the provisions of the AMAA, and allow the California quota program to operate independently of the FMMO. In doing so, the California quota program will not be diminished or disturbed in any form by California's entry into the FMMO system.

5. Definitions and Uniform Provisions

This section outlines definitions and provisions of a California FMMO that describe the persons and dairy plants affected by the FMMO and specify the regulation of those entities.

Summary of Testimony

The Cooperatives and the Institute both proposed regulatory language for an entire FMMO, including definitions and regulations specific to a California FMMO, as well as adoption of several of the uniform provisions common to other FMMOs. In many cases, hearing witnesses simply provided the list of uniform provisions for which they supported adoption, and in most cases, proponents for Proposals 1 and 2 agreed on the inclusion of these provisions.

Findings

The FMMO system currently provides for uniform definitions and provisions, which are found in Part 1000 under the General Provisions of Federal Milk Marketing Orders. Where applicable, those provisions are incorporated by reference into each FMMO. The uniform provisions were developed as part of FMMO Order Reform to prescribe certain provisions that needed to be contained in each FMMO to describe and define those entities affected by FMMO regulatory plans.

As outlined in the Order Reform Proposed Rule [20] and as implemented in the Final Rule,[21] the establishment of a set of uniform provisions provides for regulatory simplification and defines common terms used in the administration of all FMMOs, resulting in the uniform application of basic program principles throughout the system. Application of standardized terminology and administrative procedures enhances communication among regulated entities and supports effective administration of the individual FMMOs.

This final decision continues to find that a set of uniform provisions should continue to be maintained throughout the FMMO system to ensure consistency between the uses of terms. Therefore, this final decision finds that a California FMMO should contain provisions consistent with those in the 10 current FMMOs.

Marketing conditions in each regulated marketing area do not lend themselves to completely identical provisions. Consequently, some provisions are tailored to the marketing conditions of the individual order, and provisions for a California FMMO in this final decision are similarly tailored to the California market where appropriate. This section provides a brief description of the uniform definitions and provisions for a California FMMO. Where a definition or provision does not lend itself to uniform application, it is discussed in greater detail here or in other sections of this document.

Two commenters expressed support for adopting the uniform provisions as proposed in the recommended decision to ensure consistency between uses of terms and application of principles and practices in FMMO areas.

Comments filed by the Cooperatives supported adoption of all but four of the recommended uniform provisions, for which they offered modifications: Pool plant, exempt plant, producer, and producer milk. Their specific exceptions are discussed later in this decision. The Cooperatives' comments also confirmed their support for adoption of the ''miscellaneous and administrative'' provisions generally used throughout the FMMO system, which specify the reporting, accounting, and payment procedures under the orders.

This decision continues to propose a set of uniform definitions consistent with the ten current FMMOs. The definitions for a California FMMO are explained below:

Marketing Area. The *Marketing Area* refers to the geographic area where handlers who have fluid milk sales would be regulated. In this case, the marketing area should include the entire state of California. The marketing area encompasses any wharves, piers, and docks connected to California and any craft moored there. It also includes all territory within California occupied by government reservations, installations, institutions, or other similar establishments.

Route Disposition. A *Route Disposition* should be a measure of fluid milk (Class I) sales in commercial channels. It should be defined as the amount of fluid milk products in consumer-type packages or dispenser units delivered by a distributing plant to a retail or wholesale outlet, either directly or through any distribution facility.

Plant. A *Plant* should be defined as what constitutes an operating entity for pricing and regulatory purposes. Plant should include the land, buildings, facilities, and equipment constituting a single operating unit or establishment where milk or milk products are received, processed, or packaged. The definition should include all departments, including where milk products are stored, such as coolers, but not separate buildings used as reload points for milk transfers or used only as distribution points for storing fluid milk products in transit. On-farm facilities operated as part of a single dairy farm entity for cream separation or concentration should not be considered plants.

Distributing Plant. A *Distributing Plant* should be defined as a plant approved by a duly constituted regulatory agency to handle Grade A milk that processes or packages fluid milk products from which there is route disposition.

Supply Plant. A *Supply Plant* should mean a regular or reserve supplier of bulk milk for the fluid market that helps coordinate the market's milk supply and demand. A supply plant should be a plant, other than a distributing plant, that is approved to handle Grade A milk as defined by a duly constituted regulatory agency, and at which fluid milk products are received or from which fluid milk products are transferred or diverted.

Pool Plant. A Pool Plant should mean a plant serving the market to a degree that warrants its producers sharing in the added value that derived from the classified pricing of milk. The pool plant definition provides for pooling standards that are unique to each FMMO. The specifics of the pooling standards for a California FMMO are discussed in detail in the Pooling section of this final decision.

Comments filed by the Cooperatives took exception to the Department's recommended definition of *Pool Plant,* preferring instead the definition detailed in their post-hearing brief, which defined a pool plant as any California plant receiving milk from a California producer, unless otherwise exempt. The Cooperatives' definition was aligned with their inclusive pooling proposal, which is not proposed for adoption in this final decision. Therefore, this decision continues to find the Department's proposed pool plant definition appropriate. Specific details regarding pooling standards for a California FMMO are discussed in the Pooling section of this final decision.

Nonpool Plant. A *Nonpool Plant* should be defined as a plant that receives, processes, or packages milk, but does not satisfy the standards for being a pool plant. *Nonpool plant* should be further defined to include: *A Plant Fully Regulated under Another Federal Order,* which means a plant that is fully subject to the pricing and pooling provisions of another order; a *Producer-Handler Plant,* which means a plant operated by a producer-handler as defined under any Federal order; a *Partially Regulated Distributing Plant,* which means a plant from which there is route disposition in the marketing area during the month, but does not meet the provisions for full regulation; and an *Unregulated Supply Plant,* which is a supply plant that does not qualify as a pool supply plant.

Exempt Plant. An *Exempt Plant* also is a nonpool plant, and should be defined as a plant exempt from the pricing and pooling provisions of any order, although the exempt plant operator would still need to comply with certain reporting requirements regarding its route disposition and exempt status. Exempt plants should include plants operated by a governmental agency with no route disposition in commercial market channels, plants operated by duly accredited colleges or universities disposing of fluid milk products only through their own facilities and having no commercial route disposition, plants from which the total route disposition is for individuals or institutions for charitable purposes and without remuneration, and plants that have route disposition and sales of packaged fluid milk products to other plants of no more than 150,000 pounds during the month.

[20] Official Notice is taken of: Federal Order Reform Proposed Rule: 63 FR 4802.

[21] Official Notice is taken of: Federal Order Reform Final Rule: 64 FR 47898.

The exempt plant definition was standardized as part of Order Reform to provide a uniform definition of distributing plants that, because of their size, did not significantly impact competitive relationships among handlers in the market. The 150,000 pound limit on route disposition and sales of packaged fluid milk products was deemed appropriate because at the time it was the maximum amount of fluid milk products allowed by an exempt plant in any FMMO. Therefore, the uniform provisions ensured that exempt plants remained exempt from pricing and pooling provisions as part of Order Reform. This decision continues to find that to provide for regulatory consistency, the exempt plant definition in a California FMMO should be uniform with the 10 current FMMOs. This provision would allow for smaller California distributing plants that do not significantly impact the competitive relationship among handlers to be exempt from the pricing and pooling provisions of a California FMMO.

Both the Cooperatives and the Institute proposed adoption of the standard FMMO definition of exempt plants, and hearing witnesses were supportive of the proposals. However, in their post-hearing brief, the Cooperatives proposed two additional exempt plant categories to provide regulatory relief to small handlers under Proposal 1. The two additional exempt plant categories proposed include: (1) Plants that process 300,000 pounds or less of milk during the month into Class II, III, and IV products, and have no Class I production or distribution; and (2) plants that process, in total, 300,000 pounds or less of milk during the month, from which no more than 150,000 pounds is disposed of as route disposition or sales of packaged fluid milk products to other plants. Proposal 1, as originally drafted, would have fully regulated all handlers that received California milk, except for plants with 150,000 pounds or less of route disposition. Through the proposed modification, the Cooperatives sought to extend exempt plant status to smaller plants regardless of their use of milk. In essence, it would allow smaller plants with primarily manufacturing uses to be exempt from the pricing and pooling provisions.

The recommended decision found that the performance-based pooling provisions would make such additional exemptions unnecessary, as plants with manufacturing uses would have the option to elect not to pool their milk supply. In their filed comments, the Cooperatives took exception to the recommended definition of exempt plant as it did not contain the necessary language for inclusive pooling. This final decision continues to find the recommended exempt plant definition appropriate, as this decision does not propose adopting inclusive pooling for a California FMMO, negating the need for language tailored to inclusive pooling provisions. Specific details regarding pooling standards for a California FMMO are discussed in the Pooling section of this final decision.

Handler. A *Handler* should be defined as a person who buys milk from dairy farmers. Handlers have a financial responsibility for payments to dairy farmers for milk in accordance with its classified use. Handlers must file reports with the Market Administrator detailing their receipts and utilization of milk.

The handler definition for a California FMMO should include the operator of a pool plant, a cooperative association that diverts milk to nonpool plants or delivers milk to pool plants for its account, and the operator of a nonpool plant.

The handler definition should also include intermediaries, such as brokers and wholesalers, who provide a service to the dairy industry, but are not required by the FMMO to make minimum payments to producers.

The Cooperatives proposed adoption of the uniform FMMO handler definition for a California FMMO. The Institute proposed adopting the uniform handler definition, modified to include proprietary bulk tank handlers (PBTH). A witness representing the Institute and Hilmar testified regarding the PBTH provision. The witness said a PBTH provision had been included in some former FMMOs to allow proprietary handlers to pool milk in a fashion similar to cooperative handlers, without needing to first deliver milk to a pool supply plant to meet the performance standards of the order. The witness explained that under Proposal 2, a PBTH would have to operate a plant—located in the marketing area—that does not process Class I milk and further, the PBTH would have to be recognized as the responsible handler for all milk pooled under that provision. The witness was of the opinion that the PBTH provision would promote efficient milk movements, reduce transportation costs, and eliminate unnecessary milk loading and unloading simply to meet the order's performance standards.

The witness said the flexibilities of a PBTH provision would offer operational efficiencies to Hilmar and allow them to meet criteria similar to the pool supply plant qualifications advanced in Proposal 2. The witness explained that Hilmar would be able to ship milk directly from a farm to a distributing plant, rather than shipping milk first to a pool supply plant and then on to a distributing plant.

In their post-hearing briefs, the Cooperatives opposed the PBTH provision, citing disorderly marketing conditions with its use in earlier marketing orders, and stating that the provision is unnecessary, prone to create disorder, and, as proposed, administratively unworkable. No comments were filed in regard to this provision as proposed in the recommended decision. The record supports adoption of the standard FMMO handler definition without the additional PBTH provision prescribed in Proposal 2. The Department has found in the past that PBTH provisions led to the pooling of milk that was not part of the legitimate reserve supply for distributing plants in the marketing area.[22] In California, with a relatively low Class I utilization, such a provision is unnecessary to ensure an adequate supply of milk for Class I use. Therefore, this decision continues to find that the uniform handler definition, without the inclusion of a PBTH provision, is appropriate for a California FMMO.

Producer-Handler. Under the 10 existing FMMOs, *Producer-Handlers* are defined as persons who operate, as their own enterprise and at their sole risk, both a dairy farm and a distributing plant from which there is route disposition within the marketing area, and have total Class I fluid milk sales of no more than three million pounds per month. Seven of the existing orders also allow producer-handlers to receive up to 150,000 pounds of fluid milk products per month from fully-regulated handlers in any order. Producer-handlers are exempt from the pricing and pooling provisions under each of the existing orders.

As a result of their exemption from the pricing and pooling provisions, producer-handlers, in their capacity as handlers, are not required to pay the minimum class prices established under the orders, nor are they, in their capacity as producers, granted minimum price protection for disposal of their surplus milk. Producer-handlers, in their capacity as handlers, are not obligated to equalize their use-value of milk through payment of the difference between their use-value of milk and the respective order's blend price into the producer-settlement fund.

[22] Official Notice is taken of: Pacific Northwest and Western Marketing Areas Tentative Final Decision: 68 FR 49375.

Thus, producer-handlers retain the full value of milk processed and disposed of as fluid milk products by their operation.

Entities defined as FMMO producer-handlers must adhere to strict criteria that limit certain business practices, including the purchase of supplemental milk. Given these limitations, producer-handlers bear the full burden of balancing their milk production between fluid and other uses. Milk production in excess of their Class I route disposition does not enjoy minimum price protection under the orders and may be sold at whatever price is obtainable in the market.

Producer-handlers are required to submit reports and provide access to their books, records and any other documentation as deemed necessary by the Market Administrator to ensure compliance with the requirements for their regulatory status as producer-handlers. Therefore, producer-handlers are regulated under the orders, but are not ''fully regulated'' like other handlers who are subject to an order's pricing and pooling provisions.

Under the CSO, two categories of producer-handlers are recognized. ''Option 66'' producer-handlers may request exemption from the CSO's pooling regulations if both their farm production and their sales average less than 500 gallons of milk per day on an annual basis, and if they ship 95 percent of their production to retail or wholesale outlets. ''Option 66'' producer-handlers are fully exempt from the pool for their entire production and may not own quota or production base. The record reflects that there were two ''Option 66'' producer-handlers in California at the time of the hearing. No production data was submitted at the hearing to quantify the volume of ''Option 66'' producer-handler milk exempt from the CSO pool.

The CSO's second producer-handler category pertains to ''Option 70'' producer-handlers—large scale entities that own exempt quota, which exempts them from pooling a portion of their Class 1 milk. The exempt quota held by ''Option 70'' producer-handlers was discussed earlier in this decision.

Proposals 1 and 2 both include definitions and provisions for producer-handlers consistent with the 10 FMMOs that currently exempt persons who operate both dairy farms and distributing plants, and process and distribute no more than three million pounds of fluid milk per month. The producer-handler regulations under Proposal 2 more closely resemble those in the Pacific Northwest and Arizona FMMOs in that they contain additional specificity about producer-handler qualifications.

A Cooperative witness supported adoption of the standard FMMO producer-handler definition for a California FMMO as contained in Proposal 1. Under the standard definition, producer-handlers who sell or deliver up to three million pounds of Class I milk or packaged fluid milk products monthly would be exempt from the pricing and pooling provisions. The witness added that under Proposal 1, producer-handlers could own regular quota and qualify for transportation credits.

Two producer witnesses who also operate processing facilities in California described their individual experiences related to running small dairy farms and fluid milk processing operations. Both witnesses testified that they supported Proposal 1 because, among other things, they thought the proposed FMMO producer-handler definition could provide them exemptions from the pooling requirements for their Class I production and sales, something that they do not currently enjoy from the CSO.

A witness from Organic Pastures Dairy Company, LLC (Organic Pastures) testified on behalf of Organic Pastures and three other small San Joaquin Valley ''producer-distributor'' entities. According to the witness, these entities produce and bottle their own Class 1 milk, but do not qualify as ''Option 66'' producer-handlers, and must therefore account to the CSO pool. The witness explained that these businesses have taken risks to develop their own brands and customer bases, but struggle to survive financially. The witness said that Organic Pastures' monthly pool obligation for December 2014 was $50,000 for the milk they bottled and sold in California. The witness contended that because they produce, process, and distribute their own products, they should be exempt from regulation.

The entities represented by the witness supported a California FMMO because they believe they would meet the FMMO producer-handler definition and thus be exempt from the pricing and pooling provisions. The witness testified that the standard three-million pound limit would allow them to grow their businesses, but remain exempt from pricing and pooling provisions.

A witness from Dean Foods testified in support of the producer-handler provision contained in Proposal 2. The witness described similarities and differences between the producer-handler definitions in Proposals 1 and 2. The witness added that proponents of Proposal 2 recommended adoption of the additional ownership requirements, which mirror the standards in the Pacific Northwest and Arizona FMMOs. The witness explained that the additional requirements would ensure that larger-size operations typical of the western Federal orders that meet the producer-handler definition would not be able to undermine the intent of the provision.

The witness testified that Dean Foods fully supported the Institute's proposal to cap producer-handler exemptions at three million pounds of monthly Class I route disposition. The witness cited USDA decisions that found producer-handlers with greater than three million pounds of route disposition per month impacted the market, and thus their exemption from pricing and pooling provisions was disorderly.

Support for the producer-handler provisions contained in Proposal 2 was also expressed by two small California processors and by the Cooperatives in their post-hearing brief.

The FMMO system has historically exempted producer-handlers from the pricing and pooling provisions of FMMOs on the premise that the burden of disposal of their surplus milk was borne by them alone. Until 2005, there was no limit on the amount of Class I route disposition producer-handlers were allowed before they would be fully regulated. A Pacific Northwest and Arizona FMMO rulemaking established a three-million pound per month limit on Class I route disposition.[23] The record of that proceeding revealed large producer-handlers were able to market fluid milk at prices below those that could be offered by fully regulated handlers in such volumes that the practice was undermining the order's ability to establish uniform prices to handlers and producers. That proceeding found that producer-handlers with more than three million pounds of Class I route disposition significantly affected the blend prices received by producers and should therefore be fully regulated. The producer-handler provisions in all FMMOs were later amended in 2010.[24] In that proceeding, USDA found a three-million pound monthly limit on producer-handler total Class I route dispositions appropriate to maintain orderly marketing conditions throughout the FMMO system.

[23] Official Notice is taken of: Pacific Northwest and Arizona Proposed Rule: 70 FR 19636.

[24] Official Notice is taken of: FMMO Producer-Handler Final Rule: 75 FR 21157.

The recommended decision found the regulatory treatment of producer-handlers should continue to be uniform throughout the FMMO system. The monthly three million pound limit on Class I route disposition would ensure that California FMMO producer-handlers could not use their pricing and pooling exemption to undermine orderly marketing conditions.

The adoption of the standard FMMO producer-handler definition was supported by proponents of Proposals 1 and 2, as well as by entities that could meet the proposed producer-handler definition. The record does not contain data to indicate how many California entities would meet the proposed FMMO producer-handler definition, but it does indicate that only a small number would be impacted.

The additional qualification standards contained in the Pacific Northwest and Arizona FMMOs were explained in the Order Reform Proposed Rule.[25] The decision explained that the larger than average herd size of dairy farms in the western United States lent to the existence of producer-handlers that were a significant factor in the market. Therefore, the Pacific Northwest and Arizona FMMOs adopted producer-handler provisions with additional qualification standards tailored to the larger dairy farm size typical of the western region of the United States.

The record reveals that herd sizes in California tend to be typical of the larger herd sizes found in the western FMMOs. According to CDFA data, in 2015 California's average herd size was 1,215. Therefore, the recommended decision found it appropriate that the producer-handler provision in a California FMMO should include the additional qualification standards similar to those in the nearby Pacific Northwest and Arizona FMMOs.

In their post-hearing brief, the Cooperatives proposed modifying Proposal 1 to broaden the producer-handler definition to include utilization other than Class I. The modification would allow producer-handlers with Class II, Class III, or Class IV manufacturing, in conjunction with their Class I processing, to be granted producer-handler status, as long as their total production remained under the three million pound processing limit. The Cooperatives contend this would provide regulatory relief to smaller producer-handlers, who would otherwise become regulated under the inclusive pooling provisions of Proposal 1. The recommended decision found that extending the producer-handler definition to include manufacturing uses would not be necessary because the recommended package of pooling provisions would allow for optional pooling of milk used in manufacturing.

Individual comments filed by HP Hood, Kroger, and the CDC expressed support for the producer-handler provision contained in the recommended decision. Commenters agreed that producer-handlers should be treated in California the same way they are treated in the rest of the FMMO system, and that allowing exemptions for production above 3 million pounds per month would create disorder. Comments filed by the Cooperatives also confirmed their support for the recommended producer-handler definition, which mirrors the definition used in the other western orders.

This final decision continues to find that the producer-handler definition, including additional language related to producer-handler qualification, as proposed in the recommended decision would be appropriate for a California FMMO. As well, the proposed California FMMO should contain the uniform FMMO producer-handler provision that limits monthly Class I route disposition to three million pounds. Because this final decision does not propose adoption of inclusive pooling, dairy product manufacturers of all sizes are allowed to opt out of the marketwide pool, making it unnecessary to provide additional allowances for small producer-handlers under the proposed California FMMO.

California Quota Program. The *California Quota Program* should be defined as the program outlined by the applicable provisions of the California Food and Agriculture Code and related provisions of the pooling plan administered by CDFA. Details about the proposals, record evidence, and this decision's findings regarding appropriate recognition of the California quota program were discussed earlier in this decision.

Comments filed by the Cooperatives recommended modifying language for the *California Quota Program* definition to ensure all applicable statutory and regulatory language is referenced and incorporated. This comment was addressed in the Quota section of this decision.

Producer. A *Producer* should be defined as a dairy farmer that supplies the market with Grade A milk for fluid use or who is at least capable of doing so if necessary. Producers would be eligible to share in the revenue that accrues from marketwide milk pooling. The producer definition in each FMMO order typically differs with respect to the degree of association that dairy farmers must demonstrate within a marketing area, as provided in the producer milk definition.

Comments filed by the Cooperatives took exception to the definition of *Producer,* as the definition does not contain language necessary for inclusive pooling. This decision continues to find the recommended producer definition appropriate, as this final decision does not recommend adopting inclusive pooling for a California FMMO, negating the need for language tailored to inclusive pooling provisions. The details of the proposals, record evidence, and this decision's findings regarding the producer milk definition are described later in the Pooling section of this decision.

Producer Milk. Producer Milk should be defined to identify the milk of producers that is eligible for inclusion in the marketwide pool. This definition is specific to the proposed California FMMO marketing order, reflecting California marketing conditions, and it provides the parameters for the efficient movement of milk between dairy farms and processing plants.

Comments filed by the Cooperatives took exception to the definition of *Producer Milk* as the definition does not contain language necessary for inclusive pooling. This decision continues to find the definition of producer milk appropriate, as this final decision does not recommend adopting inclusive pooling for a California FMMO, negating the need for language tailored to inclusive pooling provisions. The details of the proposals, record evidence, and this decision's findings regarding the producer milk definition are described later in the Pooling section of this decision.

Other Source Milk. The order should include the uniform FMMO definition of *Other Source Milk* to include all the skim milk and butterfat in receipts of fluid milk products and bulk fluid cream products from sources other than producers, cooperative handlers, or pool plants. Other source milk should also include certain products from any source that are used to make other products and products for which a handler fails to make a disposition.

Fluid Milk Product. A California FMMO should include the standard FMMO definition of a Fluid Milk Product, which sets out the criteria for determining whether the use of producer milk and milk-derived ingredients in those products should be priced at the Class I price. Under the definition, *Fluid Milk Product* includes any milk products in fluid or frozen

[25] Federal Order Reform Proposed Rule: 63 FR 4965.

form that are intended to be used as beverages containing less than 9 percent butterfat, and containing 6.5 percent or more nonfat solids or 2.25 percent or more true milk protein. Fluid milk products would include, but not be limited to: Milk, eggnog, and cultured buttermilk; and those products could be flavored, cultured, modified with added or reduced nonfat solids, sterilized, concentrated, or reconstituted. Nonfat solid and protein sources include, but are not limited to, casein, whey protein concentrate, dry whey, and lactose, among others.

Products such as whey, evaporated milk, sweetened condensed milk, yogurt beverages containing 20 or more percent yogurt by weight, kefir, and certain packaged infant formula and meal replacements, would not be considered fluid milk products for pricing purposes.

Fluid Cream Product. The order should include the standard FMMO definition of *Fluid Cream Product.* Fluid cream product includes cream or milk and cream mixtures containing at least 9 percent butterfat. Plastic cream and frozen cream would not be considered fluid cream products.

Cooperative Association. The order should include the uniform FMMO definition of *Cooperative Association* to facilitate administration of the order as it applies to dairy farmer cooperative associations. Under the uniform definition, a *Cooperative Association* means any cooperative marketing association of producers that the Secretary determines is qualified to be so recognized under the Capper-Volstead Act. Cooperative associations have full authority to engage in the sales and marketing of their members' milk and milk products. The definition also provides the recognition of cooperative association federations that function as cooperative associations for the purposes of determining milk payments and pooling.

Commercial Food Processing Establishment. The uniform FMMO definition for *Commercial Food Processing Establishment* should be included in a California FMMO to describe those facilities that use fluid milk and cream as ingredients in other food products. The definition helps identify, for classification purposes, whether disposition to such a facility should be considered anything but Class I, and clarifies that packaged fluid milk products could not be further disposed of by the facility other than those received in consumer-type containers of one gallon or smaller. Producer milk may be diverted to commercial food processing establishments, subject to the diversion and pricing provisions of a California FMMO.

Market Administrator. The record supports a provision for the administration of the order by a *Market Administrator,* who is selected by the Secretary and responsible for the oversight of FMMO activities. The market administrator receives and reviews handler reports, allocates handlers' milk receipts to their proper utilization and classification, publicizes monthly milk prices, provides monthly written account statements to handlers, and manages the producer settlement fund which serves as a clearing house for marketwide pool revenues. The market administrator is authorized to make adjustments to the order's shipping and diversion provisions, where justified, and to investigate noncompliance with the order. The market administrator manages the marketwide pool, conducts handler audits, provides laboratory testing of milk samples, and performs many other functions that support the regulation of milk marketing in the area. Market administrator activities are funded through an administrative assessment on handlers.

Continuity and Separability of Provisions. Each FMMO prescribes uniform rules governing the implementation and maintenance of the marketing order itself, and a California FMMO should likewise include these provisions. These rules state that the Secretary determines when the FMMO becomes effective and whether and when it should be terminated. The rules also provide for the fulfillment of any outstanding obligations arising under the order and liquidating any assets held by the Market Administrator if the order is terminated or suspended. Finally, the rules provide that if, for some reason, one provision of the order—or its applicability to a person or circumstance—were to be held invalid, the applicability of that provision to other persons or circumstances and the remaining order provisions would otherwise continue in force.

Handler Responsibility for Records and Facilities. Provision should be made for the maintenance and retention by handlers of the records pertaining to their operations under a California FMMO. Records of the handler's milk purchases, sales, processing, packaging, and disposition should be included, along with records of the handler's milk utilization, producer payments, and other records required by the market administrator to verify the handler's compliance with order provisions. The market administrator should be able to review and audit each handler's records, and should have access to the handler's facilities, equipment and operations, as needed to verify the handler's obligation under the order. Handlers should be required to retain all pertinent records for three years, or longer, if part of a compliance enforcement action, or as directed by the market administrator.

Termination of Obligations. Provision should be made under a California FMMO for notification to any handler who fails to meet financial obligations under the order, including payments to producers, other handlers, and to the market administrator. Such provision is contained in the uniform provisions of all FMMOs, and specifies that the market administrator has two years after the receipt of the handler's report of receipts and utilization to notify the handler of any unmet financial obligation. Provisions are included for the enforcement of the handler's payment requirement and for the handler's opportunity to file a petition for relief as provided under the AMAA.

6. Classification

The AMAA authorizes FMMOs to regulate milk in interstate commerce, and its provisions require that milk be classified according to the form in which or purpose for which it is used. The classification of milk is uniform in all FMMOs to maintain orderly marketing conditions within and between FMMOs and to ensure that handlers competing in the national market for manufactured products have similar raw milk costs.

This decision continues to find that because California would be joining the FMMO system, it should contain the uniform classification provisions included in the 10 existing FMMOs. Adoption of standard FMMO product classification provisions in the proposed California FMMO is appropriate to maintain uniform pricing for similar products both within the California FMMO and throughout the FMMO system. This section provides a summary of the hearing evidence, post-hearing arguments, and comments or exceptions submitted regarding the proposed milk classification provisions under a California FMMO.

Summary of Testimony

Proposals 1 and 2 both offer standard FMMO product classifications for their respective California FMMO provisions. Proposal 2 also provides an additional shrinkage allowance for ESL production at qualified ESL pool distributing plants.

A Cooperative witness testified regarding the proposed classification provisions contained in Proposal 1. The

witness reviewed the evolution of the FMMO classification provisions and noted that the CSO uses a similar classification system, with limited differences. The witness was of the opinion that the FMMO classification provisions should be adopted in a California FMMO to ensure uniform classification of milk and milk products throughout the entire FMMO system.

A Cooperative witness contended that ESL products are value-added products and should not be granted additional shrinkage allowances under a California FMMO. The Cooperatives further argued that ESL shrinkage allowances should be evaluated at a national hearing because ESL products are manufactured in other FMMO marketing areas, in addition to California.

A consultant witness, appearing on behalf of the Institute, testified in support of the portion of Proposal 2 that establishes an additional shrinkage allowance for the manufacture of ESL and ultra-high temperature (UHT) milk products. The witness explained that the shrinkage allowance recognizes the inherent loss of milk from farm to plant and within the plant. The FMMO system currently allows for up to a 2 percent shrinkage allowance for pool distributing plants, depending on how the milk was received at the plant. The witness contended that the standard 2 percent allowance was developed before extensive use of ESL technology became common-place, and was based on typical shrinkage experienced in traditional high temperature, short time pasteurization (HTST) processing. The witness explained that under current FMMO classification provisions, a portion of the milk accounted for as shrinkage is classified at the lowest priced class for the month and shrinkage losses beyond 2 percent are considered excess shrinkage and classified as Class I.

The consultant witness testified that Proposal 2 provides a shrinkage allowance of an additional 3 percent on ESL production at plants qualified as ESL pool distributing plants. Under the proposed provisions, the plants eligible for the additional shrinkage allowance would be distributing plants located in the marketing area that process 15 percent of the respective plant's total receipts of fluid milk products physically received at the plant into ultra-pasteurized or aseptically-processed fluid milk products.

The intent of Proposal 2, explained the witness, is for an eligible plant to have a maximum shrinkage allowance of up to 5 percent on milk used in its ESL production, not on all milk used in the plant. Data from the witness' ESL processing clients, all located outside of California, showed their total product pound shrinkage averaged above 5 percent. The witness also estimated based on 2013 to 2014 USDA record data, that excess shrinkage in ESL and UHT plants throughout the country averaged 2.09 percent.

Another Institute consultant witness testified regarding a 19-plant shrinkage study of ESL plants; three of the plants in the study were located in California. The study showed a weighted average product pound shrinkage of 2.73 percent.

Two additional Institute consultant witnesses and a witness from HP Hood testified in support of the ESL shrinkage allowance provided in Proposal 2. The witnesses presented historical shrinkage data for ESL and UHT manufacturing facilities and offered extensive technical explanations for why shrinkage levels are higher in those systems than in HTST systems. The witnesses explained that shrinkage refers to milk lost in the manufacturing process due primarily to the fact that it sticks to the equipment pipes and is lost in the cleaning process. The witnesses stressed that ESL equipment has longer piping, and noted numerous operational differences which inherently lead to higher losses of milk when compared to HTST processing.

The HP Hood witness provided a similar explanation of ESL processing and why it lends itself to higher product losses. The witness said that even though fluid milk sales across the United States are declining, HP Hood ESL product sales have grown. The witness was of the opinion that because increases in ESL fluid milk sales benefit the entire dairy industry, dairy producers should share the burden of producing these products through greater shrinkage allowances, as reflected in the classification provisions provided in Proposal 2.

HP Hood, in its post-hearing brief, reiterated its position that the heavy investment in the development of ESL technology and market expansion for those products should be shared by dairy farmers. The Institute, in its post-hearing brief, concurred with HP Hood's points and argued the shrinkage allowances provided in Proposal 2 would assure ESL processors, like conventional fluid milk processors, would only be charged Class I prices for milk contained in fluid milk products and not for milk lost during processing. The Institute also stated that a promulgation proceeding for a new FMMO was an appropriate place to consider ESL shrinkage allowances.

The Cooperatives' reply brief reiterated that ESL products are value-added products and handlers already receive a premium in the market. Additionally, the Cooperatives claimed that the manufacturing costs cited by HP Hood in its brief were not significant enough to warrant the proposed change to the uniform classification rules.

Findings

As discussed previously in this decision, the primary objective of FMMOs is to establish and maintain orderly marketing conditions. FMMOs achieve this goal through the classified pricing and the marketwide pooling of the proceeds of milk associated with a marketing area. To that end, the AMAA specifies that a FMMO should classify milk ''in accordance with the form in which or the purpose for which it is used.'' The classification of milk ensures competing handlers have the same minimum regulated price for milk used in a particular product category. Thus, FMMOs have found it is reasonable and appropriate that milk used in identical or nearly identical products should be placed in the same class of use. This reduces the incidence of disorderly marketing that could arise from regulated price differences between competing handlers.

Currently, the provisions providing the classification of milk pooled on the existing FMMOs are identical.[26] Uniform classification provisions are particularly important in assuring orderly marketing because markets are no longer isolated, and handlers often sell products outside of their local marketing area. The current FMMO classification provisions provide four classes of milk use, and specify provisions for the classification of milk transfers and diversions, plant shrinkages and overages, allocation of handler receipts to handler utilization, and Market Administrator reporting and announcements concerning classification.

Under the current FMMO uniform provisions, Class I consists of milk used to produce fluid milk products (whole milk, lowfat milk, skim milk, flavored milk such as chocolate milk). Class II milk includes milk used to make a variety of soft products, including cottage cheese, ice cream, yogurt and yogurt beverages, sour cream, baking mixes, puddings, meal replacements, and prepared foods. Class III includes milk used to make hard cheeses that may be sliced, grated, shredded, or crumbled, cream cheese, and other spreadable cheeses. Class IV milk includes milk used to produce butter, evaporated or condensed milk in

[26] 7 CFR 1000.40 through 1000.45.

consumer-type packages, and dried milk products. Other milk dispositions, including milk that is dumped, fed to animals, or accidentally lost or destroyed, is generally assigned to the lowest priced class for the month.

The record reflects that current product classification provisions under the CSO are comparable to those under FMMOs. While the CSO has five classes of milk (1, 2, 3, 4a and 4b), the record reflects that under the uniform FMMO classification provisions, products currently classified by the CSO as Class 2 and 3 would be classified by the California FMMO as Class II; CSO Class 4b products would be classified as California FMMO Class III; and CSO Class 4a products would be classified as California FMMO Class IV products.

Both the Cooperatives and the Institute support the product classification provisions already provided in the current FMMOs. Neither group was of the opinion that the proposed FMMO classification provisions would disadvantage any handler currently regulated by the CSO.

This decision continues to find that a California FMMO should contain, to the maximum extent possible, provisions that are uniform with the FMMO system California producers are seeking to enter. To that end, the proposed California FMMO should include the same classification provisions as currently provided in existing FMMOs to allow for consistency of regulation between FMMOs. Adoption of these provisions would ensure that milk pooled on the California FMMO is classified uniformly with the rest of the FMMO system, and consequently, competing handlers will incur the same regulated minimum prices.

Therefore, this decision continues to find that a California FMMO should provide the following product classifications used in existing FMMOs: Class I milk should be defined as milk used to produce fluid milk products; Class II milk should be defined as milk used to make a variety of soft products, including cream products, high-moisture cheeses like cottage cheese, ice cream, yogurt and yogurt beverages, sour cream, baking mixes, puddings, meal replacements, and prepared foods; Class III milk should be defined as milk used to make spreadable cheeses like cream cheese, and hard cheeses that may be sliced, grated, shredded, or crumbled; Class IV milk should be defined as milk used to make butter, evaporated or condensed milk in consumer-type packages, and dried milk products. Other uses for milk, including milk that is dumped, fed to animals, or accidentally lost or destroyed, should be assigned to the lowest-priced class for the month.

This decision also finds that the California FMMO should adopt the same provisions as the existing FMMOs regarding the classification of milk transfers and diversions, plant shrinkage and overages, and allocation of handler receipts to handler utilization.

A comment submitted on behalf of the Cooperatives expressed support for the Department's recommendations to adopt a uniform classification system under a California FMMO. They wrote that, with the exception of the issue regarding ESL shrinkage, which is discussed below, all major proponents at the hearing endorsed the Department's findings that uniform classification helps equalize competing handlers throughout the system.

The existing FMMOs also contain uniform provisions recognizing that some milk loss is inevitable in milk processing. This is referred to as shrinkage and is calculated as the difference between the plant's total receipts and total utilization. Pool handlers must account for all receipts and all utilization. Shrinkage provisions assign a value to milk losses at a plant. There is, however, a limit on the quantity of shrinkage that may be allocated to the lowest priced class. The limit depends on how the milk is received. For instance, shrinkage on milk physically received at the plant directly from producers based on farm weights and tests is limited to 2 percent, whereas, shrinkage on milk received directly from producers on a basis other than farm weights and tests is limited to 1.5 percent. Similar limits are placed on other types of bulk receipts. Quantities of milk in excess of the shrinkage limit are considered ''excess shrinkage.'' Excess shrinkage is assigned to the highest class of utilization at the plant to arrive at gross utilization, from which the allocation process begins.

The CSO provides a shrinkage allowance of up to 3 percent of the plant's total receipts, which is allocated on the basis of the plant's utilization. Similar to the FMMOs, excess shrinkage in the CSO is assigned as Class 1.

The recommended decision did not propose an additional shrinkage allowance for ESL products. Comments filed by HP Hood opposed the Department's recommendation, noting that ESL products have gained popularity while overall fluid milk consumption has declined, and processors should be compensated for the investments they have made to buoy the fluid milk sector.

Comments filed by the Cooperatives supported the Department's recommendation that no additional shrinkage allowance be provided for ESL production. The Cooperatives wrote that adopting a different shrinkage allowance for ESL products would deviate from national uniformity in the FMMO system.

This final decision does not find justification for an additional shrinkage allowance for ESL production at ESL pool distributing plants. While the record contains some ESL plant shrinkage data, data pertaining to ESL production at California plants is limited. The record does indicate that ESL production occurs throughout the country. This decision continues to find that amending provisions that are uniform throughout the FMMO system to allow an additional shrinkage allowance on ESL production should be evaluated on the basis of a separate national rulemaking proceeding.

7. Pricing

The two main proposals in this proceeding offered end-product price formulas as the appropriate method for pricing producer milk pooled on a California FMMO, although the factors in the formulas differed. This section reviews arguments presented in testimony and post-hearing briefs regarding the appropriate method to value producer milk. This section further explains the finding that the recommended California FMMO include adoption of the same end-product price formulas used in the 10 existing FMMOs and addresses comments and exceptions received in response to the recommended decision.

Summary of Testimony

A LOL witness, appearing on behalf of the Cooperatives, testified in support of the classified price provisions contained in Proposal 1. The witness testified that under Proposal 1, California would adopt the classified prices (including the commodity price series, product yields, and make allowances), the component prices, and the advanced pricing factors presently used in the FMMO system. The witness stated that 65 percent of the milk produced in the United States is currently priced under these common provisions, and the same should apply to the 20 percent of the national milk supply produced in California.

The witness provided testimony regarding the evolution of a national manufacturing price, starting with the Minnesota-Wisconsin price series in the 1960's, and ending with the national classified end-product price formulas adopted in 2000. The witness discussed the national pricing system that resulted

from FMMO Order Reform (Order Reform), including the multiple component pricing (MCP) system used in 6 of the 10 current FMMOs. The witness explained that the MCP system met the criteria set forth by Congress to make pricing simple, transparent, and based on sound economic theory. Under the MCP system, the witness said, prices are derived from actual, observed market transactions for wholesale commodity milk products, and utilize yield factors and make allowances to determine the value of raw milk in each class. The witness explained that through the Dairy Product Mandatory Reporting Program (DPMRP), manufacturers of the four commodity dairy products (cheese, butter, NFDM, and dry whey) are required to submit sales information on current market transactions. The witness said that information is aggregated, released in the National Dairy Product Sales Report (NDPSR), and utilized in the FMMO price formulas. The witness stated that because many large-scale California dairy plants are part of the DPMRP, California commodity prices are reflected in the prices paid by FMMO handlers and received by producers in the rest of the country, and the same prices should be applicable to milk pooled under a California FMMO.

The witness also testified regarding the influence of California dairy manufacturing costs on the current FMMO make allowances. The witness noted that a USDA Rural Cooperative Business Service (RCBS) study, a Cornell University study of processing costs, and a CDFA cost-of-processing survey were relied upon by the Department to determine appropriate make allowance levels for cheese, butter, NFDM, and dry whey. In the witness's opinion, the inclusion of CDFA manufacturing cost data in the formulation of FMMO manufacturing allowances justifies the use of the same manufacturing allowances (butter: $0.1715 per pound; NFDM: $0.1678 per pound; cheese: $0.2003 per pound; and dry whey: $0.1991 per pound) in a California FMMO. The witness also reviewed the rulemaking history on the derivation of the product yields contained in the current FMMO price formulas, and was of the opinion that they are similar to product yields attainable by California manufacturing plants. The witness stated that the FMMO make allowances and product yields remained relevant, as they had been reaffirmed by the Department in a 2013 Final Rule.[27]

[27] Official Notice is taken of: FMMO Class III and IV Price Formula Final Rule: 78 FR 24334.

The witness also testified regarding the FMMO national Class I price surface. The witness said that Order Reform resulted in the adoption of a national pricing surface, which assigned a value to milk for every county in the United States based on milk supply and demand at those locations. The witness was of the opinion that since California was factored into the Department's Order Reform analysis to derive the price surface, it would be appropriate for the price surface to be adopted in a California FMMO. The witness noted the price surface identifies five pricing zones covering California, ranging from $1.60 to $2.10 per cwt. The witness explained that in the FMMO system, the Class I differential is added to the higher of the Class III or Class IV price to determine the Class I price for a distributing plant at its location. The witness elaborated that since Class I processors compete with Class III and IV manufacturers for a milk supply, Class I prices are linked to manufacturing prices in the FMMO system, and this concept should likewise apply to a California FMMO.

The witness also explained how the base Class I differential, $1.60 per cwt, was derived during Order Reform. The witness said that the $1.60 base differential assumes a cost per cwt of $0.40 to maintain a Grade A facility, $0.60 for marketing, and $0.60 for securing a milk supply in competition with manufacturers. The witness noted these values were established in 2000, and although still relevant, the actual costs are higher in the current marketplace. The Cooperatives provided additional information in their post-hearing brief, contending that current costs support a base Class I differential of $2.40, a 50 percent increase over the base listed above.

The witness concluded by saying that California dairy farmers should receive prices reflecting the current national market and that are comparable to what producers receive from FMMO regulated plants in the rest of the country. This position was reiterated in the Cooperatives' post-hearing brief.

Another Cooperative witness provided testimony on the handler's value of milk and related provisions. The witness proposed that handlers regulated by a California FMMO pay classified prices based on the components in the raw milk they receive (otherwise known as ''multiple component pricing''): butterfat, protein, and other solids. Under Proposal 1, the witness said, regulated handlers would pay for milk on the following components:

- Class I: butterfat and skim
- Class II: butterfat and solids nonfat
- Class III: butterfat, protein and other solids
- Class IV: butterfat and solids nonfat

The Cooperative witness reiterated the Federal Order Reform recommended decision justification for implementing a national pricing structure and contended the same reasons apply to extending national pricing to a California FMMO. The witness added that while California handlers would be paying the same national prices for milk components, there would be no need to adjust price formulas for regional product yields because handlers only pay for the components they receive. The witness also explained that Proposal 1 did not prescribe location adjustments in the price formulas because California plants are included in the price surveys that determine the national commodity prices used in the FMMO formulas.

The Cooperative witness testified that Proposal 1 includes a fortification allowance on milk solids used to fortify Class I products to meet California's fluid milk standards, as is currently provided in the CSO. The witness noted that Proposal 1 does not propose a somatic cell adjustment or producer location differentials since both features are not currently contained in the CSO.

The Cooperative witness said Proposal 1 seeks to have producers paid on the basis of butterfat, protein and other solids, and does not include a producer price differential (PPD) adjustment per se. The witness said that the PPD is typically viewed as the benefit to FMMO producers for participating in the marketwide pool since the PPD reflects the additional revenue shared from the higher value class utilizations. Instead, the witness explained that under Proposal 1, the California FMMO would calculate a monthly PPD, but the PPD value would be paid to producers according to each component's annual contribution to the Class III price. For example, said the witness, if on an annual basis butterfat accounted for 32 percent of the total value of the Class III price, then 32 percent of the monthly PPD value would be paid out through an adjustment to the butterfat price. This same adjustment, the witness said, would apply to the producer protein and other solids prices. The witness explained that FMMO producers typically find the monthly PPD concept confusing and complicated, especially in months when it is a negative value. The witness said that California producers, who do not receive a PPD

adjustment under the CSO, might find Proposal 1's method of distributing the PPD value simpler to understand.

The witness also clarified that the Cooperatives were amending the proposal regarding announcement of producer prices contained in Proposal 1 from ''on or before the 11th'' to ''on or before the 14th'' day after the end of the month.

Support for a national uniform pricing system was reiterated in the Cooperatives' post-hearing brief. The Cooperatives argued that the hearing record demonstrates California cheese competes in the national market. Having California milk priced uniformly in the FMMO system would not disadvantage California processors, reiterated the Cooperatives, but it would diminish the current pricing advantage they have under the CSO. The brief noted record evidence that many FMMO cheese processors paid higher than FMMO minimum prices for milk as proof that FMMO minimum prices are not too high.

The Cooperatives' brief also discussed California whey processing. The brief stated that 85.8 percent of cheese manufactured nationally is produced in plants that also process whey. In California, the Cooperatives wrote, the percentage is closer to 90 percent. Based on these comparable percentages, the Cooperatives stated whey pricing in California should be no different from the rest of the country.

The Cooperatives also stressed opposition to any adjustment to the price formulas to reflect a lower location value in California. The Cooperatives stated milk prices should not be California centric because manufactured products are sold nationally. If California classified prices were to be based solely on California product sales, the Cooperatives were of the opinion that California handlers would receive a raw milk cost advantage over other FMMO regulated handlers. The brief noted that the Cooperatives manufacture a majority of the butter and NFDM produced in California, and they did not believe the proposed California FMMO prices associated with those Class IV products would be too high. The Cooperatives stressed that any changes to the FMMO pricing system should be considered at a national hearing and not in this single-market proceeding.

An Institute witness testified regarding the pricing provisions included in Proposal 2. The witness explained that Class I products have the highest use value in order to encourage adequate milk production to meet Class I needs, and to attract milk to Class I rather than to manufacturing uses. As manufacturing class uses balance the supply and demand needs of the marketing area, the witness said it would be important that those classified use values not be set above market-clearing levels.

The Institute witness testified that historically, as milk began to travel greater distances for processing, FMMO pricing policy became more coordinated to promote orderly marketing conditions both within and between FMMOs. The witness said that the Minnesota-Wisconsin price series served as the basis for FMMO pricing because the area surveyed represented the largest reserve supply of milk in the country, and therefore generated an appropriate market-clearing price for manufacturing milk. The witness stated that California is now the region with the largest reserve supply and because California products must compete for sales in the east, the value of raw milk in California is lower than in eastern parts of the country. Therefore, emphasized the witness, minimum prices for a California FMMO should not be set above market-clearing levels in California. This position was reiterated in the Institute's post-hearing brief.

The Institute witness cautioned against setting minimum prices too high because it could lead to the inability of dairy farmers to find a willing buyer for their milk. Alternatively, the witness said, if minimum prices are set too low, dairy farmers could be compensated by the market through over-order premiums. The witness said Class III and IV prices for a California FMMO need to be reflective of commodity prices received by California plants, and reflective of current California manufacturing costs. The witness was of the opinion that the national values used in the current FMMO Class III and IV formulas are not appropriate for California.

The Institute witness explained their preference would be to use western commodity prices in the Class III and IV formulas. However, the witness said that, due to data confidentiality issues, the Department is unable to report these prices. As an alternative, the witness said, Proposal 2 contains default commodity values that would adjust the NDPSR prices based on the historical difference between the NDPSR prices and California or western based prices as reported by either CDFA or Dairy Market News. This western adjustment, the witness said, would result in commodity prices in the price formulas being more representative of the prices received by California handlers. The witness noted the only exception to how the adjustors are calculated is the default adjustor proposed for the Class III protein price. The Class III protein price adjustor utilized CME 40-pound block Cheddar cheese prices, because CDFA stopped reporting California 40-pound block Cheddar prices after August 2011.

The Institute witness also reviewed the manufacturing allowances contained in Proposal 2. Except for the dry whey manufacturing allowance, explained the witness, all are based on the most recent CDFA manufacturing cost survey for 2013.[28] The witness explained that CDFA no longer reports dry whey cost data. Therefore, Proposal 2 provides for a dry whey manufacturing allowance that adds the difference between the FMMO manufacturing allowances for nonfat dry milk and dry whey to the most recent CDFA weighted average manufacturing cost for nonfat dry milk. The witness was of the opinion that the yields contained in the FMMO price formulas would be appropriate for California, and are therefore also prescribed in Proposal 2.

The Institute witness testified that many California cheese plants manufacture products other than dry whey that often do not generate revenues to match the dry whey value in the regulated formulas. Other plants, according to the witness, do not have the capability to process the whey by-product from their cheese making operations. Therefore, the witness offered an alternative Class III other solids price formula that would be based on whey protein concentrate (WPC), and would cap the whey value to recognize that not all plants are able to capture value from their whey stream. The witness testified that a more appropriate reference commodity for whey products, one that would be more applicable to most California cheesemakers' operations, would be WPC. The witness explained that over the previous eight years, the production of dry whey declined 3.3 percent, while the production of various WPC and Whey Protein Isolate (WPI) products has seen increases ranging from 1.1 percent to 9.5 percent.

The Institute witness testified that cheese and whey markets are vastly different, and not all cheese plants find it profitable to invest in whey processing. According to the witness, when cheese plants do invest, it is usually in the limited processing of whey into concentrate solids for transportation savings. The witness said that only one plant in California

[28] Proposed manufacturing allowances were later amended by the Institute to incorporate a marketing cost.

consistently dries whey, and of the 57 California cheese plants, only 13 process whey in any fashion. The witness explained that the alternative other solids price formula offered by the Institute incorporates the value of liquid WPC–34 sold to a plant that would then process the product further into a dry product. While there are a variety of liquid whey products marketed, the witness said using WPC–34 prices as a reference price for other solids would be most appropriate because WPC–34 is the predominant form of liquid whey sold. The witness explained how Proposal 2 would convert the WPC–34 reference price to a dry whey equivalent basis so that the other parts of the other solids price formula could be retained. The witness added that the dry whey make allowance would need to be increased to include the cost of cooling and delivering the liquid whey to a processing facility. To provide some protection to small cheesemakers when the price is very high, and to dairy producers when the price is very low, the witness proposed another solids price floor of $0.25 per pound and a ceiling of $1.50 per pound.

The Institute's post-hearing brief discussed several of the unique aspects of the California dairy industry. The brief stated that from 1995 to 2014, while the state's population grew 23 percent, California milk production increased 82 percent, which in turn fueled the expansion of cheese processing in the state. The brief stated that three processing facilities account for 25 percent of California's cheese manufacturing, and much of that production is marketed east of the Mississippi River. The brief cautioned that increasing minimum prices would create an economic trade barrier where California processors would no longer have the ability to compete in eastern markets due to higher minimum regulated prices.

The Institute's post-hearing brief also addressed the need for a national FMMO pricing hearing. The Institute reiterated hearing testimony that current pricing formulas are based on data from the 1990s, making the prices out of alignment with current market realities. The brief stated that pricing formulas need to be updated in order to be representative of current marketing conditions. The FMMO pricing system, the Institute stressed, needs all pricing formulas to be set at market clearing levels that enable over-order premiums to be paid when appropriate.

A witness appearing on behalf of Leprino Foods, a mozzarella cheese and whey products manufacturer based in Denver, Colorado, testified regarding the Class III price formula contained in Proposal 2. Leprino operates nine plants in the U.S., three of which are in California. Leprino is a member of the Institute and supports adoption of Proposal 2 if the Department recommends a California FMMO.

The Leprino witness stressed the importance of minimizing the impacts of minimum regulated pricing on the dairy marketplace. The witness testified that the United States dairy industry is increasingly integrated with global dairy markets since more than 15 percent of United States milk solids are exported, and that many manufacturers, including Leprino, have made significant investments in developing export markets to increase demand for United States dairy products. The witness said it is important that any future California FMMO facilitate rather than inhibit the dairy industry's ability to leverage this export opportunity.

The Leprino witness testified about the importance of setting minimum regulated milk prices at market clearing levels that would allow for reasonable returns achievable under good management practices by California manufacturers. The witness testified that 80 percent of California milk production is utilized in Class III and IV products, a large percentage of which are marketed outside of California. Therefore, the witness said, California FMMO minimum prices should reflect values of California-manufactured products, f.o.b. the manufacturing plant. The witness added that because price formulas could only be changed through a hearing process, it would be important to set the regulated price formulas at minimum levels that allow market forces to function outside of the regulated system. The witness said regulated prices that are too high would lead to over-production of milk and disorderly marketing conditions. This concept was reiterated in the post-hearing briefs submitted by the Institute and Leprino.

The Leprino witness summarized findings from the Order Reform Final Decision that explained how manufacturing plant operators who find make-allowances inadequate to cover their actual costs are free to not participate in the order. The witness noted this option would not be available under Proposal 1, which underscores the importance of setting appropriate market clearing prices.

The Leprino witness testified that a California FMMO would require a Class III formula that is set in relation to achievable returns in California using the most recent data. The witness explained Leprino's preference that the Department suspend the California FMMO proceeding to defer implementation until after a national hearing could be held to review and revise the existing Class III formula. The witness added that the Department should hold a national Class III and IV price formula hearing after this rulemaking to utilize more current data and account for the impacts of a California FMMO, if necessary.

The Leprino witness testified in support of establishing a DPMRP western price survey to determine minimum milk prices under a California FMMO. The witness explained how the Department might rely on surveyed commodity prices from other western states, if necessary, to overcome any data confidentiality issues. In its brief, Leprino encouraged the Department to establish a definition for the Western Area, and recommended it include California, Oregon and Washington. In addition to these three states, the witness said that other areas should be considered in order to eliminate confidentiality constraints. However, the witness said that in the event confidentiality concerns continue to arise, Proposal 2 contained alternative default equations.

The Leprino witness discussed the justification for pricing western produced products differently than those in the rest of the country. The witness stressed that the location value of California manufactured products is lower because of the additional transportation costs required to deliver products to the population centers in the east. This opinion was reiterated in Leprino's post-hearing brief. The witness noted that nearly half of Leprino's cheese production sold domestically is shipped to markets east of the Mississippi, and they incur transportation costs ranging from $0.10 to $0.15 per pound.

The Leprino witness was of the opinion that bulk Cheddar cheese remains the most appropriate product from which to derive the FMMO Class III price, but California Class III price formulas should rely on 40-pound block Cheddar prices because all California Cheddar production is in blocks. The adoption of 40-pound block Cheddar prices was reiterated in Leprino's post-hearing brief.

The witness testified in support of modifying the make allowances in Proposal 2 to incorporate a sales and administrative cost of $0.0015 per pound. Therefore, the new proposed make allowances per pound of product would be as follows: $0.2306 for cheese, $0.1739 for butter, $0.2310 for whey, and $0.2012 for NFDM.

The Leprino witness provided extensive testimony on the appropriate valuation of whey in FMMO Class III minimum pricing. The witness explained how the explicit whey factor had been a problem for cheesemakers and led the Institute to propose an alternative valuation. Proposal 2 would value the whey portion of the Class III price formula relative to its concentrated liquid whey value, which the witness said was the most generic whey product produced. The witness stated that the WPC–34 price index is the most common reference used for the sale of liquid whey by cheese plants selling concentrated whey in California. The witness added that the prices received for liquid whey are discounted to reflect additional processing required to produce a full-value whey product. Accordingly, said the witness, California FMMO minimum prices should rely on WPC–34 survey prices to approximate a whey value in the Class III price.

The Leprino witness testified in opposition to the Class III and IV formulas contained in Proposal 1. The formulas, the witness said, do not reflect California market conditions. The witness warned that higher regulated prices in California would lead to disorderly marketing conditions. In its post-hearing brief, Leprino stated the pricing formulas in Proposal 1 use old manufacturing cost data and the national weighted average prices for the four products exceeded the prices received in California. Leprino noted that there was no evidence provided by the Cooperatives related to the relevance of the Proposal 1 formulas to California.

A witness testifying on behalf of Hilmar spoke on how the current FMMO Class III and IV pricing formulas, if applied to a California FMMO incorporating inclusive pooling, would lead to disorderly marketing conditions. In its brief, Hilmar stated that disorderly marketing conditions would negate the competitive equilibrium present between eastern and western markets and lead to a trade barrier that would hinder the California dairy industry.

The witness testified that Hilmar had not experienced difficulties in sourcing raw milk supplies, and that there was currently no disorder in California to warrant promulgation of a California FMMO. The witness described several scenarios in the past where CSO whey pricing methodology over valued whey and led to disorderly marketing conditions for Hilmar, its independent producer suppliers, and other California dairy farmers, which CDFA was able to remedy through an adjustment to the whey factor.

The Hilmar witness testified that if milk used in California cheese production was subject to the whey factor used in the current FMMO Class III price, the whey product stream in California would be overvalued. Use of that whey factor, along with the inclusive pooling provisions in Proposal 1, would give rise to disorderly marketing conditions.

The Hilmar witness was of the opinion that 2015 California milk production decreased for reasons not relevant to the differences in CSO 4b versus FMMO Class III pricing. Instead, the witness said, production was influenced by low milk powder prices related to global oversupply of milk powder, as well as drought, environmental regulations, and competition for land from other crops.

The Hilmar witness testified that CSO milk prices are minimums, and cooperatives have the ability to negotiate for higher milk prices from their proprietary plant customers. The witness said that Hilmar paid premiums of approximately $120 million for milk above the CSO 4b price over the last several years. The witness explained that these premiums were paid for milk characteristics such as component content and other market-based factors. The witness added that when CSO 4b prices were temporarily increased through CDFA's adjustment to the sliding scale whey factor, the premiums Hilmar paid for milk decreased.

The Hilmar witness testified that the make-allowances in the FMMO Class III and IV formulas are outdated, and new manufacturing cost studies are necessary. The witness stated that Hilmar's manufacturing costs for cheese and milk powders are higher than those provided for in the FMMO Class III and IV formulas. The witness said that if a California FMMO was adopted with inclusive pooling, it would be impossible for Hilmar to clear the market, unlike in existing FMMOs where manufacturing milk is not required to be pooled.

The Hilmar witness explained that California FMMO minimum milk prices need to reflect local supply and demand conditions. The witness entered Hilmar data showing that prices received for the sale of Hilmar cheese averaged $0.04 per pound lower than the announced NDPSR weighted average cheese price from 2010 to 2013. This price difference, the witness explained, is a function of the additional transportation cost incurred by Hilmar to transport product to eastern markets. The witness made similar price comparisons for NFDM and butter.

The Hilmar witness stressed that if California FMMO prices are not reflective of the California market, the California dairy industry will be less competitive in the global marketplace. The witness noted that in 2014, Hilmar exported 10 percent of its cheese, 50 percent of its WPC, and 95 percent of its lactose; and it planned to export all of the skim milk powder to be produced at a manufacturing facility nearing completion in Turlock, California. Inclusive pooling and U.S.-centric milk pricing in California, said the witness, would lead to competitive disadvantages for California manufacturers in international and domestic markets.

The Hilmar witness testified that they produce several types of whey products, but not dry whey. The witness was of the opinion that dry whey is a poor indicator of the value of Hilmar's WPC products. The witness said the potential minimum regulated cost under inclusive pooling provisions in a California FMMO would make production of Hilmar's whey products unprofitable.

In the post-hearing brief submitted by Hilmar, concerns regarding an adequate return on investment were raised. Hilmar was of the opinion that Proposal 1 does not provide an adequate level of return on investment to allow for processors to remain viable. The brief stated that adoption of provisions allowing for handlers to opt not to pool manufacturing milk could alleviate those concerns.

In its post-hearing brief, Hilmar sought to counter the Cooperatives' claim that California manufacturers have a competitive advantage over their FMMO counterparts and thus should be able to pay FMMO minimum prices. Hilmar countered that California handlers have a long-term competitive disadvantage when compared to their FMMO counterparts because of the CSO's mandatory pricing and pooling provisions. Hilmar maintained that the value of milk in California is lower than in the eastern part of the country, and California FMMO price formulas should reflect this reality.

A witness testified in support of Proposal 2 on behalf of Marquez Brothers International (Marquez), a Hispanic cheese manufacturer located in Hanford, California. The witness explained how their company invested in a processing facility in 2004 to address challenges with whey disposal. The witness explained that of the total milk solids they receive, approximately 48 percent is used in cheese, and 52

percent ends up in the whey stream. The formulation of Marquez's whey stream, the witness noted, is approximately 5.11 percent whey cream, 9.45 percent WPC–80, and 85.44 percent lactose permeate.

The Marquez witness testified that out of 57 California cheese plants, 49 plants (19.1 percent of California cheese production) have limited or no ability to process whey. The witness testified that whey disposal had been a burden for their business in the past, costing $1.5 million per year with no revenue offset and no recognition in the CSO 4b price of whey disposal costs. The witness added that the same problems existed in the FMMO Class III formula price contained in Proposal 1. The witness testified that the reliance on dry whey to price the other solids component of the FMMO Class III price would be inappropriate since cheesemakers must pay producers for the value of whey that can be generated from their milk, regardless of whether that price is actually obtained from the market.

The Marquez witness testified that adoption of Proposal 1 would discourage investment in cheese processing technologies. The witness said that a system of inclusive pooling coupled with other increases in operating costs would lead to competitive difficulties for California cheese plants.

A witness appeared on behalf of BESTWHEY, LLC (BESTWHEY), in opposition to adoption of Proposal 1. BESTWHEY provides consulting services to cheese manufacturing facilities, with a focus on specialty cheeses and whey handling and disposal. According to the witness, Proposal 1 would restrict the growth of California's cheese industry and eliminate most of the small cheese businesses in the state, and Proposal 1's inclusive pricing and pooling would lead to an over-supply of California milk. The witness highlighted the limited number of California plants with whey processing capabilities. The witness supported adoption of Proposal 2 because, according to the witness, it would provide a more realistic value for whey in the other solids price calculation, based on the actual value of liquid whey sold by cheese plants.

A witness appeared on behalf of Klondike Cheese (Klondike), a Wisconsin-based cheese manufacturer. The witness said that Klondike cools its liquid whey by-product and sells it to a larger whey processing facility. The witness provided detailed descriptions of whey processing methodology and the associated costs. The witness testified that basing the other solids price on dry whey markets is inappropriate and does not accurately reflect the revenues from whey at their operation. The witness entered Klondike 2014 data showing an average loss on its whey production of $0.6516 per cwt of milk.

A witness testified on behalf of Decatur Dairy (Decatur), a cooperative-owned, Wisconsin-based cheese manufacturer, in regard to using dry whey as the basis for the other solids price. The witness provided detailed descriptions of whey processing methodology and the associated costs. The witness said that Decatur sells warm wet whey to a nearby plant for further processing. The witness said that dry whey prices contained in the FMMO product-price formulas did not reflect the revenue they receive from their liquid whey sales, and it is not feasible for them to invest in drying equipment. The witness entered Decatur data for 2012 to 2015 showing average annual losses on its whey production ranging from $0.0627 to $0.7114 per cwt of milk.

A consultant witness appeared on behalf Joseph Gallo Farms (Gallo Farms). The witness explained that Gallo Farms owns two dairy farms, as well as cheese and whey processing facilities in California, and supports adoption of Proposal 2. Gallo Farms processes WPC from their own cheese operation and from other cheese facilities.

The Gallo Farms witness testified that if they had been required to pay the FMMO Class III price for milk, they would not have been able to make updates or improvements to their facilities. The witness estimated their cheese costs would have increased by $0.2237 per pound if Proposal 1 had been in effect from January 2014 through September 2015. The witness was of the opinion that California dairy farmers should not compare the prices received in California to prices received in the Midwest or East Coast, where significant population centers are serviced. The witness characterized the California market as significantly different from eastern markets, as it includes not only the West Coast population centers, but also Mexico and other export markets. The witness was of the opinion that a California FMMO, as provided for in Proposal 1, could lead to the closure of small and medium sized manufacturing plants.

The Gallo Farms witness supported the portion of Proposal 2 that relies on WPC to determine the other solids price, as most whey pricing is related to the WPC market rather than dry whey. An Institute witness testified regarding Class I pricing. The witness was of the opinion that the policy of assigning Class I milk the highest classified value should be reevaluated, given current market realities. The witness said that Proposal 1 relied on the current Class I price surface and fluid milk pricing system incorporated in the existing FMMOs, while other potential fluid milk pricing options have not been thoroughly investigated. The witness argued that although the ''higher of'' pricing mechanisms dampens Class I sales and limits the ability of fluid milk processors to hedge their Class I milk volumes, the Institute still supported the Class I milk pricing mechanism advanced in Proposal 2.

The Institute witness also testified regarding a technical modification to Proposal 2 that would affect how handlers pay for the milk components used in Class I products and how handler credits for fortifying fluid milk products would be determined. The witness explained that milk standards set by the State of California require a higher nonfat solids content than the Food and Drug Administration standard used elsewhere in the country. California fluid milk processors fortify raw milk with either condensed or nonfat dry milk to meet these higher standards.

The Institute witness described the differences between CSO and FMMO accounting for fluid milk fortification. Under FMMOs, the witness said, handlers account to the pool at the Class IV price for the solids used to fortify milk, but then are charged the two-factor (butterfat and skim) Class I price for the volumetric increase in fluid milk realized through fortification. Under the CSO, handlers account to the pool using a three-factor (butterfat, nonfat solids, and fluid carrier) Class 1 price for all solids used in Class 1 products, but then receive a credit for the solids used to fortify milk to meet the state standards. The Institute witness was of the opinion that the CSO three-factor system, coupled with its fortification credits, is superior to the FMMO system because it encourages orderly milk movements by making fluid milk handlers indifferent to the solids content of milk they receive, and it ensures that Class 1 handlers do not have a regulated milk price advantage over one another. The witness explained that plants receiving milk with a higher solids content might pay a higher Class 1 price for the raw milk, but less for fortification, while plants receiving milk with a lower solids content might pay a lower Class 1 price for the milk, but more for fortification, making both plants competitive with each other. The

witness emphasized that in the absence of a fortification credit for meeting the California milk solids requirement, handlers under a California FMMO might make milk sourcing decisions solely to take advantage of a two-factor Class I price formula.

A witness appeared on behalf of Hilmar to outline the history of FMMO surplus milk pricing policies. The witness, referring to decisions from previous FMMO rulemakings and reports, stated that FMMO minimum pricing should be set at levels aligning with net revenues received by manufacturers in the local marketing area in order for milk to ''clear'' the market. Therefore, the witness concluded, the Department must examine the local California market situation when determining appropriate minimum prices in a California FMMO.

A Cooperative witness addressed the alternative Other Solids price formula that was offered by the Institute. The witness stressed that no verifiable price series for WPC–34 exists, nor did the Institute present any third-party WPC–34 manufacturing cost studies. The witness estimated that 86 percent of the Class 4b milk was processed at plants that had whey drying capabilities. In addition, the witness said that the Cooperatives' modified exempt plant provision would exempt as many as 25 of the 57 cheese plants from FMMO minimum price regulation.

Findings

Handler's Value of Milk

The FMMO program currently uses product price formulas relying on the wholesale price of finished products to determine the minimum classified prices handlers pay for raw milk in the four classes of products. Class III and Class IV prices are announced on or before the 5th day of the month following the month to which they apply. The Class III and Class IV price formulas form the base from which Class I and Class II prices are determined. The Class I price is announced in advance of the applicable month. It is determined by adding a Class I differential assigned to the plant's location to the higher of an advanced Class III or Class IV price computed by using the most recent two weeks' DPMRP data released on or before the 23rd of the preceding month. The Class II skim milk price is announced at the same time as the Class I price, and is determined by adding $0.70 per cwt to the advanced Class IV skim milk price. The Class II butterfat price is announced at the end of the month, at the same time as the Class III and Class IV prices, by adding $0.007 per pound to the Class IV butterfat price.

AMS administers the DPMRP to survey weekly wholesale prices of four manufactured dairy products (cheese, butter, NFDM and dry whey), and releases weekly average survey prices in the NDPSR. The FMMO product price formulas use these surveyed products to determine the component values in raw milk. The pricing system determines butterfat prices for milk used in products in each of the four classes from surveyed butter prices; protein and other solids prices for milk used in Class III products from surveyed cheese and dry whey prices, respectively; and a nonfat solids price for milk used in Class II and Class IV products from surveyed NFDM product prices. The skim milk portion of the Class I price is the higher of either the protein and other solids prices of the advanced Class III skim milk price or the NFDM price of the advanced Class IV skim milk price.

The butterfat, protein, other solids, and nonfat solids prices are derived through the average monthly NDPSR survey price, minus a manufacturing (make) allowance, multiplied by a yield factor. The make allowance factor represents the cost manufacturers incur in making raw milk into one pound of product. The yield factor is an approximation of the product quantity that can be made from a hundredweight of milk received at the plant. The milk received at the plant is adjusted to reflect farm-to-plant shrinkage when using farm weights and tests. This end-product pricing system was implemented as a part of Order Reform on January 1, 2000,[29] and last amended on July 1, 2013.[30]

The pricing methodology described above was proposed by the Cooperatives to apply in a California FMMO and is contained in Proposal 1. The Cooperatives maintain that the Department has for many years held that the market for manufactured dairy products is national in scope and that the price of milk used to manufacture those products should therefore be the same across the nation. Proponents of Proposal 1 explained that the commodity prices used in the formulas are based on a survey of prices for manufactured dairy products from plants across the country, including California. Proponents went on to point out that the surveyed manufacturing costs were from plants in California, as well as in other states. These surveyed costs have been used to determine FMMO make allowances in the product-price formulas since their inception.

The Cooperatives, through witness testimony and post-hearing briefs, stressed that prices used to determine California handlers' value of milk should be based on the same national average factors as those used in the FMMOs. The Cooperatives repeatedly stressed that manufactured products compete in a national market, and therefore California dairy farmers should receive a milk price reflective of those commodity values. The Cooperatives' primary justification for a California FMMO is that the CSO does not provide California dairy farmers a milk price reflective of these national values, and they are now seeking to be included in the FMMO system so California dairy farmers can receive prices similar to their counterparts in the rest of the country.

The Institute, through witness testimony and post-hearing briefs, argued that classified prices in a California FMMO must be reflective of the current market conditions in California. They were of the opinion that not only has data used in the formulas become outdated, but that the value of California milk is inherently lower because of California's geographic location in the West and the additional cost of transporting finished product to population centers in the East. The Institute argued that these conditions make it hard for its dairy manufacturing member companies to remain competitive in the market.

In Proposal 2, the Institute proposed several changes to the current FMMO pricing formulas that would be applicable in California. First, the Institute proposed a western states price series for each commodity surveyed by the DPMRP. If a western price could not be used because of data confidentiality issues, the Institute proposed that a fixed value for each commodity be subtracted from the current NDPSR prices to represent the lower value of products in the West. Second, the Institute suggested that a Western states manufacturing cost survey be conducted to determine relevant California make allowances for each commodity, and if this was not feasible, they proposed specific make allowance levels they asserted are representative of manufacturing costs in California. Third, they proposed the NDPSR Cheddar cheese price used in the FMMO protein price formula for California only consider 40-pound block prices. They proposed that 500-pound barrel Cheddar cheese prices should not

[29] Federal Order Reform Final Rule: 64 FR 70868.

[30] FMMO Class III and IV Price Formula Final Rule: 78 FR 24334.

be included as they are in current FMMOs.

Class III and Class IV Pricing. The record evidence supports the finding that the classified and component price formulas used in the 10 current FMMOs [31] be utilized without change in the proposed California FMMO. These national formulas were adopted as part of Federal Order Reform and are described earlier in this decision. The Order Reform Final Decision [32] found that because commodity dairy products compete in the national market, it was appropriate that the raw milk used in those products be priced uniformly across the FMMO system. This hearing record contains testimony explaining the FMMO evolution toward national uniform pricing for manufactured products. Such explanation was also outlined in the Order Reform Final Decision.

In the early 1960s, FMMOs used a Minnesota-Wisconsin (M–W) manufacturing grade milk price series to determine a price for milk used in manufactured products based on the supply and demand for Grade B milk. As Grade B milk production and the number of plants purchasing Grade B milk declined, FMMOs moved to a Basic Formula Price (BFP). The BFP price incorporated an updating formula with the base M–W price to account for the month-to-month changes in the prices paid for butter, NFDM, and cheese. The Order Reform decision recognized that Grade B milk would only continue to decline and that the FMMO system needed a more accurate method for determining the value of producer milk.

As outlined in the Order Reform Final Decision, the goals for replacing the BFP price were: (1) To meet the supply and demand criteria set forth in the AMAA; (2) not to deviate greatly from the general level of the current BFP; and (3) to demonstrate the ability to change in reaction to changes in supply and demand. The product-price and component formulas currently used in the FMMO system were found to be the appropriate market-oriented alternative to the BFP. Additionally, that final decision specifically addressed the national market for commodity dairy products:

''. . . the current BFP may have a greater tendency to reflect supply and demand conditions in Minnesota and Wisconsin rather than national supply/demand conditions. The formulas in this decision use national commodity price series, thereby reflecting the national supply and demand for dairy products and the national demand for milk.'' [33]

The Department subsequently reiterated the necessity for FMMO classified prices to reflect national markets in a later final decision on Class III and IV pricing when it specifically addressed public comments pertaining to the relationship between the CSO and FMMOs:

''Class III and Class IV dairy products compete in a national market. Because of this, Class III and Class IV milk prices established for all Federal milk marketing order areas are the same.'' [34]

The evidentiary record of this proceeding supports and validates the same conclusion that prices used in a California FMMO should reflect the national marketplace for cheese, butter, NFDM and dry whey. The record reflects that commodity products produced in California compete in the same national market as products produced throughout the country. Uniform FMMO price formulas ensure similarly situated handlers have equal minimum raw milk costs regardless of where the handler is regulated, and as California is seeking to join the FMMO system, it is appropriate that the milk pooled on the California FMMO be priced under the same uniform price provisions found in all current FMMOs. Additionally, the record evidence supports the finding that by pricing California milk under these uniform pricing provisions, prices received by farmers whose milk is pooled on the California FMMO would be more reflective of the national market for commodity products for which their milk is utilized. Therefore, adopting a western adjusted price series, a 40-pound only Cheddar cheese price, and California-specific make allowances is not appropriate.

FMMO price formulas already account for California market conditions; therefore, it is reasonable and appropriate to use these price formulas in a California FMMO. This decision finds that the national FMMO pricing policy continues to reflect the marketing conditions of the entire FMMO system and is appropriate for adoption in California.

FMMO product-price formulas generally consist of three factors: commodity price, manufacturing allowance, and yield factor. Product yields contained in the formulas reflect standard industry norms. Yield factors were last updated in 2013,[35] and the record shows that these values continue to reflect current market conditions, as there was no dispute as to their continued relevancy.

Commodity prices used in the FMMO formulas are announced by AMS in the NDPSR every month and reflect current commodity prices received for products over the previous four or five weeks. While surveyed plant names and locations are not released by USDA, several witnesses testified that California dairy product sales meeting the reporting specifications [36] are included in the NDPSR. These California sales are part of the NDPSR prices used by the FMMOs in the same way that sales from plants located in other areas of the United States are currently included. FMMO pricing formulas currently contain the following per-pound make allowances: Cheese—$0.2003, butter—$0.1715, NFDM—$0.1678, and dry whey—$0.1991. These make allowances were last updated in 2013.[37] They were determined on the basis of a 2006 CDFA survey (plants located inside of California) and a 2006 Cornell Program on Dairy Markets and Policy (CPDMP) survey (plants located outside of California) of manufacturing costs. The butter and NFDM make allowances were computed by taking a weighted average of the CDFA and CPDMP surveys, weighted by national commodity production volumes, and adjusting for marketing costs. The cheese make allowance was computed by relying solely on the CDFA survey and adjusting for marketing costs. The dry whey make allowance was computed by relying solely on the CPDMP survey and adjusting for marketing costs. California dry whey data was not considered because at the time it was restricted and therefore not available.

As the record demonstrates, most of the manufacturing allowances already account for California manufacturing costs. In regard to the Institute's position that data used to determine make allowance levels is not current, this decision recognizes 2006 data was used to determine current make allowance levels. Since that time, the Department has not received a hearing request to amend the levels. It may be appropriate to amend these levels in the future, and the Department would evaluate any changes to those levels on

[31] 7 CFR 1000.50 and 1000.52.

[32] Official Notice is taken of Federal Order Reform Final Decision: 64 FR 16026.

[33] Federal Order Reform Final Decision: 64 FR 16026.

[34] Official Notice is taken of: FMMO Class III and IV Final Decision: 67 FR 67906.

[35] FMMO Class III and IV Price Formula Final Rule: 78 FR 24334.

[36] 7 CFR 1170.8.

[37] FMMO Class III and IV Price Formula Final Rule: 78 FR 24334.

the basis of a formal rulemaking record in that proceeding.

Institute witnesses stressed that California manufacturers would be competitively harmed should California FMMO minimum classified prices not reflect a solely western location value. This decision finds that California manufacturers would not face competitive harm with the adoption of the uniform FMMO prices. Western manufacturing handlers who purchase milk pooled on the Pacific Northwest and Arizona FMMOs already routinely pay these prices. The record reflects that the Institute's primary concern was the adoption of the current FMMO price formulas for California, coupled with the adoption of the inclusive pooling provisions contained in Proposal 1. The provisions recommended by this decision allow handlers to elect to not pool milk used in manufacturing as determined appropriate for their individual business operations. Further, the proposed California FMMO provisions would not prohibit handlers and producers from utilizing the Dairy Forward Pricing Program [38] to forward contract for pooled manufacturing milk.

Other Solids Price. Currently, the FMMO system determines the other solids price using the same basic formula used to determine the other component prices: Commodity price, less a make allowance, times a yield factor, using dry whey as the NDPSR-referenced commodity price. As the market price for dry whey moves and is reflected in the NDPSR price, it moves the other solids price moves accordingly.

At the hearing, the Institute proposed an alternative method for computing the whey value in the other solids formula. The Institute argued, in testimony and post-hearing brief, that dry whey is not an appropriate reference commodity for California because little dry whey is produced in the state. Instead, they testified that prices from the more commonly produced WPC–34 should be used. The Institute provided evidence regarding WPC–34 production in California. The record contains testimony explaining how WPC–34 and dry whey production practices and manufacturing costs differ.

This decision finds that the prices adopted in the California FMMO should be uniform with all current FMMOs and be reflective of the dry whey market. Therefore, it is not appropriate on the basis of this hearing record to adopt a change in other solids pricing for only one FMMO. While, the data and testimony presented by the Institute may warrant further consideration for that purpose, to consider such a change for only one FMMO is not appropriate. While an academic expert did provide testimony on the record about a WPC–34 manufacturing cost survey, results of the survey, which would be of interest if such a proposal was being evaluated, were not available.

Comments filed by the Cooperatives in response to the recommended decision supported the Class III and IV price formulas contained in the proposed California FMMO. Their comments reiterated that because manufactured dairy products, including those manufactured in California, compete in a national market, classified prices paid by all regulated handlers should reflect that national market through the uniform, national Class III and IV end-product price formulas.

Additional comments submitted by Select, CDC, and WUD supported adoption of the end-product price formulas contained in the recommended decision. These entities were of the opinion that through national uniform manufacturing prices, California producers would receive the same prices as producers in the rest of the country, and milk movements would be based on economic decisions, not government regulation.

Comments filed by the Institute, Hilmar and Leprino took exception to the classified prices contained in the proposed California FMMO. The Institute maintained that the Department did not properly analyze all record evidence nor indicate what record evidence was accepted and rejected when making its determination. The Institute specifically took exception to the factors contained in the Class III price formula, arguing that they did not take into account local marketing conditions that demonstrate higher manufacturing costs and lower Class III product values. The Institute was of the opinion that the Department provided no basis for why record evidence on whey data was not considered.

Hilmar argued that the Department relied on past decisions and outdated data to wrongly conclude that the proposed California FMMO should contain the same price formulas as the current 10 FMMOs. Hilmar objected to the recommended decision's finding that adoption of the proposed price formulas would not result in competitive harm. Hilmar provided extensive comments on the competitive harm, in the form of loss in manufacturing revenue, profits, or market share they assert would result if the proposed California FMMO is established.

Hilmar reiterated comments similar to the Institute's that the proposed price formulas are not justified because they do not take into account local marketing conditions. It contended that the proposed price formulas would require California manufacturers to pay more for milk than is needed to clear the market and make a profit. Hilmar argued that because the Department did not rule on each proposed finding of fact, interested parties do not know what data did or did not factor into the Department's recommendation.

Hilmar also took exception with the Department's finding that changes to the pricing formulas should be done on a national, not individual market level. Hilmar concluded that adoption of the proposed California FMMO as contained in the recommended decision would, at a minimum, put California manufacturers in a less competitive position than they are in now. It further objected to waiting for a future national hearing to address any changes to the national uniform end-product product formulas.

Leprino was of the opinion that the Department did not consider record evidence regarding local California marketing conditions that they assert should result in different product price formula factors. Leprino wrote the Department incorrectly found the national uniform minimum regulated price structure should remain throughout the FMMO system, including a proposed California FMMO. Leprino reiterated a California FMMO should have different price formulas that recognize the different manufacturing costs, commodity prices received, and whey products produced in California.

Leprino contended that incorporation of Western-based commodity prices and manufacturing allowances, as contained in Proposal 2, was the only method for accurately valuing manufactured dairy products produced in California. It also reiterated support for deriving the whey value in the Class III product price formula through liquid whey rather than dry whey values, the latter being more representative of California whey production.

Leprino noted that a national hearing should be held to address these factors throughout the FMMO system, and that promulgation of a California FMMO should be delayed until such hearing is held.

Comments filed by Cacique Cheese (Cacique), Farmdale Creamery, and Pacific Gold Creamery took exception to the proposed end-product price formulas as appropriate for the California market. Cacique argued that

[38] 7 CFR part 1145.

the recommended make allowances underestimate the cost of manufacturing and should be updated to reflect current costs. Cacique took exception to the Department's finding to price other solids on dry whey, instead of proposed liquid whey. Pacific Gold was of the opinion that regional differences should be accounted for through a Western-based price series and California-specific make allowances.

As detailed above, the primary theme of exceptions filed regarding the recommend price formulas revolve around the assertion that the Department ignored record evidence demonstrating local market conditions warrant different price formulas for California. Commenters suggested that because a California FMMO is only now being proposed, the pricing formulas in a California FMMO must only reflect the local marketing conditions of California. Additional exceptions were raised that the Department did not rule on every proposed finding of fact and only took Official Notice of a selected number of documents that were requested by stakeholders in post-hearing and reply briefs.

The decision to recommend promulgating a California FMMO and its specific provisions was based on the entire hearing record. The record reveals that during Order Reform, end-product price formulas were found to be an appropriate methodology for reflecting the national market for manufactured products as well as the local marketing conditions for the consolidated orders. Because of California's prominence in the national marketplace, California local marketing conditions were considered and factored into the end-product price formulas when those formulas were established, even though California did not join the FMMO system at that time.

As proposed, California regulated handlers would pay FMMO minimum classified prices that already account for their local marketing conditions, rather than a different set of state-regulated prices. By incorporating manufacturing costs and commodity prices received throughout the country, FMMO minimum classified prices reflect national supply and demand conditions. California products, sold throughout the country, are an integral part of the national supply and demand conditions of manufactured products. Therefore, adoption of these national end-product price formulas, without change, into a California FMMO is appropriate as they will continue to include California local marketing conditions and meet the pricing requirement of the AMAA.

It should be noted that regulated handler minimum prices throughout the country are currently affected by California marketing conditions through California plants whose DPMRP prices are incorporated in the NDPSR, and through California manufacturing costs that were incorporated into the current FMMO manufacturing allowances. In a national uniform pricing system, it is appropriate for California plants that become regulated by a FMMO to pay minimum classified prices that likewise incorporate local marketing conditions in other parts of the country through the same factors.

This final decision continues to find that any change to the nationally coordinated pricing system should be considered through a national rulemaking. FMMOs hearings are requested by the industry. To delay implementation of a California FMMO for a national pricing hearing that may or may not be requested, as suggested by some commenters, is not appropriate.

Evidence was introduced in the record regarding specific California manufacturing costs, commodities produced, and prices received. However, the FMMO system has a nationally coordinated pricing system and any changes to that system must be evaluated together in a rulemaking where all industry stakeholders can participate and all factors can be considered. While changes to the nationally coordinated FMMO pricing system may or may not be found to provide for more orderly marketing conditions, the current pricing system already takes into account marketing conditions from throughout the country, including California, which are incorporated in the pricing system on a monthly basis.

Comments received took exception to the finding that adoption of the recommended price formulas would not cause competitive harm by citing examples of reduced revenue, profits, and market share. The REIA released in conjunction with this decision demonstrates there would be an impact in all sectors of the industry and throughout the country. This final decision continues to find the recommended end-product price formulas appropriate for California and clarifies that manufacturers would not face competitive harm in the form of different minimum regulated prices than their competitors located in the other FMMOs.

One comment received stated that because the CSO had already increased prices to offset higher milk production costs, adoption of a California FMMO with higher minimum prices is not warranted. Throughout this decision, it has been repeated that adoption of the recommended end-product price formulas is warranted because they more accurately reflect the national commodity markets where dairy products are sold. The recommended decision did not find, nor does this final decision find, that these price formulas should be adopted in order to offset higher milk production costs, except to the extent that the prices indirectly reflect higher production costs through the supply and demand conditions that generate the resulting commodity prices received.

Some commenters took exception to the fact that the Department did not rule on each offered finding of fact presented in post-hearing and reply briefs. The Department is required to discuss relevant issues and the evidence relied upon in making its findings. The recommended decision encompassed those issues, taking into account arguments made on all sides of the issues presented. Particularized rulings on every argument presented by interested parties are not required.

In its post-hearing brief, the Institute filed a Negative Inference Motion asserting that because the Cooperatives did not enter into the record of this proceeding a study they commissioned evaluating their proposed milk pricing provisions, the Department should conclude that the study results contradict the Cooperatives' justification for adopting the price formulas contained in Proposal 1 without a need to draw any inferences about documents not in the record.

It is left to the discretion of the trier of fact to determine whether or not a negative inference will be drawn from the failure to present any specific piece of evidence under one party's exclusive control. The Department finds that the recommended pricing provisions are properly based on testimony of those witnesses who appeared and the evidence that has been presented by all parties on the record.

Class II Pricing. The FMMO system currently prices milk used in Class II products uniformly. The Class II skim milk price is computed as the advanced Class IV skim price plus $0.70 per cwt. The Class II butterfat price is the Class III butterfat price for the month, plus $0.007 per pound. The $0.70 differential between the Class IV and Class II skim milk prices adopted in the Order Reform Final Decision was an estimate of the cost of drying condensed milk and re-wetting the solids for use in Class II products.

The record reflects, and this decision continues to find, that milk pricing in

the FMMO system should be as uniform as possible. Therefore, this decision finds that Class II pricing in the California FMMO should be the same as in current FMMOs. Class II pricing in the California FMMO would result in forward pricing the skim portion of Class II while pricing butterfat on a current basis. Butterfat used in Class II products competes on a current-month basis with butterfat used in cheese and butter, and its price should be determined on the basis of the same month's value.

No comments or exceptions were received in regard to the Class II price as proposed in the recommended decision.

Class I Pricing. Currently, FMMOs determine Class I prices as the higher of the advanced Class III or Class IV price, plus a location-specific differential referred to as a Class I differential. Class I differentials have been determined for every county in the continental United States, including those in California.[39] Class I prices paid in all current FMMO's are on a skim/butterfat basis. Handlers who fortify their Class I products have the NFDM or condensed skim used to fortify classified as a Class IV use, and pay the Class I price for the volumetric increase attributed to fortification.

The Cooperatives have proposed that the California FMMO adopt the same Class I pricing structure: the higher of the advanced Class III or Class IV price plus a Class I differential based on the plant location. They argued that the Class I price surface was designed as a nationally coordinated structure and already includes differential levels for all California counties. According to the Cooperatives, any change to the Class I differential surface should be done through a national rulemaking hearing where all interested parties can participate.

The Institute argued, in testimony and post-hearing briefs, that the Class I differential surface adopted as part of Order Reform did not consider California in its inception, and is not appropriate for adoption here. The Institute did not offer an alternative.

This decision continues to find that the Class I price formula contained in Proposal 1, and as currently used in all current FMMOs, and proposed in the recommended decision, would be appropriate for the proposed California FMMO. This decision finds that prices for milk pooled on the California FMMO and used in Class I products should be location-specific, since Class I products generally compete on a more local market. Therefore, the Class I differential surface that applies in all current FMMOs continues to be recommended for the California FMMO. As such, Class I prices for milk pooled on the California FMMO would be determined by the higher of the advanced Class III or Class IV milk price announced on or before the 23rd day of the preceding month, adjusted by the Class I differential at a plant's location.

This decision continues to recommend for a California FMMO the same Class I differential surface used in the current FMMOs. Contrary to Institute testimony, this differential surface was determined through a United States Dairy Sector Simulator (USDSS) model that included California supply and demand factors. An academic expert testifying in this proceeding was one of the lead authors of the model and stated that California was included when the model was constructed. This price surface was designed to facilitate the movement of milk to Class I markets without causing disorderly marketing conditions within or across markets. Therefore, it is not appropriate on the basis of this hearing record to make a change to the nationally coordinated Class I price surface.

Prior to January 1, 2000, there were 31 FMMOs. As part of the 1996 Farm Bill, the Department was instructed by Congress to consolidate the existing orders into as few as 10, and no more than 14, FMMOs, reserving one place for California. Since California stakeholders did not express a desire to enter the FMMO system at that time, the Order Reform process only considered the FMMO marketing areas in existence at the time for consolidation. In the Order Reform Final Decision, the reference to ''not including the State of California''[40] pertained to determining appropriate consolidated marketing areas, not the analysis pertaining to Class I pricing, which included California.

Comments filed by the Cooperatives supported the proposed Class I price surface and concurred that California market conditions were considered when the surface was first established. Their comments stressed that the nationally coordinated price surface accounted for California market conditions and is appropriate for adoption in the proposed California FMMO.

Exceptions filed by the Institute in response to the recommended decision continued to assert that California was not considered when the price surface was developed and the Department did not provide an evidentiary citation from which to conclude otherwise. The Order Reform Recommended Decision outlined the committee process undertaken by the Department to address specific issues during the Reform process. The decision explained that partnerships were established with two university consortia to provide expert analysis on issues relating to price structure. The decision referenced two published papers by researchers at Cornell University, ''U.S. Dairy Sector Simulator: A Spatially Disaggregated Model of the U.S. Dairy Industry'' (USDSS) and ''An Economic and Mathematical Description of the U.S. Dairy Sector Simulator''.[41] The Department also explained the USDSS model results were used as a basis for developing the Class I price surface.[42]

The ''U.S. Dairy Sector Simulator: A Spatially Disaggregated Model of the U.S. Dairy Industry'' paper[43] expressly explains how the USDSS transshipment model took into account milk production, manufacturing and consumption points for all states, including California. This final decision continues to find that California marketing conditions were accounted for in the development of the FMMO Class I price surface, and therefore inclusion of that price surface in a California FMMO is appropriate.

The Institute argued in their exceptions the Department did not take into account changes in the dairy industry after Federal Order Reform which should lead to a finding that a different price surface for California is justified.

As reiterated in other parts of this decision, establishing a California FMMO is not done in isolation. California is seeking to enter a Federally regulated system with current policy predicated on a system of nationally coordinated regulated prices. This includes the current Class I price surface. The record of this proceeding demonstrates that California market conditions, which continue to be reflected in the price formulas, were considered when the end-product pricing and Class I price surface provisions were developed. This nationally coordinated system has been

[39] 7 CFR 1000.52.

[40] Federal Order Reform Final Decision: 64 FR 16044.

[41] Federal Order Reform Proposed Rule: 63 FR 4802.

[42] Federal Order Reform Proposed Rule: 63 FR 4807.

[43] Official Notice is taken of: Cornell University: *U.S. Dairy Sector Simulator: A Spatially Disaggregated Model of the U.S. Dairy Industry,* November 1996. *https://dairymarkets.org/pubPod/pubs/SP9606.pdf.*

in place since January 1, 2000, and this decision does not find it appropriate on the basis of this record to alter the system for one region of the country.

Three-Factor FMMO Class I Pricing and Fortification. The Institute proposed that California Class I prices be paid on a 3-factor basis: Butterfat, nonfat solids, and fluid carrier, as well as incorporate a fortification credit similar to what is currently provided for in the CSO. The fortification credit offered in Proposal 2 provides a credit to a Class I handler's pool obligation for the NFDM or condensed skim milk a handler uses to fortify Class I products to meet the State's higher nonfat solids content requirement. The proposed fortification credit would be paid out of the California FMMO marketwide pool funds.

The Institute explained these two features are currently provided for in the CSO and work together to financially assist Class 1 handlers in meeting the State-mandated higher nonfat solids content for Class 1 products. The Institute explained that handlers receiving high solids milk pay a higher Class 1 price, but use less solids to fortify Class 1 products, and thus incur less cost to meet the state's nonfat solids standards for fluid milk products. Conversely, handlers purchasing low solids content milk pay a lower Class 1 price, but then incur a higher cost to fortify their Class 1 products. The Cooperatives supported this concept in their post-hearing brief.

The record of this proceeding does not contain sufficient evidence to justify deviation from the uniform FMMO treatment of Class I pricing. Therefore, Class I milk pooled on the proposed California FMMO is proposed to be paid on a skim and butterfat basis. This uniform treatment would avoid disorderly marketing with adjacent or other Federal orders, as otherwise handlers could engage in inefficient milk movements solely for the purpose of seeking a Class I price advantage.

Comments and exceptions received in response to the recommended decision uniformly supported 3-factor Class I pricing.

The Institute, Dean, HP Hood, and Kroger requested that the Department reconsider this issue. The Institute was of the opinion that the State-mandated higher nonfat solids standard, a local marketing condition, should be recognized in the California FMMO through 3-factor Class I pricing and the fortification allowances outlined in Proposal 2.

Dean said the Department did not provide an adequate justification to reject 3-factor Class I pricing, which they contend would prevent disorderly marketing conditions and was supported by the Cooperatives in their reply-brief. Dean reiterated its hearing arguments that 3-factor Class I pricing is necessary to avoid unequal raw product costs for products requiring fortification to meet state-mandated standards and would remove incentives for processors to seek higher nonfat solids content producer milk. Dean contended that without 3-factor Class I pricing, fortification costs between handlers would vary such that handlers would face non-uniform raw milk costs for the same end product. Dean wrote that the Department erred when finding for uniform Class I pricing among all FMMOs instead of recognizing the local California marketing conditions that Dean contends require 3-factor Class I pricing.

Comments filed by the Cooperatives and CDC supported the reconsideration of 3-factor Class I pricing but did not support reconsideration of the fortification credits denied in the recommended decision.

This decision continues to find that additional fortification credits as contained in Proposal 2 are not justified. The record indicates the CSO fortification credit system was designed in response to California's legislatively mandated higher nonfat solids standard for Class 1 products. The record does not address how incorporation of the CSO fortification credit system would operate in the context of the existing FMMO fortification classification provisions without resulting in a double credit for fortification. Dean contends in their exceptions that the proposed fortification credits are for the handling of fortification ingredients, not a reduction in the cost of those ingredients and therefore would not be double counting.

The record indicates the current CSO fortification credit system accounts for the fortification ingredients as Class 1 and then provides the handler with a per pound fortification credit based on the amount of the nonfat solids in the fortifying ingredient used. This is different than how current FMMOs provide for fortification by allocating the fortifying ingredients to Class IV, and then classifying the incremental volume increase as Class I. If the fortification credits provided for in Proposal 2 were adopted, it would result in the handler not only receiving the lower Class IV allocation for its fortifying ingredients (as opposed to accounting for them as Class 1 as is currently done under the CSO), but they would then also receive a handling credit based on the amount of product used to fortify. This would result in the handler receiving two forms of credit for fortifying, as opposed to only one form of credit currently provided for in some way in both the FMMO and CSO.

Furthermore, the record of this proceeding does not provide a justification for why the fortification credit levels contained in Proposal 2 are appropriate. Those credit levels, of $0.1985 per pound of nonfat solids in nonfat dry milk and $0.0987 per pound of nonfat solids in condensed milk, were established by CSO. No evidence was presented at the hearing to justify how the credits for handling were determined and why they might still be set at appropriate levels.

In regard to 3-factor pricing, record evidence offered by proponents concentrated on the pricing impact for reduced fat and lowfat milk products that have to be fortified to meet minimum state requirements using theoretical component tests for milk supplies. While record evidence does examine how 3-factor pricing would equalize costs between reduced fat and lowfat products, the analysis is incomplete as it does not address the net effect of such pricing across all Class I products, including whole and nonfat milk. Considering that a typical fluid processor makes a full array of Class I products, the total impact must be considered, given that each product has its own associated costs per gallon and a fluid processor would not typically process one or two products. Lastly, theoretical component tests may provide an understanding of relationships in manufacturing costs of different products. However, in the absence of actual tests of Class I handler milk supplies and an analysis encompassing the net effect across all Class I products, record evidence is not sufficient to justify deviation from 2-factor pricing of Class I milk.

Producer's Value of Milk

Currently, six of the 10 FMMOs utilize multiple component pricing to determine both the handler's and producer's value of milk. In those six orders, producers are paid for the pounds of butterfat, pounds of protein, pounds of other solids of milk pooled, as well as a per hundredweight (cwt) price known as the producer price differential (PPD). The PPD reflects the producer's pro rata share of the value of Class I, Class II, and Class IV use in the market relative to Class III use. The Class III butterfat, protein, and other solids prices are the same component prices charged to handlers based on the value of the use of milk in Class III. In four of these six FMMOs, there is an

adjustment to the producer's payment for the somatic cell count (SCC) of the producers' milk.

Proposal 1 and Proposal 2 seek to pay producers on a multiple component basis for the milk they produce. As will be discussed below, the proposals differ on how they would apply a PPD to producer payments. Unlike Proposal 2, Proposal 1 does not specify a somatic cell adjustment to the producer's value of milk.

The record reflects that milk use in California is concentrated in manufactured dairy products. In 2015, California Class 1 utilization was 13 percent, Class 2 and Class 3 utilization combined was 8.6 percent, while 78.4 percent was used in Class 4a and Class 4b products (cheese, butter and dried milk powders). As California is clearly a manufacturing market, it is appropriate for producers to be paid for the components they produce that are valued by the manufacturers. Therefore, this final decision continues to recommend producer payments on a multiple component basis. Producers would be paid for the butterfat, protein, and other solids components in their producer milk and for the cwt of milk pooled.

This decision continues to propose that producers under the proposed California FMMO be paid a PPD calculated in the same manner as in six current FMMOs. The PPD represents to the producer the value from the Class I, Class II, and Class IV uses they are entitled to share for supplying the market and participating in the FMMO pool. In general, the PPD is computed by deducting the Class III component values from the total value of milk in the pool, and then dividing the result by the total pounds of producer milk in the pool. The PPD paid to producers participating in the California FMMO pool would be adjusted to reflect the applicable producer location adjustment for the handler location where their milk is received.

Therefore, under the proposed California FMMO, the minimum payment to producers would be determined by summing the result of: Multiplying the hundredweight of a producer's milk pooled by the PPD adjusted for handler location; multiplying the pounds of butterfat in the producer's milk by the butterfat price; multiplying the pounds of protein in a producer's milk by the protein price; and multiplying the pounds of other solids in a producer's milk by the other solids price.

Proponents of Proposal 1 proposed distributing the PPD value across the butterfat, protein and other solids components, based on the average value each component contributed to the Class III price during the previous year. The Cooperatives purported that the PPD is confusing to producers, particularly when it is negative, and spreading the value of the PPD across the components would be a simpler method of distribution.

The PPD is the difference between value associated with all the milk pooled during the month and the producers' value for the butterfat, protein, and other solids priced at the Class III component prices for the month. In general, if the marketwide utilization value of all milk in the pool, on a per cwt basis, is greater than the marketwide utilization value of the producer's components priced at Class III component values, dairy farmers receive a positive PPD.

A negative PPD occurs when the value of the priced producer components in the pool exceeds the total value generated by all classes of milk. This is possible since all producer components are priced at the Class III components values, but pooled milk is utilized in all four classes, each with its own separately derived value.

Specifically, negative PPDs can happen when large increases occur in NDPSR survey prices from one month to the next, resulting in the Class III price (announced at the close of the month) exceeding, or being in a close relationship to, the Class I price (announced in advance of the month). Negative PPDs can also occur in markets with a large Class IV use when the Class IV price is significantly lower than the Class III price. A negative PPD does not mean that there is less total revenue available to producers. It often means the Class III component values are high relative to Class I prices. Because component values are the biggest portion of a producer's total revenue, high component prices coupled with negative PPDs often result in higher *overall* revenue to producers than when component prices are lower and PPDs are large and positive.

This final decision does not find justification for distributing the PPD through the component prices as offered in Proposal 1. Current FMMO producers receive and understand that the PPD represents the additional value from the higher classified markets that they are able to share because they participate in the FMMO. This includes months when the PPD is negative.

While the proponents claim a negative PPD is confusing, this decision continues to find that distributing the PPD through the component prices would distort market signals to producers. As in the current FMMOs, a negative PPD in the California FMMO would inform producers that component values are rising rapidly. Regulated FMMO prices should not block those market signals. Producers in other FMMOs have been able to adapt to a multiple component pricing system that incorporates an announced PPD. This decision finds that California producers can do the same.

Comments filed by the Cooperatives, the Institute and MPC in response to the recommended decision expressed support for the proposed producer milk pricing provisions. The Cooperatives noted in their comments they did not object to the PPD provisions as proposed in the recommended decision.

Comments filed by NAJ also expressed support for the producer payment provisions, and contended any changes to the producer price formulas should occur through a national hearing.

Four of the current FMMOs provide for a SCC adjustment on producer milk values. The CSO does not include any such adjustment. Proposal 1 did not include a provision for a SCC adjuster, and a Cooperative witness specifically testified against its inclusion. Proposal 2 included a SCC adjuster, but no Proposal 2 witnesses testified regarding this aspect of their proposal. This final decision does not recommend a SCC adjuster for the California FMMO, as the record does not contain evidence to support its inclusion.

This final decision proposes that handlers regulated by the California FMMO should be allowed to make various deductions from a producer's milk check, identical to what is allowed in the current FMMOs. These deductions include such things as hauling expenses and National Dairy Promotion Program charges, as well as other authorized deductions such as insurance payments, feed bills, equipment expenses, and other dairy-related expenses. Authorized deductions from the producer's check must be authorized in writing by the producer. For the California FMMO, authorized deductions would necessarily include any assessment identified by CDFA for the payment of California quota values. A quota assessment would be authorized upon announcement by CDFA; it would not have to be authorized in writing by the producer.

Some hearing witnesses suggested that changes to the FMMO pricing system need to be considered in a separate rulemaking proceeding before California producers vote on a FMMO. Similar arguments were presented in

some comments and exceptions filed in response to the recommended decision. This final decision finds no justification for California producers to wait for a decision on a California FMMO until after what would most likely be a lengthy proceeding on national FMMO pricing. California producers should have the opportunity to vote on whether to join the FMMO system and adopt the provisions recommended in this decision with the full awareness that prices can be re-evaluated at a future hearing.

8. Pooling

This section addresses the pooling provisions of the proposed California FMMO. A summary of the proposals, hearing testimony, post-hearing briefs, and comments on and exceptions to the recommended decision related to pooling provisions is provided below. Additionally, the proposed treatment of out-of-state milk is addressed in this section, as one of the initial proposals submitted to AMS sought to allow handlers to elect partially regulated distributing plant status with respect to milk received from farmers located outside of the marketing area. The proposal would have continued the reported practice of handlers paying the plant blend price—instead of the market's blend price—for milk produced from outside of the state, since such interstate transactions cannot be regulated by the CSO. Essentially, the proposal addressed whether out-of-state milk should be incorporated into the proposed California FMMO marketwide pool. Therefore, the topic is addressed in this section.

This final decision recommends pooling provisions for a California FMMO conceptually similar to those in the 10 current FMMOs, but tailored for the California market. The recommended pooling provisions are performance-based and are designed to identify those producers who consistently supply the Class I market and therefore should share in the revenues from the market. There would be no regulatory difference in producer payments for milk based on the location of the dairy farm where it was produced.

Summary of Testimony

A Cooperative witness testified regarding the pooling provisions contained in Proposal 1. The witness said the Proposal 1 pooling provisions are designed to address the wide disparity between current producer and handler prices in California and those under the FMMO system. The witness stated that in order to design adequate California pooling standards, the Cooperatives evaluated historical producer blend prices using both CSO classified prices and the proposed California FMMO classified prices, from January 2000 through July 2015. The witness estimated that producer blend prices would have averaged $14.65 per cwt using CSO classified prices and $15.22 per cwt using the proposed California FMMO classified prices, an average difference of $0.57 per cwt. The witness's analysis showed that in every month, the estimated CSO blend price was less than the FMMO blend price, and that when considering only the most recent data (January 2015 through July 2015), the average difference was $0.86 per cwt. The witness stressed that to bring California producer blend prices into closer alignment with FMMO producer blend prices, the pooling provisions of a California FMMO must require the pooling of all classified use values.

The witness was of the opinion that California's combination of low utilization in the higher valued classes (Class 1, 2, and 3) and a state-administered quota program requires strict pooling provisions to prevent handlers from electing not to pool a significant portion of California milk each month. The witness was of the opinion that when the California overbase price is below Class 4a or 4b prices, there is an incentive to not pool milk in those classes because the handler can avoid a payment into the marketwide pool. The witness stated that from January 2000 through July 2015, the California overbase price was below either the Class 4a or 4b price 91 percent of the time. Thus, in those months, if all milk had not been pooled, producers would have received different minimum prices: Those producers whose milk was pooled would have received the minimum FMMO blend price, while the producers whose milk was not pooled would have had the potential to receive a higher price because the handler could have avoided sharing the additional revenue with all the producers in the market through the marketwide pool. This concern regarding producer price disparity was reiterated in the Cooperatives' post-hearing brief.

The Cooperative witness added that even after adjusting producer blend prices to account for quota payments (−$0.37), transportation credits (−$0.09), and RQAs ($0.03), there would have been a financial incentive to not pool a significant portion of California milk in most months. Using the pricing provisions contained in Proposal 1, the witness estimated that from August 2012 through July 2015, handlers would have chosen not to pool Class III or Class IV milk 94 percent of the time. The consequence, the witness emphasized, would not only be unstable producer prices, but the inability of the FMMO to achieve uniform producer prices. The witness stressed that to accumulate the revenue needed to provide adequate, uniform producer blend prices and facilitate orderly marketing, all the milk delivered to California plants must be pooled. Provisions requiring all milk to be pooled cannot be found in any other current FMMO.

However, the witness explained that FMMO pooling provisions have always been tailored to the market, and the pooling provisions contained in Proposal 1 are no different. The Cooperatives' post-hearing brief stressed California's need to have tailored pooling provisions that are different from other FMMOs. The Cooperatives' brief reiterated that allowing for milk to not be pooled would inhibit a California producer's ability to receive the national FMMO prices they are seeking.

The Cooperative witness proceeded to describe the pooling provisions contained in Proposal 1. The witness explained that under Proposal 1, any California plant receiving milk from California farms would be qualified as a pool plant, and all California milk delivered to that plant would be qualified as producer milk. The witness said Proposal 1 also provides for plants located outside of the marketing area that demonstrate adequate service to the California Class I market to qualify as pool plants on the order. The witness highlighted an additional provision that would regulate all plants located in Churchill County, Nevada, and receiving milk from farms located in Churchill County or California. According to the witness, producers in the Churchill County milkshed have historically supplied milk to the California Class 1 market, and this provision would ensure they could remain affiliated. The witness proposed the partially regulated distributing plant (PRDP) provision should be the same as in other FMMOs: A plant qualifies as a PRDP if not more than 25 percent of its total route disposition is within the marketing area.

The Cooperative witness defined a producer as any dairy farmer producing Grade A milk received by a pool plant or a cooperative handler. This definition would allow dairy farmers located inside or outside of the marketing area to qualify as producers under the order, the witness added. The witness said a majority of the producer milk pooled on

a California FMMO would be milk received by a pool plant directly from qualified producers or cooperative handlers. Proposal 1 also contains a provision to allow producer milk to be pooled on the order if the milk is received by a cooperative handler, the witness noted.

The Cooperative witness explained that Proposal 1 would prohibit milk from being diverted to nonpool plants outside of the marketing area and qualifying for pooling on a California FMMO until five days' production is delivered to a pool plant; subsequent diversions would be limited according to the amount the plant delivers to distributing plants. The witness said the California market appears to have an adequate reserve supply of Class I milk, so strict diversion limit standards are needed to ensure that additional milk being pooled is needed in the market.

The Cooperative witness provided examples of previous FMMO changes that the witness described as significant policy shifts, including the elimination of individual handler pools in favor of marketwide pools, the regulation of large producer-handlers, adoption of multiple component pricing, and the establishment of transportation credit programs. The witness said that in these examples the Department found it appropriate to significantly deviate from historical precedent because market conditions justified such changes. The witness stated Federal Order Reform provided a FMMO foundation national in scope, while also allowing for some provisions to be tailored to meet the marketing conditions of individual orders. The witness concluded the AMAA provides the Department the flexibility to tailor pooling provisions, and Proposal 1 recognizes the unique needs of the California market.

Another Cooperative witness offered testimony modifying Proposal 1 to include call provisions. The witness explained that call provisions are currently contained in the CSO, and while not often utilized, their existence alone encourages milk to be supplied to fluid processing plants when needed. As proposed, the witness said, call provisions should only be used on a temporary basis when the market's milk supply cannot meet distributing plant demand, not when an individual distributing plant is short on milk.

The Cooperatives' post-hearing brief reiterated the justification for the inclusive pooling provisions contained in Proposal 1. The brief stressed the AMAA authorizes the pooling of milk, irrespective of use.

The Cooperatives' post-hearing brief also offered a modification to extend exempt plant status to small plants that process products other than, or in addition to, fluid milk products. The modification would increase the exempt plant production limit from route sales under 150,000 pounds of fluid milk product to sales under 300,000 pounds of milk in Class I, II, III or IV products during the month. The brief explained this would allow for small fluid and manufacturing plants to be exempt from the pricing and pooling provisions of the order that would otherwise be required to participate in the marketwide pool under Proposal 1.

A witness testifying on behalf of WUD said that without inclusive pooling provisions, as outlined in Proposal 1, handlers could opt not to pool large amounts of milk. The witness said this would have a substantial impact on the pool value and consequently lower blend prices to those producers who remain pooled.

An Institute witness testified regarding the pooling provisions contained in Proposal 2. The witness explained how current FMMO provisions work together to assure an adequate milk supply for fluid use. First, said the witness, higher Class I revenues attract producers and producer milk to participate in the pool, then pooling provisions direct the producer milk to fluid plants. Class I plants, which by regulation are required to be pooled and pay the higher Class I price, receive in exchange the assurance that the regulations provide them an adequate supply of milk, the witness explained. The witness summarized a previous USDA decision finding that performance-based pooling provisions are the appropriate method for determining those producers who are eligible to share in the marketwide pool. The witness stressed performance-based pooling provisions are essential in maintaining orderly milk movements to Class I.

The Institute witness objected to the Cooperatives' assertion that Class I premiums would be sufficient to move milk to Class I use. The witness was of the opinion that Class I plants already pay a high regulated Class I price and they should not have to pay additional over-order Class I premiums to attract milk to their plant. The witness questioned the purpose of Class I differentials if the use of premiums would be the primary way to attract milk for fluid uses in a California FMMO.

The Institute witness also spoke to Proposal 1's dependence on transportation credits to ensure the Class I market is served. The witness was of the opinion that transportation credits are not an appropriate substitute for performance-based pooling standards.

The Institute witness testified that Proposal 1 provides no incentive for plants to serve the Class I market in order to qualify its producers to share in the market's Class I revenues. Instead, said the witness, Proposal 1 would allow plants to gain access to Class I revenues for their producers without bearing any burden in servicing the Class I market, thus making pooling provisions ineffective.

Another issue the Institute witness highlighted was inclusive pooling provisions in combination with regulated classified prices that are not market-clearing. The witness asserted that if regulated classified prices are set above what plants can pay for that milk, many of those plants would exit the industry and available market plant capacity would shrink. According to the witness, this would lead to uneconomic milk movements, as excess milk would need to find willing processing capacity.

The Institute witness opposed Proposal 1's provision to automatically grant pooling status to any dairy manufacturing plant located in Churchill County, Nevada. The witness said that all plants, whether located in state or out of state, should qualify for pooling by meeting appropriate performance-based pooling standards.

The Institute witness concluded that pooling standards play a pivotal role in ensuring consumers an adequate supply of fluid milk. Inclusive pooling challenges the usefulness of pooling standards by allowing producers and handlers to benefit from the pool without actually being required to serve the Class I market, the witness said. The witness urged the Department to adopt the performance-based pooling standards contained in Proposal 2.

The Institute's post-hearing brief reiterated its position that the Department's policy has consistently ensured marketwide pool proceeds are distributed to those who demonstrate service to the Class I market. The brief maintained this standard should be upheld through performance-based pooling standards in a California FMMO. The Institute stressed the inclusion of provisions to recognize the California quota program is not an adequate justification to exclude performance-based pooling standards.

The Institute also raised the issue in its post-hearing brief that adoption of mandatory pooling in California would result in trade barriers prohibited by the AMAA. The brief stressed that with no way to avoid minimum regulatory pricing, California handlers would be at

a disadvantage, since handlers regulated by other FMMOs can elect not to pool milk and avoid minimum regulated prices. The Institute was of the opinion that if manufacturing handlers couldn't elect not to pool, they would be discouraged from expanding plant capacity to handle surplus milk because they would be required to pay prices above market-clearing values for that surplus. Lastly, as it pertains to the proposed pooling provisions, the Institute expressed the opinion that inclusive pooling would de facto regulate farmers, something expressly prohibited by the AMAA.

A Dean Foods witness, on behalf of the Institute, testified regarding specific pooling provisions contained in Proposal 2. The witness revised Proposal 2 and expressed support for the distributing plant in-area route disposition standard of 25 percent offered by the Cooperatives. The witness explained the Class I route disposition levels that determine a plant's pool status are set by each of the individual orders, depending on the Class I utilization of the market, among other factors. The witness was of the opinion that a 25 percent in-area route disposition standard is appropriate for a California FMMO with a low Class I utilization.

The Dean Foods witness also supported the unit pooling provision provided in Proposal 2. The witness testified that the unit pooling provision would allow two or more plants, operated by the same handler and located in the marketing area, to qualify for pooling as a unit by meeting the total and in-area route disposition standards as an individual distributing plant. Proposal 2 would require one of the plants to qualify as a distributing plant and other plant(s) in the unit to process 50 percent or more of the total milk processed or diverted by the plant into Class I or II products.

The witness expressed concern that the pooling provisions contained in Proposal 1 would not ensure an adequate milk supply to meet Dean Foods' needs because the provisions offered no incentive to supply Class I plants.

A Hilmar consultant testified on behalf of the Institute regarding the pool supply plant performance standards contained in Proposal 2. The witness explained the proposed supply plant performance standards and diversion limits would establish the volume of milk that could be associated with the California marketwide pool. The witness said that 10 percent is an appropriate base shipping standard for supply plants seeking to be pooled on a California FMMO. The witness explained this standard is similar to that in the Upper Midwest FMMO, which has a similar Class I utilization. The witness described Proposal 2's sliding scale system that would automatically change the supply plant shipping standard based on market Class I utilization over the previous three months. The witness was of the opinion that the sliding scale system would ensure the Class I market is adequately served by automatically adjusting, should there be a change in the market's Class I utilization.

The Hilmar consultant witness also described different performance standards proposed for pool supply plants that receive quota milk. Proposal 2 would require 60 percent, or a volume equivalent, of a pool supply plant's quota receipts to be delivered to pool distributing plants, the witness said. The witness was of the opinion this additional requirement on quota milk would ensure that Class I needs would always be met. However, if additional milk is needed, that responsibility would fall first on quota milk, as the Market Administrator would have the ability to adjust the quota milk shipping standard up to 85 percent if warranted. The witness added that this additional standard on quota milk is similar to provisions in the CSO.

The Hilmar consultant witness also testified that servicing the fluid milk needs of the market, the responsibility of quota milk to service the fluid market, and flexibility and supply chain efficiency should guide the Department in its decision making. The witness highlighted additional proposed provisions that would provide regulatory flexibility, such as allowing for split-plants, the pooling of supply plant systems, and a provision to allow the Market Administrator to investigate market conditions and adjust shipping percentages if warranted by current market conditions.

The Hilmar consultant witness also addressed what Hilmar believes are appropriate producer milk provisions for a California FMMO, namely provisions modeled after the Upper Midwest FMMO. The witness was of the opinion that an appropriate producer touch-base standard would be the lesser of one-day's production or 48,000 pounds of milk, delivered to a pool plant during the first month the dairy farmer is a producer. In the following months, explained the witness, the producer's milk would be eligible for diversion to nonpool plants and still be pooled and priced under the terms of a California FMMO. The witness testified that handlers should not be allowed to pool more than 125 percent of the volume they pooled during the previous month, except during March when the appropriate limit should be 135 percent, due to the fewer number of days in February. The witness testified that the Institute relied on justification and methodology provided in Upper Midwest FMMO rulemaking decisions to determine appropriate repooling standards for a California FMMO.

In addition, the Hilmar consultant witness said that a California FMMO should not allow milk to be simultaneously pooled on a FMMO and a State order with marketwide pooling. Handlers, or a group of handlers, should be penalized if they attempt to not pool large volumes of Class III or Class IV milk to avoid pooling standards, the witness added.

A Leprino witness expressed opposition to mandatory-regulated minimum prices as advanced in Proposal 1. The witness characterized the inclusive pooling provisions of Proposal 1 as actually being mandatory minimum pricing provisions because they would cause all California milk to be pooled and priced under the terms of the FMMO. The witness explained how the CSO has applied minimum regulated pricing to all Grade A milk produced and processed in the state for decades, which the witness believed has led to negative market impacts. For example, the witness described how mandatory pricing and pooling has reduced competition across manufactured product classes and lessened incentives for milk to move to higher-valued uses.

The Leprino witness did not characterize the CSO as disorderly, but rather explained how there had been periods of dysfunction when CDFA set regulated minimum prices that exceeded market-clearing levels, leading to overproduction of milk. The witness added that when there have been periods of large milk surpluses, milk has been shipped and sold outside of the state at discounted rates. The witness said this led to losses for California producers that could have been reduced under a more flexible regulatory scheme.

The Leprino witness stressed that a California FMMO should have voluntary pricing and pooling for manufactured milk, as is the case in all other FMMOs. The witness was of the opinion this promotes market efficiency, allowing milk to move to its highest valued use. In its brief, Leprino stated that the inclusive pooling provisions that would regulate all milk are over-reaching and inconsistent with the goals of the AMAA. Leprino stated that

inclusive pooling standards combined with overvalued pricing formulas would result in a disorderly California market.

Another witness appeared on behalf of HP Hood in support of adoption of Proposal 2. HP Hood operates fluid milk processing facilities in California and in existing FMMO areas, and is a member of the Institute. The witness testified that if a California FMMO were adopted that included inclusive pooling, there would be an oversupply of California milk, leading to decreased investment in dairy product manufacturing facilities. The witness supported a California FMMO that allows for optional milk pooling for non-fluid milk uses.

A Gallo Farms consultant witness testified that unlike under other FMMOs, Proposal 1 would not allow handlers the option not to pool manufacturing milk, which would lead to disorderly marketing conditions and increased operational costs for cheese plants. The witness supported the ability of cheese plants to elect not to pool milk, as provided in Proposal 2.

A witness spoke on behalf of Nestle S.A. (Nestle) in support of Proposal 2. Nestle is the world's largest food company, headquartered in Switzerland. Its U.S. operations include Nestle USA, Nestle Nutrition, Nestle Purina Pet Care Company, and Nestle Waters North America.

The Nestle witness was of the opinion that milk marketing in California is orderly. However, if a California FMMO is adopted, Nestle supports Proposal 2, which would allow for optional pooling of manufactured milk. The witness stated that in all current FMMOs, handlers have the option to pool manufacturing milk. Inclusive pooling as contained in Proposal 1, according to the witness, would place Nestle at a disadvantage with competitors in other FMMOs that can avoid regulated minimum prices. Should mandatory pooling standards, in conjunction with the higher regulated prices contained in Proposal 1 be adopted, the witness asserted that Nestle would seek to move more of its manufacturing outside of the state.

The Nestle witness added that the vast majority of the manufactured dairy powder products it utilizes in its international plants are purchased in California. The witness said that if California regulated prices increase and pooling becomes mandatory, Nestle would look elsewhere globally to replace those products. The witness concluded that Nestle would like to see a consistent approach to regulations in all FMMOs so that its business could continue to be competitive and grow.

Proposal 4 was submitted by Ponderosa Dairy (Ponderosa) in response to the Cooperatives' original Proposal 1. Proposal 4 would amend the provisions that regulate payments by a handler operating a partially-regulated distributing plant—under either Proposal 1 or Proposal 2—to allow handlers to elect partially regulated distributing plant status with respect to milk received from out-of-state farms.

A consultant witness on behalf of Ponderosa testified in support of Proposal 4. The witness described past judicial decisions regarding the treatment of out-of-state milk delivered to California handlers. According to the witness, out-of-state producers cannot currently obtain quota, are not eligible for transportation benefits under the CSO, and do not participate in the CSO marketwide pool. Instead, the witness said, they negotiate separate prices with the California handlers who buy their milk. The witness speculated that out-of-state producers receive the plant's blend price, although that practice is neither enforced nor verified by CDFA. The Ponderosa consultant witness outlined the provisions of Proposal 4, which would modify the standard payment provisions for partially-regulated plants under a California FMMO.

Proposal 4 would allow California handlers to elect partially-regulated status with respect to milk from out-of-state producers, and out-of-state milk would be classified according to the plant's overall utilization and receive the plant blend price. Since the milk would not be pooled under the FMMO, it would not necessarily receive the marketwide blend price. The witness clarified that although the out-of-state milk would be isolated for payment purposes, the handler's status as a fully regulated pool plant should not be lost if it otherwise meets the definition of a pool plant.

The Ponderosa consultant witness said that features of Proposal 4 are similar to those of individual handler pools that are no longer provided in the FMMO system. Such accommodation is needed, the witness said, to counter the inherent inequalities of California's unique quota system, which would otherwise disadvantage out-of-state producers. In the witness's opinion, the provisions of Proposal 4 should be contained in any California FMMO recommended by the Department, as they would establish a regulated and audited pricing mechanism to ensure out-of-state producers receive at least the price they would have if they shipped to an otherwise fully-regulated plant—something that is not provided in the CSO.

A witness representing Ponderosa explained that Ponderosa Dairy was founded in southern Nevada to supply raw milk to the Rockview plant in southern California with the expectation of receiving the plant blend price reflective of Rockview's plant utilization even though the plant was regulated by the CSO. With a Class 1 utilization of approximately 85 percent, the witness said that the plant blend price compensates Ponderosa for its inability to participate in the California quota program and for the higher transportation expenses to haul its milk 280 miles to Rockview.

Another Nevada producer, representing Desert Hills Dairy (Desert Hills), a dairy farm with 4,000 cows that delivers 50 percent of its production to California processing plants, testified in opposition to any California FMMO. However, the witness said that should a FMMO be adopted, Proposal 4 should be included as it most closely resembles the current CSO provisions for out-of-state milk. The witness testified that Desert Hills receives the plant blend price for the milk shipped to California, and that the dairy farm pays all transportation costs. The Desert Hills witness said it would be harmed financially if Proposal 4 is not adopted. Otherwise, the witness claimed, its milk would be pooled on a California FMMO and the price it currently receives for milk shipped to California would be reduced by more than $1.00 per cwt.

Without addressing Ponderosa's concern that out-of-state producers are unable to own quota, the Cooperatives modified Proposal 1 in their post-hearing brief. Modified Proposal 1 would provide for the payment of a blend price adjuster to out-of-state producers so that those producers' total receipts would not be diminished by the deduction of quota premium payments from the marketwide pool.

The Cooperatives' brief argued that out-of-state producers have taken advantage of the fact that the CSO cannot regulate out-of-state milk and have sold milk to California Class 1 handlers for prices higher than the CSO regulated blend price but lower than the CSO classified use value. According to the Cooperatives, modified Proposal 1 would not erect trade barriers as it would provide for uniform payment to California producers in similar circumstances by establishing uniform payments for milk covered by quota, and establishing a uniform blend price for milk not covered by quota.

An Institute witness explained that under Proposal 2, out-of-state producers

would receive the traditional FMMO blend price for their milk pooled on a California FMMO. That blend price, the witness said, would be determined before the value of quota is deducted from total marketwide pool revenues. According to the witness, out-of-state producers, who could never own quota under California's current laws, and in-state producers should be paid uniformly through a traditional FMMO blend price calculation.

The Institute witness explained they originally considered proposing the establishment of two marketwide pools or blend price calculations. The first would pay out-of-state producers, and then the second would recalculate and apportion all the remaining funds to California producers in the pool on the bases of quota/non-quota prices and whether handlers elected to pool their milk. But the witness said that upon further consideration they realized this solution would present additional problems.

The Institute witness provided hypothetical examples of two producers shipping into the same California plant receiving different prices by virtue of their farms' locations. The witness was of the opinion that this treatment would erect a trade barrier, provide non-uniform payments to producers, and violate the AMAA.

The Institute witness said Proposal 2 would address these issues by providing for out-of-state producers to receive the traditional FMMO blend price for their milk pooled on a California FMMO. According to the witness, no trade barrier would be erected with respect to out-of-state milk by paying the traditional blend to out-of-state producers rather than the non-quota price. A consultant witness representing Hilmar supported the Institute's position regarding the treatment of out-of-state milk.

Ponderosa's reply brief argued that the Cooperatives' proposed remedy—the out-of-state adjustment rate—would not resolve the discriminatory trade barrier issue raised in Ponderosa's initial brief. Ponderosa asserted the mechanics of the Cooperatives' proposal are unclear, but they seemed to add complication to the pooling process without fairly compensating out-of-state producers for their inability to participate in the quota program. According to Ponderosa, out-of-state producers can never realize the historic and ongoing benefits of quota ownership and can only avoid discriminatory treatment by being allowed to receive the plant blend price.

Findings

Two fundamentally different pooling philosophies have been proposed in this proceeding. The first, contained in Proposal 1, has been termed ''inclusive pooling'' and would automatically pool all California produced milk delivered to California plants, similar to how milk currently becomes pooled by the CSO. The Cooperatives are of the opinion that any change that would allow handlers to opt not to pool milk would be disorderly in an industry where all of the milk has historically been regulated. The Cooperatives testified that because California has a high percentage of both Class III and Class IV milk, in any given month handlers would elect to not pool a large portion of one of those classes of milk because of price. The Cooperatives estimated there could be an incentive to not pool one or both classes of manufacturing milk 94 percent of the time. The resulting fluctuation in uniform producer prices, they claim, would be disorderly.

The second pooling philosophy, offered by the Institute, relies on performance-based pooling standards that are more typical of the 10 current FMMOs. These standards require the pooling of plants with predominantly Class I milk sales. Handlers have the option of pooling Class II, III and IV milk diverted to unregulated plants. The provisions set out standards for which plants, producers, and producer milk are eligible to be pooled and priced by the FMMO. The Institute testified that the inclusive pooling standards offered in Proposal 1 are not authorized by the AMAA, and that performance-based pooling standards are the only means of ensuring that Class I demand is always met.

The pooling standards of all current FMMOs are contained in the *Pool Plant, Producer* and *Producer Milk* provisions of an order. Taken together, these provisions are intended to ensure an adequate supply of milk is available to meet the Class I needs of the market and provide the criteria for determining which producers have demonstrated a reasonable measure of service to the Class I market and thereby should share in the marketwide distribution of pool proceeds. Performance-based pooling standards provide a viable method for determining those eligible to share in the marketwide pool. It is primarily the additional revenue generated from the higher-valued Class I use of milk that adds value to the pool, and it is reasonable to expect that only producers who consistently bear the costs of supplying the market's fluid needs should share in the returns arising from higher-valued Class I sales. Therefore, FMMOs require the pooling of milk received at pool distributing plants, which is predominately Class I milk. Pooling of Class II, III and IV milk is optional at unregulated plants. Handlers of Class II, III and IV uses of milk qualify their milk to be pooled by meeting the pooling and performance standards of an order. By delivering a portion of their milk receipts to Class I distributing plants, handlers can benefit from the marketwide pool and receive the difference between their use-value of milk and the order's blend price in order to pay their producer suppliers the uniform producer blend price. The record supports adoption of performance-based pooling provisions as appropriate for the proposed California FMMO.

Ten public comments filed in regard to the recommended decision supported the recommended pooling provisions, agreeing that they would be consistent with those in other FMMOs, would fairly determine those producers and milk eligible to participate in the marketwide pool, and would enable dairy product manufacturers to manage costs and remain competitive in the national market.

The Institute, which continued to argue against the need for a California FMMO, nevertheless concurred with the Department's position that performance-based pooling standards are the appropriate method for determining handlers who are ready, willing, and able to serve the fluid market and should share the benefits of the Class I market. Similar sentiments were expressed in comments from HP Hood, Select, Kroger, Farmdale, NAJ, Dean, and an anonymous commenter, noting that the pooling provisions in the proposed California FMMO would be consistent with the Department's principles and with other FMMOs in the system. Kroger added that the recommended pooling provisions and performance standards are appropriately tailored to local California marketing conditions.

Cacique noted in their comment that the ability to opt out of the marketwide pool allows manufacturers to compete fairly with their counterparts elsewhere in the country. A comment from Pacific Gold added that voluntary depooling is essential to ensure survival for California cheese manufacturers, who would otherwise be faced with Class III prices that are too high under Proposal 1, prices that would not recognize the cost to make or transport California cheese to market.

Comments filed by the Cooperatives took exception to the proposed pooling

provisions and continued to support the inclusive pooling provisions in Proposal 1. The Cooperatives reiterated their argument that California FMMO provisions should be tailored to address local marketing conditions. The Cooperatives argued that relying on pooling provisions that work in other FMMOs because of certain similarities such as Class I utilization fails to recognize California's unique market characteristics, such as the size and location of its handlers, wide differences in location differentials, and high Class III and IV utilization. The Cooperatives stressed that divergence from the prevailing performance-based pooling model is authorized under the AMAA and is necessary for California.

DFA filed a separate comment to supplement the Cooperatives' comments and exceptions. DFA concurred with the Cooperatives on the need for inclusive pooling, and opined that voluntary pooling in California would create disparate producer prices and shifting handler advantages on a scale different from any other FMMO.

A comment submitted by WUD stated that allowing high percentages of milk to go in and out of the pool each month would undermine the pool's integrity and lead to unstable producer pricing. WUD said that allowing depooling defeats the California industry's purpose for seeking a FMMO—to enjoy class prices like the rest of the country. CDC echoed WUD's sentiment, commenting that less certainty about milk prices would jeopardize California's dairy farm futures and fail to establish orderly marketing.

While the Cooperatives have continued to argue that inclusive pooling is authorized by the AMAA, the analysis of the record of this proceeding, including the comments on and exceptions to the recommended decision, finds that performance-based pooling standards remain the appropriate method for identifying the producers and producer milk that serve the Class I market. Therefore, performance-based pooling provisions, tailored to the local market, are recommended for a California FMMO.

Pool Plant. The *Pool Plant* definition for each order provides the standards to identify plants engaged in serving the fluid needs of the marketing area and that receive milk eligible to share in the marketwide pool. The *Pool Plant* provisions proposed in this final decision reflect a combination of those offered in both Proposal 1 and Proposal 2. Both proposals recommended similar distributing plant and supply plant provisions. However, Proposal 1 would automatically regulate any plant located in California that receives milk from a producer located in the marketing area, while the remaining proposed pool plant provisions (both distributing plant and supply plant provisions) would apply to only plants located outside of the marketing area. As discussed earlier, this decision continues to find that pooling provisions should be performance based, and therefore it is not appropriate to propose provisions that would regulate plants based solely on location.

There are two performance standards applicable to distributing plants. First, this decision continues to find that a minimum of 25 percent of the total quantity of fluid milk products physically received at a pool distributing plant (excluding concentrated milk received from another plant by agreement for other than Class I use) should be disposed of as route disposition or transferred in the form of packaged fluid milk products to other distributing plants. This decision continues to find that a 25 percent route disposition standard for the proposed California FMMO is adequate to determine those plants that are sufficiently associated with the fluid market. The second criterion is an ''in-area'' standard and is designed to recognize plants that have an adequate association with the fluid market in the California marketing area. The record supports the adoption of the same in-area standard that is found in the 10 current FMMOs, specifying that 25 percent of the pool distributing plant's route distribution or transfers must be to outlets in the marketing area.

The *Pool Plant* definition would also provide for regulation of distributing plants that distribute ultra-pasteurized or aseptically-processed fluid milk products. The record evidence shows that plants specializing in these types of products tend to have irregular distribution patterns that could cause plants to shift regulatory status. This shifting can be considered disorderly to the producers and cooperatives who supply those plants. Regulating those plants according to their location, as is done in other FMMOs, would provide regulatory stability, and continues to be proposed for a California FMMO. Under current FMMOs, these plants are regulated in the marketing areas where they are located, as long as they process a minimum percentage of their milk receipts into ultra-pasteurized or aseptically-processed fluid milk products during the month.

The record indicates that both the Cooperatives and the Institute used the Upper Midwest FMMO, which contains a 15 percent standard for distributing plants producing ultra-pasteurized or aseptically-processed products, as a template for pooling provisions. However, as explained in the Federal Order Reform Final Decision,[44] this standard in each order was set equal to the total route disposition standard required for pool distributing plants in the respective FMMOs. In this final decision, the pool distributing plant standard continues to be proposed at 25 percent. Accordingly, this final decision continues to propose that plants located in the marketing area that process at least 25 percent of their total quantity of fluid milk products into ultra-pasteurized or aseptically-processed fluid milk products would be fully regulated by the proposed California FMMO.

Performance standards for pool supply plants are designed to attract an adequate supply of milk to meet the demands of the fluid milk market by encouraging pool supply plants to move milk to pool distributing plants that service the marketing area. The record shows that California utilizes significant volumes of manufacturing milk, while California Class 1 utilization in 2015 was only 13 percent.

The recommended decision proposed that a pool supply plant should deliver at least 10 percent of its total milk receipts from producers, including milk diverted by the handler, to plants (qualified as pool distributing plants, plants in a distributing plant unit, producer-handlers, partially regulated distributing plants, or distributing plants fully regulated by another order) each month in order to qualify all of the milk associated with the supply plant for pricing and pooling under a California FMMO.

In response to the recommended decision, the Cooperatives commented that a lower supply plant shipping standard of 7.5 percent would prevent uneconomic deliveries made just for the sake of pool eligibility. According to the Cooperatives, the recommended 10 percent performance standard would likely disrupt current supply relationships and cause disorder. The Cooperatives noted that the supply plant shipping standard for the Upper Midwest FMMO had recently been lowered, which should signal a comparably appropriate level for California. In any event, the commenter added that the Market Administrator should be authorized to adjust the level as appropriate.

MPC also urged the Department to propose a lower supply plant shipping

[44] Federal Order Reform Final Decision: 64 FR 16026.

standard to better reflect California's geography and market characteristics and encourage maximum pool participation.

This final decision continues to find that the recommended 10 percent supply plant shipping standard would be appropriate for the proposed California FMMO. The record of this proceeding lacks data from which to justify changing the proposed standard. Given the market's approximate Class I utilization and the fact that the Market Administrator would be able to make adjustments in response to changing circumstances, the standard is reasonable and should help identify the milk that should be associated with the pool. The adjustment to the Upper Midwest FMMO standards was based on market conditions in that marketing area and does not automatically justify a similar adjustment to the proposed standards for California.

To prevent uneconomic shipments of milk solely for the purpose of pool qualification, this final decision continues to propose two additional pooling provisions. First, a unit pooling provision is proposed that would allow two or more plants located in the marketing area and operated by the same handler to qualify for pooling as one unit. This would apply as long as one or more of the plants in the unit qualified as a pool distributing plant and the other plant(s) processed at least 50 percent of its bulk fluid milk products into Class I or II products. The unit pooling provision is designed to provide regulatory flexibility and deter uneconomic milk movements in markets, like California, where there is often specialization in plant operations.

Second, a system pooling provision is proposed to allow two or more supply plants, located in the marketing area and operated by one or more handlers, to qualify for pooling as a system by meeting the supply plant shipping requirements jointly as a single plant. The system pooling provision recognizes the role supply plants play in balancing the market's fluid needs, while ensuring that the plants in the system are consistent market suppliers and therefore eligible to benefit from participation in the marketwide pool. Both unit and system pooling provisions are included in other FMMOs.

The Cooperative and Institute witnesses testified in support of authorizing the market administrator to adjust shipping percentages if warranted by changing market conditions. Public comments filed in response to the recommended decision supported the inclusion of such a provision. This final decision continues to find it appropriate to adopt such a provision, should the market administrator conclude, after conducting an investigation, that adjusting shipping standards for supply plants and systems of supply plants to encourage shipments of milk to meet Class I demand, or to prevent uneconomic shipments of milk, is warranted. This provision would ensure that California FMMO provisions can quickly be adapted to changing market conditions and that orderly marketing can be maintained. Additionally, this flexibility would negate the need to add call provisions, as advanced by the Cooperatives, to ensure that fluid milk demand is always met.

Like other FMMOs, the proposed California FMMO would allow a plant, qualifying as a pool plant in the immediately preceding three months, to be granted relief from performance standards for no more than two consecutive months if it is determined by the market administrator that it cannot meet the performance standards because of circumstances beyond the control of the handler operating the plant. Examples of such circumstances include natural disaster, breakdown of equipment, or work stoppage.

In their post-hearing brief, the Cooperatives offered a modification to the exempt plant definition that would expand exempt plant status to plants with less than 150,000 pounds of Class I route disposition, and less than 300,000 pounds of total Class I, II, III or IV milk usage during the month. This modification was offered to exempt smaller manufacturing plants that would otherwise be regulated under the inclusive pooling provisions of Proposal 1. However, since any size plant with manufacturing uses could elect not to participate in the marketwide pool under the proposed California FMMO, there is no need to alter the exempt plant definition.

Proposal 2 offered a sliding scale supply plant shipping standard that would automatically be adjusted if the average Class I utilization percentage over the prior three months changed. Justification provided for this provision centered on administrative ease and flexibility of the regulations to change in order to reflect market conditions without necessitating a formal rulemaking hearing. However, under the proposed supply plant shipping standards, the market administrator would have flexibility to adjust supply plant shipping standards if warranted by changing market conditions. Therefore, it is not necessary to incorporate automatic adjustments to the standards.

This final decision does not propose separate pooling standards for plants receiving California quota milk, as offered in Proposal 2. As discussed previously, this decision continues to find that proper recognition of the California quota program could be through an authorized deduction from producer payments, if deemed appropriate by CDFA. Therefore, it would not be appropriate for the supply plant shipping standards to differ on the basis of whether a plant receives quota milk.

Proposal 1 contained a provision that would regulate a plant located in Churchill County, Nevada, receiving milk from producers within the county or in the California marketing area. The Cooperatives argued that currently a plant located in Churchill County has a long standing association with the California market, and this provision would ensure the plant would remain associated within the FMMO framework. The recommended decision did not find it appropriate to regulate a supply plant based on its location and not in combination with some form of performance standard. No public comments were submitted on this finding. This final decision continues to find it unnecessary to include such a provision. If the Churchill County plant meets the pool plant provisions of the recommended California FMMO, and thus demonstrates an adequate association to the market, then that plant would become regulated and enjoy the benefits of participating in a California FMMO marketwide pool.

Lastly, this final decision continues to propose the incorporation of provisions contained in all other FMMOs, implementing the provisions of the Milk Regulatory Equity Act of 2005 (MREA). The MREA amended the AMAA to ensure regulatory equity between and among dairy farmers and handlers for sales of packaged fluid milk in FMMO areas and into certain non-Federally regulated milk marketing areas from Federal milk marketing areas. Incorporation of these provisions is required to ensure that the proposed California FMMO does not violate the MREA. No comments were received regarding this proposal, other than the previously mentioned comments generally supporting the provisions that are similar in all FMMOs.

Producer. The *Producer* definition identifies dairy farmers supplying the market with milk for fluid use, or who are at least capable of doing so if necessary. Producers are eligible to share in the revenue that accrues from the marketwide pooling of milk. The *Producer* provisions proposed in

Proposals 1 and 2 were virtually identical. This final decision continues to find that the proposed California FMMO should recognize a producer as any person who produces Grade A milk that is received at a pool plant directly from the producer or diverted from the plant, or received by a cooperative in its capacity as a handler. A dairy farmer would not be considered a producer under more than one FMMO with respect to the same milk. Additionally, the proposed California FMMO would exempt producer-handlers and exempt plants from the pricing provisions, so the term producer would not apply to a producer-handler, or any dairy farmer whose milk is delivered to an exempt plant, excluding producer milk diverted to such exempt plant.

The Cooperatives proposed an additional provision that would identify dairy farmers who had lost their Grade A permit for more than 30 consecutive days as dairy farmers for other markets and therefore would lose their ability to qualify as a producer on a California FMMO for 12 consecutive months. The Cooperatives explained that this provision was part of the inclusive pooling provisions and was designed to prevent producers from voluntarily giving up their Grade A status to avoid regulation. This final decision continues to recommend performance-based pooling provisions, making such a provision as proposed by the Cooperatives unnecessary. The performance-based pooling provisions would serve to identify dairy farmers who meet the producer definition and should be entitled to share in the marketwide pool. Under the proposed order, any dairy farmer who delivers Grade A milk to a pool plant would be considered a producer.

Producer milk. The *Producer Milk* definition identifies the milk of producers that is eligible for inclusion in the marketwide pool. The proposed definition reflects a combination of the provisions contained in Proposals 1 and 2, and upholds the performance-based pooling philosophy advanced in this final decision.

This decision finds that, for the proposed California FMMO, producer milk should be defined as the milk of a producer that is received at a pool plant or received by a cooperative association in its capacity as a handler.

The proposed California FMMO must also provide for the diversion of producer milk to facilitate its orderly and efficient disposition when not needed for fluid use. Diversion provisions are needed to ensure that milk pooled on the order but not used for Class I purposes is part of the legitimate reserve supply of Class I handlers. Providing for milk diversion is a desirable and necessary FMMO feature because it facilitates the orderly and efficient disposition of milk when it is not needed for fluid use.

Accordingly, the proposed California FMMO would allow a pool plant to divert milk to another pool plant, and pool plants and cooperatives in their capacity as handlers could also divert milk to nonpool plants located in California, or in the surrounding states of Arizona, Nevada, and Oregon. Milk could not be diverted to a nonpool plant and remain priced and pooled under the terms of the proposed California FMMO unless at least one day of the dairy farmer's production was physically received as producer milk at a pool plant during the first month the dairy farmer was qualifying as a producer on the order. Given the large supply of milk for manufacturing use in California, the record supports a one-day ''touch base'' provision during the first month to define the producer milk that should be included in a California marketwide pool. Proposal 2 offered an alternative touch base standard of the lesser of one-day's production or 48,000 pounds. This final decision continues to find that a one-day touch base standard is an adequate demonstration of a dairy farmer's ability to service the market. Conversely, a higher standard, such as the five-day standard contained in Proposal 1, could lead to uneconomic milk movements for the sole purpose of meeting regulatory standards.

It is equally appropriate to safeguard against excessive milk supplies becoming associated with the market, as the proposed California FMMO one-day touch base standard could lead to milk from far distances associating with a California marketwide pool without actually being available to service the market's fluid needs. Therefore, this final decision proposes that diversions be limited to 100 percent minus the supply plant shipping percentage (or 90 percent of all milk being pooled by the handler). Diversions would further be limited to nonpool plants within California and its surrounding states. This limit should allow the economic movement of milk to balance the fluid needs of the market, while simultaneously preventing the milk of distant producers from associating with the California FMMO pool, and thus receiving the order's blend price, when most of the milk is diverted to distant plants and not a legitimate reserve supply of the market.

The proposed California FMMO includes repooling limits of 125 percent for the months of April through February, and 135 percent for the month of March, of the producer milk receipts pooled by the handler in the previous month. The record contains evidence that other FMMOs have experienced large swings in the volume of milk pooled on the order. This volatility was attributed to manufacturing handlers opting to not pool all their eligible milk in order to avoid payment to the marketwide pool for a given month. The Department has found unrestricted repooling conditions in some FMMO's to be inequitable and contrary to the intent of the FMMO system based on the hearing record of those proceedings.[45] The recommended decision found that the proposed repooling limits would not prevent manufacturing handlers or cooperatives from electing to not pool milk, but they should serve to maintain and enhance orderly marketing by encouraging participation in the marketwide pooling of all classified uses of milk.

In comments to the recommended decision, the Institute was of the opinion that the proposed repooling standards were an appropriate starting level given the lack of historical California data that could be used as a basis for change.

In their comments to the recommended decision, the Cooperatives and MPC supported lowering the repooling standards to 110 percent in order to further discourage handlers from electing to not pool large volumes of milk if inclusive pooling standards are not adopted.

Cacique commented that the recommended repooling limits proposed for California are more restrictive than those in other low Class I utilization orders and advocated for uniform repooling limits throughout the FMMO system.

Hilmar noted that even through the proposed California FMMO would provide manufacturers the option to not pool, the proposed repooling limits would competitively harm California manufacturers who compete with manufacturers in nearby FMMOs (Pacific Northwest and Arizona) whose provisions do not contain repooling limits.

In their exceptions to the recommended decision, DFA cautioned that significant volumes of milk could be depooled under the proposed California FMMO, a condition that the Department previously characterized as disorderly. DFA explained that because

[45] Official Notice is taken of: Upper Midwest Final Decision: 71 FR 54136, Central Final Decision: 71 FR 54152, and Mideast Final Decision: 71 FR 54172.

of the relatively high percentages of both Class III and Class IV utilization in California, repooling standards would not adequately deter handlers from electing to not pool large volumes of milk from month-to-month. Using updated hearing data, DFA provided an analysis to demonstrate how handlers could opt to not pool large volumes of milk in one month and then opt to pool essentially 100 percent of its milk the following month without any financial penalty.

Several factors were considered when evaluating the need for repooling standards and the appropriate levels. When determining appropriate levels, it was important to not set levels so low that they could not account for normal fluctuations in production volumes due to the number of days in each month and to the natural seasonality of milk production and manufacturing. As well, handlers need the ability to absorb unexpected surpluses while continuing to have the option to pool all the producer milk associated with that handler. If repooling limits are too restrictive, handlers may be unwilling to manufacture additional milk volumes because they would not have the flexibility to pool the additional milk volume.

This final decision continues to find repooling standards are justified for the proposed California FMMO to ensure orderly marketing conditions. The hearing record reflects that the proposed repooling standards were offered because of the similarities between California and the Upper Midwest FMMO, which currently has the same repooling standards.

Typically, when determining repooling standards, record data considered includes monthly and daily fluctuations in handler pooled volumes. As California is currently regulated by the CSO, which does not provide for voluntary pooling, there is no data on the record to discern which milk plants would qualify as pool plants, and how much milk would be associated with those plants on the recommended California FMMO. Lacking additional record evidence, the proposed 125 and 135 percent repooling standards serve as a starting point for identifying a handler's consistent supply of milk available to service the market's fluid milk needs under a California FMMO.

FMMOs are tailored to the local Class I market and therefore their provisions may not be identical in all cases. The Hilmar comment mentioned that two of California's neighboring marketing areas have no repooling limits which Hilmar claims put California manufacturers at a competitive disadvantage as they would be subject to repooling limits. The pooling provisions for those areas were established based on the dairy industry market characteristics of those marketing order areas. Likewise, the pooling provisions proposed in this final decision are intended to fit the specific needs of the California milk market.

It should be noted that any milk delivered to a pool distributing plant in excess of the previous month's pooled volume would not be subject to the repooling standards. The recommended California FMMO would also authorize the market administrator to waive these restrictions for new handlers, or for existing handlers with significant changes in their milk supplies due to unusual circumstances.

Lastly, milk that is subject to inclusion and participation in a State-authorized marketwide equalization pool and classification system should not be considered producer milk. Without such exclusion, milk could be simultaneously pooled on a California FMMO and on a marketwide equalization pool administered by another government entity, resulting in a double payment on the same milk and giving rise to competitive equity issues between producers.

The record indicates that milk serving the California Class 1 market, but produced from outside the state, is not currently priced and pooled under the CSO. According to witnesses, out-of-state producers commonly receive the plant blend price. Proposal 4 seeks to allow plants that would otherwise qualify as fully regulated distributing plants to elect partially regulated distributing plant status with respect to milk received from out-of-state farms. If Proposal 4 were adopted, the proposed California FMMO would enforce payment to out-of-state producers of at least the plant blend price on the out-of-state milk and out-of-state producers would presumably continue to receive the same prices they do now.

Throughout the hearing, California producers extolled the virtues of joining the FMMO system and enjoying system wide uniform product classification and pricing, which they believed would put them on a level-playing field with their producer counterparts across the country. In an effort to fairly compensate out-of-state producers while accommodating the California quota program under the proposed FMMO, proponents offered various payment alternatives. Under the modified provisions of Proposal 1, out-of-state producers would be entitled to a uniform blend price adjusted for quota. Under Proposal 2, out-of-state producers would be entitled to the traditional FMMO blend price calculated before quota premiums are paid.

Proponents of Proposal 4 argued that out-of-state producers should be allowed to continue receiving the plant blend price for milk shipped to plants regulated under a California FMMO to compensate for the fact that they have not historically been entitled to own and benefit from California quota and cannot expect to do so in the future. Under Proposal 4, otherwise fully regulated handlers could elect partially regulated distributing plant status with respect to out-of-state milk, for which they would pay the plant's blend price, based on classified use.

The record reflects that out-of-state milk is not priced and pooled by the CSO because the State of California, like all other states, is prohibited from regulating interstate commerce. One benefit of Federal regulation is the ability to regulate interstate milk marketing. FMMO provisions ensure that all milk servicing a market's Class I needs is appropriately classified and priced, and the producers who supply that milk share in the marketwide revenues from all Class I sales in the market.

A key feature of FMMOs is that producer milk is classified and priced at the plant where it is utilized, regardless of its source. Similarly situated handlers pay at least the class prices under each order, and producers are paid at least the order's minimum uniform blend price, determined through marketwide pooling. This allows producers to share equally in the classified use value of milk in the market, while minimizing uneconomic milk movements.

Three commenters, the Cooperatives, CDC and MPC, supported the recommended regulation of milk from outside the state, which would be pooled on the proposed California FMMO in the same manner of treatment as in other FMMOs. CDC wrote that California producers have been harmed by out-of-state milk sales not subject to the CSO because handlers can purchase that milk for less than the price of CSO pooled milk. Both the Cooperatives and MPC commented that regulating out-of-state milk would enhance orderly marketing.

As explained earlier, this final decision continues to propose that a California FMMO operate independent of the State's quota program. Under the proposed provisions, no quota premium would be subtracted from the FMMO pool, and all producers delivering to regulated pool plants under the order would be paid at least the same minimum producer blend price, less

authorized deductions. Therefore, all producers would be paid uniformly, as specified by the uniform payments provision of the AMAA.

Accordingly, this final decision continues to find no justification for differential producer treatment for milk servicing California's Class I needs when it is produced outside the marketing area. If an out-of-state dairy farmer qualifies as a producer under the proposed California FMMO, the producer's milk would be priced and pooled uniformly with the milk of all other producers serving the Class I market.

9. Transportation Credits

Transportation credits were contained in both Proposals 1 and 2 to reimburse handlers for part of the cost of transporting milk to Class I and/or Class II use. This final decision continues to propose no transportation credit provisions for a California FMMO.

Summary of Testimony

A witness appearing on behalf of the Cooperatives testified in support of the transportation credit provisions contained in Proposal 1. The witness said that transportation credits are needed because Class I differentials are not high enough to cover the cost of moving milk from the Central Valley where most of the milk is produced, to Class I distributing plants, which are primarily located on the coast where most of the population resides.

The Cooperative witness utilized April 2013 to October 2014 CDFA hauling cost data of milk deliveries to plants with Class 1, 2 and/or 3 utilization, and compared it to the proposed California FMMO Class I differentials that would be applicable for comparable hauls. The witness said the average cost to haul a load of milk from a supply region to a demand region was $0.75 per cwt, with a range of $0.35 to $1.82 per cwt. According to the witness, in all instances, the difference in FMMO Class I differentials between the two locations was much less than the actual haul cost, therefore an additional cost recovery mechanism is needed to assure orderly movements of milk to Class I plants.

The Cooperative witness explained that Proposal 1 contains transportation credit provisions similar to the current CSO where marketwide pool monies are used to provide a credit for farm-to-plant milk movements within designated transportation zones to handlers with greater than 50 percent Class 1, 2, and/or 3 utilization. The witness said that the transportation credit zones represent current market procurement patterns where transportation credit assistance is necessary, and a similar credit system should be incorporated into a California FMMO. The witness stressed that the proposed credits would be mileage and transaction based, with a reimbursement rate cap of 175 miles,[46] and a fuel cost adjustor. The witness noted that the transportation credit rate would be calculated on a per-farm basis, so one haul route could have more than one farm stop and each farm stop would be eligible individually for a transportation credit. In their post-hearing brief, the Cooperatives modified their proposal to allow for milk outside the marketing area to be eligible for transportation credits.

The Cooperative witness explained that their proposed reimbursement equations were a result of Cooperative members' transportation cost data analyzed by the Pacific Northwest FMMO office. The Cooperatives requested that the FMMO office analyze the data and determine cost equations based on actual observed costs, minus $0.30 per cwt, which represents the producer's responsibility for a local haul. The witness said that the resulting equations are valid because they calculated a $5.205 million payment, which was close to the actual observed costs of $5.261 million. The witness explained that because diesel prices are a key variable cost to transportation, a monthly fuel cost adjustor is needed to ensure that the transportation credit provisions maintain an accurate reflection of costs. The witness noted that Proposal 1 does not contain transportation credit reimbursement for plant-to-plant milk movements.

The Cooperative witness elaborated that Proposal 1 seeks to pay all producers the same FMMO blend price, unadjusted for location. Therefore the incentive to supply milk to Class I plants is borne solely through their proposed transportation credit provisions. The witness said that because all producers share in the higher valued class uses, it is appropriate that they share in the cost of supplying and balancing those markets by using marketwide pool monies to provide a handler credit on those milk movements.

The Institute, in its post-hearing brief, expressed support for the transportation credit provisions contained in Proposal 1, subject to the transportation credits being adjusted for the difference in location differentials.

[46] The mileage rate cap was modified at the hearing to 175 miles.

A witness representing Ponderosa testified that any proposed California FMMO should allow for transportation credits of out-of-state milk that serves the California Class I and/or Class II market. The witness explained that Ponderosa experiences high transportation costs because they haul their milk approximately 280 miles to a southern California Class I plant. The witness was of the opinion that this milk should be eligible for transportation credits if it is serving the California fluid market.

Findings

The record of this proceeding reflects that the California fluid market is structured such that some handlers and cooperative associations rely on the current CSO transportation credit system to assist them in making an adequate milk supply available for fluid use. The record reveals the Los Angeles, San Francisco, San Diego, and Sacramento metropolitan areas contain an overwhelming majority of the state's population, as well as the Class I plants servicing those areas. However, these plants must often source milk from milk production regions of the state located farther away. The record reveals that this supply/demand imbalance, coupled with flat producer pricing, necessitated the development of the CSO transportation credits for milk deliveries from designated supply regions to Class 1, 2, and/or 3 handlers located in demand regions where a majority of the population resides. The Cooperatives designed their transportation credit proposal to replicate the transportation credits currently paid by the CSO on farm-to-plant milk shipments, but attempted to make the proposed system more transaction based.

As previously discussed, this decision does not recommend flat producer pricing. The record of this proceeding supports the finding that producer payments should be adjusted to reflect the applicable producer location adjustment for the handler location where their milk is received. Therefore, the incentive to producers to supply Class I plants is embodied within the proposed producer payment provisions. As in all FMMOs, producers are responsible for finding a market for their milk, and consequently bear the cost of transporting their milk to a plant. Therefore the record of this proceeding does not support reducing the producers' value of the marketwide pool through the payment of transportation credits to handlers.

Comments filed by the Cooperatives took exception with the Department's finding on this issue. According to the

Cooperatives, the proposed Class I price differentials do not adequately account for the higher cost of moving milk from production points to California Class I markets. The Cooperatives argued that failure to provide transportation credits undermines the foundation of the FMMO system by eroding both producer and handler price uniformity. The Cooperatives reiterated their position that the Department should adopt Class I transportation credits at rates indicated in Proposal 1, adjusted for the location price difference between the point of origin and the receiving plant. In their exceptions, the Cooperatives proposed that the credits be processor-, not producer-funded. The Cooperatives opined that if a system of transportation credits is not adopted, the California FMMO as proposed would lead to significant tension between similarly located producers supplying local manufacturers and those supplying distant Class I plants. The Cooperatives argued that either the Class I plants would pay significant over order charges on all milk delivered to them, or that supplying producers would need to accept significantly less in their mailbox price than neighboring producers supplying local markets.

Comments filed by Dean Foods expressed support for the Cooperatives' position on transportation credits. Other commenters opined that the proposed Class I differentials would not be adequate to draw the necessary milk supplies to the Southern California deficit area, and argued that lack of transportation assistance of some sort would be detrimental to producers, handlers, and ultimately consumers.

Comments filed by HP Hood recognized that while Class I differentials were intended to attract milk to processing plants, California has long had a transportation assistance program funded through the pool that has helped attract milk to fluid plants.

Comments filed by Kroger noted that both the Cooperatives and the Institute offered workable proposals for transportation assistance. Kroger stated that existing location differentials are not adequate to draw enough milk into the Southern California deficit area, which is why the CSO adopted its current system of transportation credits and allowances.

Comments filed by the Institute urged the Department to reconsider its position on transportation credits, but agreed with the Department's finding that flat producer pricing must not be implemented in a California FMMO.

Comments filed by MPC supported the Department's recommendation and reiterated its opposition to any producer-funded transportation subsidy system that would deduct producer revenue from the pool.

This decision continues to find that including a producer-funded transportation credit program in a California FMMO is not warranted. In their exceptions, the Cooperatives suggested implementing a processor-funded transportation credit program. This suggestion was not part of any proposal evaluated at the hearing and the record lacks evident to support its adoption.

Currently, the CSO uses a flat producer payment, which contains no built-in incentive for moving milk from production to population areas. The CSO accomplishes this milk movement through transportation credits. Implementing a FMMO would change the current CSO flat producer payment structure into a Class I differential structure with higher differentials for California's population centers. The incentive to producers to supply Class I plants is therefore embodied within the FMMO Class I differential structure, as producers would receive the higher location differential for supplying plants located in major metropolitan areas, as the cost to supply those plants is higher. Some commenters noted that this would result in neighboring producers receiving different prices based on where there milk is delivered. The objective of the producer price surface is to encourage producers to service Class I plants through a higher location differential. While this will lead to producers receiving different prices, those producers receiving the higher differential also incur higher costs to service those plants. If additional monies are needed above minimum classified prices to supply Class I plants, marketplace principles should dictate the source and amount of those additional funds.

10. Miscellaneous and Administrative Provisions

This section discusses the various miscellaneous and administrative provisions necessary to administer the proposed California FMMO. All current FMMOs contain administrative provisions that provide for the handler reporting dates, announcements by the Market Administrator, and payment dates necessary to administer the provisions of the FMMOs. A California FMMO likewise needs similar administrative provisions to ensure its proper administration. The provisions outlined below generally conform to provisions contained in the 10 current FMMOs with reporting and payment dates tailored to the California dairy market.

Findings

Handler Reports. Handlers subject to a California FMMO would be required to submit monthly reports detailing the sources and uses of milk and milk products so market average use values, or uniform prices, could be determined and administered. Under a California FMMO, handler reports of receipts and utilization would be due by the 9th day following the end of the month. To ensure the minimum payments to producers are made in accordance with the terms of a California FMMO, handlers would need to report producer payroll by the 20th day following the end of the month to the Market Administrator.

Announcements by the Market Administrator. In the course of administering a California FMMO, the Market Administrator would be required to make several announcements each month with respect to classification, class prices and component prices, an ''equivalent price'' when necessary, and various producer prices. Under a California FMMO, the Market Administrator would make these announcements on or before the 14th day following the end of the month.

Producer-Settlement Fund. Handlers regulated by a California FMMO would be required to pay minimum class prices for the milk received from producers. These minimum values would be aggregated in a California FMMO marketwide pool so producers could receive a uniform price or blend price for their milk. The equalization of a handler's use value of milk and the uniform value would occur through the producer-settlement fund established and administered by the Market Administrator.

The producer-settlement fund ensures all handlers would be able to return the market blend price to producers whose milk was pooled under the order. Payments into the producer-settlement fund would be made each month by handlers whose total classified use value of milk exceeds the values of such milk calculated at the announced producer prices. In a California FMMO, handlers would be required to pay into the producer-settlement fund by the 16th day following the end of the month.

Payments out of the producer-settlement fund would be made each month to any handler whose use value is below the value of their milk at producer prices. Under a California FMMO, the Market Administrator

would distribute payments from the producer-settlement fund by the 18th day following the end of the month. This transfer of funds would enable handlers with a classified use value of milk below the average for the market to pay their producers the same uniform price as handlers whose classified use value of milk exceeds the market average.

In view of the need to make timely payments to handlers from the producer-settlement fund, it is essential that money due to the fund is received by the due date. Accordingly, payment to the producer-settlement fund is considered made upon receipt of funds by the Market Administrator. Payment cannot be received on a non-business day. Therefore, if the due date for a payment, including a payment to or from the producer-settlement fund, falls on a Saturday, Sunday, or national holiday, the payment would not be due until the next business day.

Payments to Producers and Cooperative Associations. The AMAA states that handlers must pay the uniform price to all producers and producer associations. As under other FMMOs, a California FMMO would provide for proper deductions authorized by the producer in writing. Such authorized deductions would be expenses unrelated to the minimum value of milk in the transaction between the producer and handler. The proposed California FMMO would also allow a deduction for any assessment announced by CDFA for the administration of the California quota program. The producer would not need to authorize this deduction in writing.

As in other FMMOs, producer associations would be allowed to ''reblend'' their payments to their producer members. The Capper Volstead Act and the AMAA make it clear that cooperative associations are unique in this regard.

A California FMMO would require handlers to make at least one partial payment to producers in advance of the announcement of the applicable uniform prices. The partial payment rate for milk received during the first 15 days of the month could not be less than the lowest announced class price for the preceding month, and would be paid to producers by the last day of the month. The final payment for milk under a California FMMO would be required to be made so that it is received by producers no later than the 19th day after the end of the month.

Handlers would pay Cooperatives for bulk milk and skim milk, and for bulk milk received by transfer from a cooperative's pool plant, on the terms described for individual producers, with the exception that payment would be due one day earlier. An earlier payment date for cooperative associations is warranted because it would then give cooperative associations the time they need to distribute payments to individual producer members.

All payment dates specified in the proposed California FMMO are receipt dates. Since payment cannot be received on a non-business day, payment dates that fall on a Saturday, Sunday, or national holiday would be delayed until the next business day. While this has the effect of delaying payments to cooperatives and producers, the delay is offset by the shift from ''date of payment'' to ''date of payment receipt.''

Payment Obligation of a Partially Regulated Distributing Plant. All FMMOs provide a method for determining the payment obligations due to producers by handlers that operate plants not fully regulated under any Federal order. These unregulated handlers are not required to account to dairy farmers for their milk at classified prices or to return a minimum uniform price to producers who have supplied the handler with milk. However, such handlers may sell fluid milk products on routes in a regulated area in competition with handlers who are fully regulated. To address this, FMMOs provide a minimum degree of regulation to all handlers who have route sales in a regulated marketing area. Partial regulation preserves the integrity of the FMMO classified pricing and pooling provisions and assures that orderly marketing conditions are maintained. Without these provisions, milk prices under an order would not be uniform among handlers competing for sales in the marketing area, a milk pricing requirement of the AMAA. Like the other FMMOs, a California FMMO would partially regulate handlers who have route sales into the marketing area, but do not meet the threshold to be fully regulated.

The proposed California FMMO provides regulatory options for a partially regulated plant handler. All partially regulated plant handlers would account to the California FMMO producer-settlement fund on the volume of packaged Class I sales in the California marketing area that exceeds receipts previously priced as Class I under a FMMO. Under the first option, a payment could be made by the partially regulated plant handler into the producer-settlement fund of the California FMMO at a rate equal to the difference between the Class I price and the California FMMO uniform price. Under the second option, the operator of a partially regulated plant handler could pay any positive difference between the gross obligation of the plant, had it been fully regulated, and the actual payments made for its milk supply. This is commonly referred to as the Wichita Option. The third option applies to a partially regulated plant handler that is subject to a marketwide pool operated under the authority of a state. In this last case, the partially regulated plant handler would account to the producer settlement fund at the difference between the Federal order Class I value and the value at which the handler accounts to the State order pool on such route sales, but not less than zero.

Adjustment of Accounts. Current FMMOs provide for the audit of handler reports by the Market Administrator. The Market Administrator may adjust, based on verification of handler records, any amount due to or from the Market Administrator, or to a producer or cooperative association. Adjustments can affect the Producer-Settlement Fund, the Administrative Fund, and/or the Marketing Service Fund. A California FMMO would likewise provide for the adjustment of handler accounts based on audits of handler reports and records. The Market Administrator would promptly notify the handler of any necessary adjustments so that payments could be made on or before the next date for the payment related to the adjustment.

Charges for Overdue Accounts. The proposed California FMMO provisions require handlers to make payments to producers and cooperatives by the dates described earlier in this section. Payments not made by the specified due dates would be subject to a late payment charge of 1 percent per month by the Market Administrator and would accrue to the administrative fund. Additional late payment charges would accrue on any amounts that continue to be late on the corresponding due dates each succeeding month.

Assessment of Order Administration. The AMAA provides that the cost of order administration be financed by an assessment on handlers. Under the proposed California FMMO, a maximum rate of $0.08 per cwt would apply to all of a handler's receipts pooled under the order. The specific rate would be announced by the Market Administrator. Partially-regulated handlers would be assessed the same administrative rate on their volume of Class I route disposition inside of the marketing area. The money paid to the administrative fund is each handler's proportionate share of the cost of administering the FMMO.

Deduction for Marketing Services. The proposed California FMMO would provide marketing services to producers for whom cooperative associations do not perform services. Such services include providing market information and establishing or verifying weights, samples, and tests of milk received from such producers. In accordance with the AMAA, these marketing services are intended to benefit all nonmember producers under a California FMMO. Accordingly, as is uniform in the current FMMOs, each handler regulated by a California FMMO would be allowed to deduct a maximum of $0.07 per cwt from amounts due each producer for whom a cooperative association does not provide such services. The specific allowable rate would be announced by the Market Administrator and would be subtracted from the handler's obligation.

11. Ruling on Official Notice Documents

In accordance with 7 CFR 900.8, USDA published a Request for Public Comments (82 FR 37827; published August 14, 2017) (request) inviting interested parties to submit comments on whether various documents were relevant to the material issues of this proceeding. Three public comments were received. All the commenters supported taking official notice of the documents listed in the request. Accordingly, official notice is taken of the documents listed in the notice (82 FR 37827).

In addition to the documents referenced above, commenters highlighted the unintentional omission of 31 documents for consideration. Those documents are either previous **Federal Register** publications, USDA and CDFA publically available data, or previous AMS publications. As all of these documents are published government resources, the Department does not object to their inclusion in the hearing record. Three of the 31 documents were already contained in the list within the request, but two did not reflect the exact lines referenced in the requests for official notice. As a result, AMS is taking official notice of the 29 documents as listed below. A complete list of these documents, along with links and sources to access them, is available at *www.ams.usda.gov/caorder.*

Agricultural Marketing Service (AMS) Data and Publications:

- AMS FMMO Reform Basic Formula Price Committee, Preliminary Report, April 1997;
- AMS FMMO Reform Classification Committee, Preliminary Report, November 1996;
- AMS FMMO Reform Identical Provisions Committee, Preliminary Report, November 1996;
- AMS FMMO Reform Price Structure Committee, Preliminary Report, November 1996; and
- AMS National Dairy Product Sales Reports National Average Survey Prices for Commodity Butter and Nonfat Dry Milk, January 2016–July 2016

California Department of Food and Agriculture (CDFA) Data and Publications:

- CDFA Commodity Butter Market Price Reports, January 2016–July 2016;
- CDFA Nonfat Dry Milk Market Price Reports, January 2016–July 2016;

USDA Office of the Chief Economist Publication:

- North American Drought Monitor Map: April 2017, released May 12, 2017;

Federal Register Publications:

- 30 FR 13143, 13144 regarding milk in the Tampa Bay marketing area, October 1965;
- 31 FR 7062, 7065 regarding a Puget Sound, Washington, market area expansion and amendments to producer-handler definition, May 1966;
- 34 FR 960, 962 regarding milk in the Georgia marketing area, January 1969;
- 46 FR 21944, 21950–21951 regarding milk in the Southwestern Idaho and Eastern Oregon marketing area, April 1981;
- 47 FR 5214, 5125–5128 regarding milk in the Alabama-West Florida marketing area, February 1982;
- 52 FR 38240 regarding Milk in the Chicago marketing area, October 1987;
- 53 FR 49154, 49169–49170 regarding milk in the Oregon-Washington and Puget Sound-Inland Empire marketing areas, December 1988;
- 54 FR 27179, 27182 regarding milk in the Texas and Southwest Plains marketing areas, June 1989;
- 56 FR 42240, 42248 regarding milk in the Rio Grande Valley and Other Marketing Areas, August 1991;
- 59 FR 12436, 12461–12462 regarding milk in the Minneapolis-St. Paul and Other Marketing Areas, March 1976;
- 64 FR 16026–16169 regarding milk in the Northeast and Other Marketing Areas, April 1999;
- 67 FR 67906, 67939 regarding Milk in the Northeast and Other Marketing Areas, November 2002;
- 68 FR 37674, 37678 regarding Milk in the Upper Midwest Marketing Area, April 2004;
- 69 FR 18834, 18838 regarding Milk in the Pacific Northwest Marketing Area, April 2004;
- 69 FR 19292, 19298 regarding Milk in the Mideast Marketing Area, April 2004;
- 69 FR 57233, 57238–57239 regarding Milk in the Northeast and Other Marketing Areas, September 2004;
- 70 FR 4932, 4943 regarding Milk in the Northeast Marketing Area, January 2005;
- 70 FR 74166, 74185–74186, 74188 regarding amendments to the Pacific Northwest and Arizona-Las Vegas Marketing Areas, December 2005;
- 71 FR 54152, 54157 regarding Milk in the Central Marketing Area, September 2006;
- 75 FR 10122, 10151–1015 regarding Milk in the Northeast and Other Marketing Areas, March 2010; and
- 79 FR 12963, 12976 regarding Milk in the Appalachian, Florida and Southeast Marketing Areas, March 2014.

12. Rulings on Proposed Findings, Conclusions, and Exceptions

In accordance with the Administrative Procedure Act, 5 U.S.C. 557(c), USDA has analyzed and reached a conclusion on all material issues of facts, law, and discretion presented on the record. Briefs, proposed findings and conclusions, comments and exceptions, and the evidence in the record were considered in making the findings and conclusions set forth in this final decision. To the extent that the suggested findings and conclusions filed by interested parties are inconsistent with the findings and conclusions of this final decision, the requests to make such findings or reach such conclusions are denied for the reasons stated in this decision.

General Findings

(a) The proposed marketing agreement and order, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(b) The parity prices of milk, as determined pursuant to Section 2 of the AMAA, are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions that affect market supply and demand for the milk in the marketing area, and the minimum prices specified in the proposed marketing agreement and order are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(c) The proposed marketing agreement and order will regulate the handling of milk in the same manner as, and will be applicable only to, persons in the

respective classes of industrial and commercial activity specified in the marketing agreement and order upon which a hearing has been held.

(d) All milk and milk products handled by handlers covered by the proposed marketing agreement and order are in the current of interstate commerce or directly burden, obstruct, or affect interstate commerce in milk or its products; and

(e) It is hereby found that the necessary expense of the market administrator for the maintenance and functioning of such agency will require the payment by each handler, as their *pro rata* share of such expense, 8 cents per hundredweight or such lesser amount as the Secretary may prescribe with respect to the milk specified in § 1051.85 of the aforesaid tentative marketing agreement and the order.

(This order shall not become effective until the requirements of 7 CFR 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.)

Marketing Agreement and Order

The proposed order regulating the handling of milk in the California marketing area is recommended as the detailed and appropriate means by which the foregoing conclusions may be carried out. The proposed marketing agreement is not included in this decision because the regulatory provisions thereof would be the same as those contained in the order, as hereby proposed to be established.

Referendum Order To Determine Producer Approval; Determination of Representative Period; and Designation of Referendum Agent

It is hereby directed that a referendum be conducted and completed on or before the 45th day from the date this decision is published in the **Federal Register**, in accordance with the procedures for the conduct of referenda [7 CFR 900.300–311], to determine whether the issuance of the order regulating the handling of milk in the California marketing area is approved or favored by producers, as defined under the terms of the order, who during such representative period were engaged in the production of milk for sale within the aforesaid marketing area. The representative period for the conduct of such referenda is hereby determined to be May 2017.

The agent of the Secretary of Agriculture to conduct such referenda is hereby designated to be the Director of Operations and Accountability, Dairy Program, AMS, USDA.

List of Subjects in 7 CFR Part 1051

Milk marketing orders.

■ For the reasons stated in the preamble, the Agricultural Marketing Service proposes to add 7 CFR part 1051 to read as follows:

PART 1051—MILK IN THE CALIFORNIA MARKETING AREA

Subpart A—Order Regulating Handling

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Authority: 7 U.S.C. 601–608.

Subpart A—Order Regulating Handling

General Provisions

§ 1051.1 General provisions.

The terms, definitions, and provisions in part 1000 of this chapter apply to this part unless otherwise specified. In this part, all references to sections in part 1000 refer to part 1000 of this chapter.

Definitions

§ 1051.2 California marketing area.

The marketing area means all territory within the bounds of the following states and political subdivisions, including all piers, docks, and wharves connected therewith and all craft moored thereat, and all territory occupied by government (municipal, State, or Federal) reservations, installations, institutions, or other similar establishments if any part thereof is within any of the listed states or political subdivisions:

California

All of the State of California.

§ 1051.3 Route disposition.

See § 1000.3 of this chapter.

§ 1051.4 Plant.

See § 1000.4 of this chapter.

§ 1051.5 Distributing plant.

See § 1000.5 of this chapter.

§ 1051.6 Supply plant.

See § 1000.6 of this chapter.

§ 1051.7 Pool plant.

Pool plant means a plant, unit of plants, or system of plants as specified in paragraphs (a) through (f) of this section, but excluding a plant specified in paragraph (h) of this section. The pooling standards described in paragraphs (c) and (f) of this section are subject to modification pursuant to paragraph (g) of this section:

(a) A distributing plant, other than a plant qualified as a pool plant pursuant to paragraph (b) of this section or § _____.7(b) of any other Federal milk order, from which during the month 25 percent or more of the total quantity of fluid milk products physically received at the plant (excluding concentrated milk received from another plant by agreement for other than Class I use) are disposed of as route disposition or are transferred in the form of packaged fluid milk products to other distributing plants. At least 25 percent of such route disposition and transfers must be to outlets in the marketing area.

(b) Any distributing plant located in the marketing area which during the month processed at least 25 percent of the total quantity of fluid milk products physically received at the plant (excluding concentrated milk received from another plant by agreement for other than Class I use) into ultra-pasteurized or aseptically-processed fluid milk products.

(c) A supply plant from which the quantity of bulk fluid milk products shipped to (and physically unloaded into) plants described in paragraph (c)(1) of this section is not less than 10 percent of the Grade A milk received from dairy farmers (except dairy farmers described in § 1051.12(b) of this chapter) and handlers described in § 1000.9(c) of this chapter, including milk diverted pursuant to § 1051.13 of this chapter, subject to the following conditions:

(1) Qualifying shipments may be made to plants described in paragraphs (c)(1)(i) through (iv) of this section, except that whenever shipping requirements are increased pursuant to paragraph (g) of this section, only shipments to pool plants described in paragraphs (a), (b), and (d) of this section shall count as qualifying shipments for the purpose of meeting the increased shipments:

(i) Pool plants described in § 1051.7(a), (b), and (d) of this chapter;

(ii) Plants of producer-handlers;

(iii) Partially regulated distributing plants, except that credit for such shipments shall be limited to the amount of such milk classified as Class I at the transferee plant; and

(iv) Distributing plants fully regulated under other Federal orders, except that credit for shipments to such plants shall be limited to the quantity shipped to (and physically unloaded into) pool distributing plants during the month and credits for shipments to other order plants shall not include any such shipments made on the basis of agreed-upon Class II, Class III, or Class IV utilization.

(2) Concentrated milk transferred from the supply plant to a distributing plant for an agreed-upon use other than Class I shall be excluded from the supply plant's shipments in computing the supply plant's shipping percentage.

(d) Two or more plants operated by the same handler and located in the marketing area may qualify for pool status as a unit by meeting the total and in-area route disposition requirements of a pool distributing plant specified in paragraph (a) of this section and subject to the following additional requirements:

(1) At least one of the plants in the unit must qualify as a pool plant pursuant to paragraph (a) of this section;

(2) Other plants in the unit must process Class I or Class II products, using 50 percent or more of the total Grade A fluid milk products received in bulk form at such plant or diverted therefrom by the plant operator in Class I or Class II products; and

(3) The operator of the unit has filed a written request with the market administrator prior to the first day of the month for which such status is desired to be effective. The unit shall continue from month-to-month thereafter without further notification. The handler shall notify the market administrator in writing prior to the first day of any month for which termination or any change of the unit is desired.

(e) A system of two or more supply plants operated by one or more handlers may qualify for pooling by meeting the shipping requirements of paragraph (c) of this section in the same manner as a single plant subject to the following additional requirements:

(1) Each plant in the system is located within the marketing area. Cooperative associations or other handlers may not use shipments pursuant to § 1000.9(c) of this chapter to qualify supply plants located outside the marketing area;

(2) The handler(s) establishing the system submits a written request to the market administrator on or before July 15 requesting that such plants qualify as a system for the period of August through July of the following year. Such request will contain a list of the plants participating in the system in the order, beginning with the last plant, in which the plants will be dropped from the system if the system fails to qualify. Each plant that qualifies as a pool plant within a system shall continue each month as a plant in the system through the following July unless the handler(s) establishing the system submits a written request to the market administrator that the plant be deleted from the system or that the system be discontinued. Any plant that has been so deleted from a system, or that has failed to qualify in any month, will not be part of any system for the remaining months through July. The handler(s) that have established a system may add a plant operated by such handler(s) to a system if such plant has been a pool plant each of the 6 prior months and would otherwise be eligible to be in a system, upon written request to the market administrator no later than the 15th day of the prior month. In the event of an ownership change or the business failure of a handler who is a participant in a system, the system may be reorganized to reflect such changes if a written request to file a new marketing agreement is submitted to the market administrator; and

(3) If a system fails to qualify under the requirements of this paragraph (e), the handler responsible for qualifying the system shall notify the market administrator which plant or plants will be deleted from the system so that the remaining plants may be pooled as a system. If the handler fails to do so, the market administrator shall exclude one or more plants, beginning at the bottom of the list of plants in the system and continuing up the list as necessary until the deliveries are sufficient to qualify the remaining plants in the system.

(f) Any distributing plant, located within the marketing area as described in § 1051.2 of this chapter:

(1) From which there is route disposition and/or transfers of packaged fluid milk products in any non-federally regulated marketing area(s) located within one or more States that require handlers to pay minimum prices for raw milk, provided that 25 percent or more of the total quantity of fluid milk products physically received at such plant (excluding concentrated milk received from another plant by agreement for other than Class 1 use) is disposed of as route disposition and/or is transferred in the form of packaged fluid milk products to other plants. At least 25 percent of such route disposition and/or transfers, in aggregate, are in any non-federally regulated marketing area(s) located within one or more States that require handlers to pay minimum prices for raw

milk. Subject to the following exclusions:

(i) The plant is described in § 1051.7(a), (b), or (e) of this chapter;

(ii) The plant is subject to the pricing provisions of a State-operated milk pricing plan which provides for the payment of minimum class prices for raw milk;

(iii) The plant is described in § 1000.8(a) or (e) of this chapter; or

(iv) A producer-handler described in § 1051.10 of this chapter with less than three million pounds during the month of route disposition and/or transfers of packaged fluid milk products to other plants.

(2) [Reserved]

(g) The applicable shipping percentages of paragraphs (c) and (e) of this section and § 1051.13(d)(2) and (3) of this chapter may be increased or decreased, for all or part of the marketing area, by the market administrator if the market administrator finds that such adjustment is necessary to encourage needed shipments or to prevent uneconomic shipments. Before making such a finding, the market administrator shall investigate the need for adjustment either on the market administrator's own initiative or at the request of interested parties if the request is made in writing at least 15 days prior to the month for which the requested revision is desired effective. If the investigation shows that an adjustment of the shipping percentages might be appropriate, the market administrator shall issue a notice stating that an adjustment is being considered and invite data, views, and arguments. Any decision to revise an applicable shipping or diversion percentage must be issued in writing at least one day before the effective date.

(h) The term pool plant shall not apply to the following plants:

(1) A producer-handler as defined under any Federal order;

(2) An exempt plant as defined in § 1000.8(e) of this chapter;

(3) A plant located within the marketing area and qualified pursuant to paragraph (a) of this section which meets the pooling requirements of another Federal order, and from which more than 50 percent of its route disposition has been in the other Federal order marketing area for 3 consecutive months;

(4) A plant located outside any Federal order marketing area and qualified pursuant to paragraph (a) of this section that meets the pooling requirements of another Federal order and has had greater route disposition in such other Federal order's marketing area for 3 consecutive months;

(5) A plant located in another Federal order marketing area and qualified pursuant to paragraph (a) of this section that meets the pooling requirements of such other Federal order and does not have a majority of its route disposition in this marketing area for 3 consecutive months, or if the plant is required to be regulated under such other Federal order without regard to its route disposition in any other Federal order marketing area;

(6) A plant qualified pursuant to paragraph (c) of this section which also meets the pooling requirements of another Federal order and from which greater qualifying shipments are made to plants regulated under the other Federal order than are made to plants regulated under the order in this part, or the plant has automatic pooling status under the other Federal order; and

(7) That portion of a regulated plant designated as a nonpool plant that is physically separate and operated separately from the pool portion of such plant. The designation of a portion of a regulated plant as a nonpool plant must be requested in advance and in writing by the handler and must be approved by the market administrator.

(i) Any plant that qualifies as a pool plant in each of the immediately preceding 3 months pursuant to paragraph (a) of this section or the shipping percentages in paragraph (c) of this section that is unable to meet such performance standards for the current month because of unavoidable circumstances determined by the market administrator to be beyond the control of the handler operating the plant, such as a natural disaster (ice storm, wind storm, flood, fire, earthquake, breakdown of equipment, or work stoppage, shall be considered to have met the minimum performance standards during the period of such unavoidable circumstances, but such relief shall not be granted for more than 2 consecutive months.

§ 1051.8 Nonpool plant.

See § 1000.8 of this chapter.

§ 1051.9 Handler.

See § 1000.9 of this chapter.

§ 1051.10 Producer-handler.

Producer-handler means a person who operates a dairy farm and a distributing plant from which there is route disposition in the marketing area, from which total route disposition and packaged sales of fluid milk products to other plants during the month does not exceed 3 million pounds, and who the market administrator has designated a producer-handler after determining that all of the requirements of this section have been met.

(a) *Requirements for designation.* Designation of any person as a producer-handler by the market administrator shall be contingent upon meeting the conditions set forth in paragraphs (a)(1) through (5) of this section. Following the cancellation of a previous producer-handler designation, a person seeking to have their producer-handler designation reinstated must demonstrate that these conditions have been met for the preceding month:

(1) The care and management of the dairy animals and the other resources and facilities designated in paragraph (b)(1) of this section necessary to produce all Class I milk handled (excluding receipts from handlers fully regulated under any Federal order) are under the complete and exclusive control, ownership, and management of the producer-handler and are operated as the producer-handler's own enterprise and at its sole risk.

(2) The plant operation designated in paragraph (b)(2) of this section at which the producer-handler processes and packages, and from which it distributes, its own milk production is under the complete and exclusive control, ownership, and management of the producer-handler and is operated as the producer-handler's own enterprise and at its sole risk.

(3) The producer-handler neither receives at its designated milk production resources and facilities nor receives, handles, processes, or distributes at or through any of its designated milk handling, processing, or distributing resources and facilities other source milk products for reconstitution into fluid milk products or fluid milk products derived from any source other than:

(i) Its designated milk production resources and facilities (own farm production);

(ii) Pool handlers and plants regulated under any Federal order within the limitation specified in paragraph (c)(2) of this section; or

(iii) Nonfat milk solids which are used to fortify fluid milk products.

(4) The producer-handler is neither directly nor indirectly associated with the business control or management of, nor has a financial interest in, another handler's operation; nor is any other handler so associated with the producer-handler's operation.

(5) No milk produced by the herd(s) or on the farm(s) that supplies milk to the producer-handler's plant operation is:

(i) Subject to inclusion and participation in a marketwide equalization pool under a milk classification and pricing program under the authority of a State government maintaining marketwide pooling of returns; or

(ii) Marketed in any part as Class I milk to the non-pool distributing plant of any other handler.

(b) *Designation of resources and facilities.* Designation of a person as a producer-handler shall include the determination of what shall constitute milk production, handling, processing, and distribution resources and facilities, all of which shall be considered an integrated operation, under the sole and exclusive ownership of the producer-handler.

(1) Milk production resources and facilities shall include all resources and facilities (milking herd(s), buildings housing such herd(s), and the land on which such buildings are located) used for the production of milk which are solely owned, operated, and which the producer-handler has designated as a source of milk supply for the producer-handler's plant operation. However, for purposes of this paragraph (b)(1), any such milk production resources and facilities which do not constitute an actual or potential source of milk supply for the producer-handler's operation shall not be considered a part of the producer-handler's milk production resources and facilities.

(2) Milk handling, processing, and distribution resources and facilities shall include all resources and facilities (including store outlets) used for handling, processing, and distributing fluid milk products which are solely owned by, and directly operated or controlled by the producer-handler or in which the producer-handler in any way has an interest, including any contractual arrangement, or over which the producer-handler directly or indirectly exercises any degree of management control.

(3) All designations shall remain in effect until canceled pursuant to paragraph (c) of this section.

(c) *Cancellation.* The designation as a producer-handler shall be canceled upon determination by the market administrator that any of the requirements of paragraph (a)(1) through (5) of this section are not continuing to be met, or under any of the conditions described in paragraph (c)(1), (2), or (3) of this section. Cancellation of a producer-handler's status pursuant to this paragraph (c) shall be effective on the first day of the month following the month in which the requirements were not met or the conditions for cancellation occurred.

(1) Milk from the milk production resources and facilities of the producer-handler, designated in paragraph (b)(1) of this section, is delivered in the name of another person as producer milk to another handler.

(2) The producer-handler handles fluid milk products derived from sources other than the milk production facilities and resources designated in paragraph (b)(1) of this section, except that it may receive at its plant, or acquire for route disposition, fluid milk products from fully regulated plants and handlers under any Federal order if such receipts do not exceed 150,000 pounds monthly. This limitation shall not apply if the producer-handler's own-farm production is less than 150,000 pounds during the month.

(3) Milk from the milk production resources and facilities of the producer-handler is subject to inclusion and participation in a marketwide equalization pool under a milk classification and pricing plan operating under the authority of a State government.

(d) *Public announcement.* The market administrator shall publicly announce:

(1) The name, plant location(s), and farm location(s) of persons designated as producer-handlers;

(2) The names of those persons whose designations have been cancelled; and

(3) The effective dates of producer-handler status or loss of producer-handler status for each. Such announcements shall be controlling with respect to the accounting at plants of other handlers for fluid milk products received from any producer-handler.

(e) *Burden of establishing and maintaining producer-handler status.* The burden rests upon the handler who is designated as a producer-handler to establish through records required pursuant to § 1000.27 of this chapter that the requirements set forth in paragraph (a) of this section have been and are continuing to be met, and that the conditions set forth in paragraph (c) of this section for cancellation of the designation do not exist.

(f) Any producer-handler with Class I route dispositions and/or transfers of packaged fluid milk products in the marketing area described in § 1131.2 of this chapter of this chapter shall be subject to payments into the Order 1131 producer settlement fund on such dispositions pursuant to § 1000.76(a) of this chapter and payments into the Order 1131 administrative fund, provided such dispositions are less than three million pounds in the current month and such producer-handler had total Class I route dispositions and/or transfers of packaged fluid milk products from own farm production of three million pounds or more the previous month. If the producer-handler has Class I route dispositions and/or transfers of packaged fluid milk products into the marketing area described in § 1131.2 of this chapter of three million pounds or more during the current month, such producer-handler shall be subject to the provisions described in § 1131.7 of this chapter or § 1000.76(a) of this chapter.

§ 1051.11 California quota program.

California Quota Program means the applicable provisions of the California Food and Agriculture Code, and related provisions of the pooling plan administered by the California Department of Food and Agriculture (CDFA).

§ 1051.12 Producer.

(a) Except as provided in paragraph (b) of this section, *producer* means any person who produces milk approved by a duly constituted regulatory agency for fluid consumption as Grade A milk and whose milk is:

(1) Received at a pool plant directly from the producer or diverted by the plant operator in accordance with § 1051.13 of this chapter; or

(2) Received by a handler described in § 1000.9(c) of this chapter.

(b) Producer shall not include:

(1) A producer-handler as defined in any Federal order;

(2) A dairy farmer whose milk is received at an exempt plant, excluding producer milk diverted to the exempt plant pursuant to § 1051.13(d) of this chapter;

(3) A dairy farmer whose milk is received by diversion at a pool plant from a handler regulated under another Federal order if the other Federal order designates the dairy farmer as a producer under that order and that milk is allocated by request to a utilization other than Class I; and

(4) A dairy farmer whose milk is reported as diverted to a plant fully regulated under another Federal order with respect to that portion of the milk so diverted that is assigned to Class I under the provisions of such other order.

§ 1051.13 Producer milk.

Except as provided for in paragraph (e) of this section, *producer milk* means the skim milk (or the skim equivalent of components of skim milk), including nonfat components, and butterfat in milk of a producer that is:

(a) Received by the operator of a pool plant directly from a producer or a

handler described in § 1000.9(c) of this chapter. All milk received pursuant to this paragraph (a) shall be priced at the location of the plant where it is first physically received;

(b) Received by a handler described in § 1000.9(c) of this chapter in excess of the quantity delivered to pool plants;

(c) Diverted by a pool plant operator to another pool plant. Milk so diverted shall be priced at the location of the plant to which diverted; or

(d) Diverted by the operator of a pool plant or a cooperative association described in § 1000.9(c) of this chapter to a nonpool plant located in the States of California, Arizona, Nevada, or Oregon, subject to the following conditions:

(1) Milk of a dairy farmer shall not be eligible for diversion unless at least one day's production of such dairy farmer is physically received as producer milk at a pool plant during the first month the dairy farmer is a producer. If a dairy farmer loses producer status under the order in this part (except as a result of a temporary loss of Grade A approval or as a result of the handler of the dairy farmer's milk failing to pool the milk under any order), the dairy farmer's milk shall not be eligible for diversion unless at least one day's production of the dairy farmer has been physically received as producer milk at a pool plant during the first month the dairy farmer is re-associated with the market;

(2) The quantity of milk diverted by a handler described in § 1000.9(c) of this chapter may not exceed 90 percent of the producer milk receipts reported by the handler pursuant to § 1051.30(c) of this chapter provided that not less than 10 percent of such receipts are delivered to plants described in § 1051.7(c)(1)(i) through (iii) of this chapter. These percentages are subject to any adjustments that may be made pursuant to § 1051.7(g) of this chapter; an

(3) The quantity of milk diverted to nonpool plants by the operator of a pool plant described in § 1051.7(a), (b) or (d) of this chapter may not exceed 90 percent of the Grade A milk received from dairy farmers (except dairy farmers described in § 1051.12(b) of this chapter) including milk diverted pursuant to this section. These percentages are subject to any adjustments that may be made pursuant to § 1051.7(g) of this chapter.

(4) Diverted milk shall be priced at the location of the plant to which diverted.

(e) Producer milk shall not include milk of a producer that is subject to inclusion and participation in a marketwide equalization pool under a milk classification and pricing program imposed under the authority of a State government maintaining marketwide pooling of returns.

(f) The quantity of milk reported by a handler pursuant to either § 1051.30(a)(1) or (c)(1) of this chapter for April through February may not exceed 125 percent, and for March may not exceed 135 percent, of the producer milk receipts pooled by the handler during the prior month. Milk diverted to nonpool plants reported in excess of this limit shall be removed from the pool. Milk in excess of this limit received at pool plants, other than pool distributing plants, shall be classified pursuant to § 1000.44(a)(3)(v) and (b) of this chapter. The handler must designate, by producer pick-up, which milk is to be removed from the pool. If the handler fails to provide this information, the market administrator will make the determination. The following provisions apply:

(1) Milk shipped to and physically received at pool distributing plants in excess of the previous month's pooled volume shall not be subject to the 125 or 135 percent limitation;

(2) Producer milk qualified pursuant to § __.13 of any other Federal Order and continuously pooled in any Federal Order for the previous six months shall not be included in the computation of the 125 or 135 percent limitation;

(3) The market administrator may waive the 125 or 135 percent limitation:

(i) For a new handler on the order, subject to the provisions of paragraph (f)(4) of this section; or

(ii) For an existing handler with significantly changed milk supply conditions due to unusual circumstances; and

(4) A bloc of milk may be considered ineligible for pooling if the market administrator determines that handlers altered the reporting of such milk for the purpose of evading the provisions of this paragraph (f).

§ 1051.14 Other source milk.

See § 1000.14 of this chapter.

§ 1051.15 Fluid milk product.

See § 1000.15 of this chapter.

§ 1051.16 Fluid cream product.

See § 1000.16 of this chapter.

§ 1051.17 [Reserved]

§ 1051.18 Cooperative association.

See § 1000.18 of this chapter.

§ 1051.19 Commercial food processing establishment.

See § 1000.19 of this chapter.

Market Administrator, Continuing Obligations, and Handler Responsibilities

§ 1051.25 Market administrator.

See § 1000.25 of this chapter.

§ 1051.26 Continuity and separability of provisions.

See § 1000.26 of this chapter.

§ 1051.27 Handler responsibility for records and facilities.

See § 1000.27 of this chapter.

§ 1051.28 Termination of obligations.

See § 1000.28 of this chapter.

Handler Reports

§ 1051.30 Reports of receipts and utilization.

Each handler shall report monthly so that the market administrator's office receives the report on or before the 9th day after the end of the month, in the detail and on the prescribed forms, as follows:

(a) Each handler that operates a pool plant shall report for each of its operations the following information:

(1) Product pounds, pounds of butterfat, pounds of protein, pounds of solids-not-fat other than protein (other solids) contained in or represented by:

(i) Receipts of producer milk, including producer milk diverted by the reporting handler, from sources other than handlers described in § 1000.9(c) of this chapter; and

(ii) Receipts of milk from handlers described in § 1000.9(c) of this chapter;

(2) Product pounds and pounds of butterfat contained in:

(i) Receipts of fluid milk products and bulk fluid cream products from other pool plants;

(ii) Receipts of other source milk; and

(iii) Inventories at the beginning and end of the month of fluid milk products and bulk fluid cream products;

(3) The utilization or disposition of all milk and milk products required to be reported pursuant to this paragraph (a); and

(4) Such other information with respect to the receipts and utilization of skim milk, butterfat, milk protein, and other nonfat solids as the market administrator may prescribe.

(b) Each handler operating a partially regulated distributing plant shall report with respect to such plant in the same manner as prescribed for reports required by paragraph (a) of this section. Receipts of milk that would have been producer milk if the plant had been fully regulated shall be reported in lieu of producer milk. The report shall show also the quantity of any reconstituted

skim milk in route disposition in the marketing area.

(c) Each handler described in § 1000.9(c) of this chapter shall report:

(1) The product pounds, pounds of butterfat, pounds of protein, pounds of solids-not-fat other than protein (other solids) contained in receipts of milk from producers; and

(2) The utilization or disposition of such receipts.

(d) Each handler not specified in paragraphs (a) through (c) of this section shall report with respect to its receipts and utilization of milk and milk products in such manner as the market administrator may prescribe.

§ 1051.31 Payroll reports.

(a) On or before the 20th day after the end of each month, each handler that operates a pool plant pursuant to § 1051.7 of this chapter and each handler described in § 1000.9(c) of this chapter shall report to the market administrator its producer payroll for the month, in the detail prescribed by the market administrator, showing for each producer the information described in § 1051.73(f) of this chapter.

(b) Each handler operating a partially regulated distributing plant who elects to make payment pursuant to § 1000.76(b) of this chapter shall report for each dairy farmer who would have been a producer if the plant had been fully regulated in the same manner as prescribed for reports required by paragraph (a) of this section.

§ 1051.32 Other reports.

In addition to the reports required pursuant to §§ 1051.30 and 1051.31 of this chapter, each handler shall report any information the market administrator deems necessary to verify or establish each handler's obligation under the order.

Subpart B—Milk Pricing

Classification of Milk

§ 1051.40 Classes of utilization.

See § 1000.40 of this chapter.

§ 1051.41 [Reserved]

§ 1051.42 Classification of transfers and diversions.

See § 1000.42 of this chapter.

§ 1051.43 General classification rules.

See § 1000.43 of this chapter.

§ 1051.44 Classification of producer milk.

See § 1000.44 of this chapter.

§ 1051.45 Market administrator's reports and announcements concerning classification.

See § 1000.45 of this chapter.

Class Prices

§ 1051.50 Class prices, component prices, and advanced pricing factors.

See § 1000.50 of this chapter.

§ 1051.51 Class I differential and price.

The Class I differential shall be the differential established for Los Angeles County, California, which is reported in § 1000.52 of this chapter. The Class I price shall be the price computed pursuant to § 1000.50(a) of this chapter for Los Angeles County, California.

§ 1051.52 Adjusted Class I differentials.

See § 1000.52 of this chapter.

§ 1051.53 Announcement of class prices, component prices, and advanced pricing factors.

See § 1000.53 of this chapter.

§ 1051.54 Equivalent price.

See § 1000.54 of this chapter.

Producer Price Differential

§ 1051.60 Handler's value of milk.

For the purpose of computing a handler's obligation for producer milk, the market administrator shall determine for each month the value of milk of each handler with respect to each of the handler's pool plants and of each handler described in § 1000.9(c) of this chapter with respect to milk that was not received at a pool plant by adding the amounts computed in paragraphs (a) through (h) of this section and subtracting from that total amount the values computed in paragraphs (i) and (j) of this section. Unless otherwise specified, the skim milk, butterfat, and the combined pounds of skim milk and butterfat referred to in this section shall result from the steps set forth in § 1000.44(a), (b), and (c) of this chapter, respectively, and the nonfat components of producer milk in each class shall be based upon the proportion of such components in producer skim milk. Receipts of nonfluid milk products that are distributed as labeled reconstituted milk for which payments are made to the producer-settlement fund of another Federal order under § 1000.76(a)(4) or (d) of this chapter shall be excluded from pricing under this section.

(a) Class I value.

(1) Multiply the hundredweight of skim milk in Class I by the Class I skim milk price; and

(2) Add an amount obtained by multiplying the pounds of butterfat in Class I by the Class I butterfat price; and

(b) Class II value.

(1) Multiply the pounds of nonfat solids in Class II skim milk by the Class II nonfat solids price; and

(2) Add an amount obtained by multiplying the pounds of butterfat in Class II times the Class II butterfat price.

(c) Class III value.

(1) Multiply the pounds of protein in Class III skim milk by the protein price;

(2) Add an amount obtained by multiplying the pounds of other solids in Class III skim milk by the other solids price; and

(3) Add an amount obtained by multiplying the pounds of butterfat in Class III by the butterfat price.

(d) Class IV value.

(1) Multiply the pounds of nonfat solids in Class IV skim milk by the nonfat solids price; and

(2) Add an amount obtained by multiplying the pounds of butterfat in Class IV by the butterfat price.

(e) Multiply the pounds of skim milk and butterfat overage assigned to each class pursuant to § 1000.44(a)(11) of this chapter and the corresponding step of § 1000.44(b) by the skim milk prices and butterfat prices applicable to each class.

(f) Multiply the difference between the current month's Class I, II, or III price, as the case may be, and the Class IV price for the preceding month and by the hundredweight of skim milk and butterfat subtracted from Class I, II, or III, respectively, pursuant to § 1000.44(a)(7) of this chapter and the corresponding step of § 1000.44(b).

(g) Multiply the difference between the Class I price applicable at the location of the pool plant and the Class IV price by the hundredweight of skim milk and butterfat assigned to Class I pursuant to § 1000.43(d) of this chapter and the hundredweight of skim milk and butterfat subtracted from Class I pursuant to § 1000.44(a)(3)(i) through (vi) of this chapter and the corresponding step of § 1000.44(b), excluding receipts of bulk fluid cream products from plants regulated under other Federal orders and bulk concentrated fluid milk products from pool plants, plants regulated under other Federal orders, and unregulated supply plants.

(h) Multiply the difference between the Class I price applicable at the location of the nearest unregulated supply plants from which an equivalent volume was received and the Class III price by the pounds of skim milk and butterfat in receipts of concentrated fluid milk products assigned to Class I pursuant to §§ 1000.43(d) of this chapter and 1000.44(a)(3)(i) of this chapter and the corresponding step of § 1000.44(b) and the pounds of skim milk and butterfat subtracted from Class I pursuant to § 1000.44(a)(8) and the corresponding step of § 1000.44(b), excluding such skim milk and butterfat

in receipts of fluid milk products from an unregulated supply plant to the extent that an equivalent amount of skim milk or butterfat disposed of to such plant by handlers fully regulated under any Federal milk order is classified and priced as Class I milk and is not used as an offset for any other payment obligation under any order.

(i) For reconstituted milk made from receipts of nonfluid milk products, multiply $1.00 (but not more than the difference between the Class I price applicable at the location of the pool plant and the Class IV price) by the hundredweight of skim milk and butterfat contained in receipts of nonfluid milk products that are allocated to Class I use pursuant to § 1000.43(d) of this chapter.

§ 1051.61 Computation of producer price differential.

For each month the market administrator shall compute a producer price differential per hundredweight. The report of any handler who has not made payments required pursuant to § 1051.71 of this chapter for the preceding month shall not be included in the computation of the producer price differential, and such handler's report shall not be included in the computation for succeeding months until the handler has made full payment of outstanding monthly obligations. Subject to the conditions of this introductory paragraph, the market administrator shall compute the producer price differential in the following manner:

(a) Combine into one total the values computed pursuant to § 1051.60 of this chapter for all handlers required to file reports prescribed in § 1051.30 of this chapter;

(b) Subtract the total values obtained by multiplying each handler's total pounds of protein, other solids, and butterfat contained in the milk for which an obligation was computed pursuant to § 1051.60 of this chapter by the protein price, other solids price, and the butterfat price, respectively;

(c) Add an amount equal to the minus location adjustments and subtract an amount equal to the plus location adjustments computed pursuant to § 1051.75 of this chapter;

(d) Add an amount equal to not less than one-half of the unobligated balance in the producer-settlement fund;

(e) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(1) The total hundredweight of producer milk; and

(2) The total hundredweight for which a value is computed pursuant to § 1051.60(i) of this chapter; and

(f) Subtract not less than 4 cents nor more than 5 cents from the price computed pursuant to paragraph (e) of this section. The result shall be known as the producer price differential for the month.

§ 1051.62 Announcement of producer prices.

On or before the 14th day after the end of each month, the market administrator shall announce publicly the following prices and information:

(a) The producer price differential;

(b) The protein price;

(c) The nonfat solids price;

(d) The other solids price;

(e) The butterfat price;

(f) The average butterfat, nonfat solids, protein and other solids content of producer milk; and

(g) The statistical uniform price for milk containing 3.5 percent butterfat, computed by combining the Class III price and the producer price differential.

Subpart C—Payments for Milk

Producer Payments

§ 1051.70 Producer-settlement fund.

See § 1000.70 of this chapter.

§ 1051.71 Payments to the producer-settlement fund.

Each handler shall make payment to the producer-settlement fund in a manner that provides receipt of the funds by the market administrator no later than the 16th day after the end of the month (except as provided in § 1000.90 of this chapter). Payment shall be the amount, if any, by which the amount specified in paragraph (a) of this section exceeds the amount specified in paragraph (b) of this section:

(a) The total value of milk to the handler for the month as determined pursuant to § 1051.60 of this chapter.

(b) The sum of:

(1) An amount obtained by multiplying the total hundredweight of producer milk as determined pursuant to § 1000.44(c) of this chapter by the producer price differential as adjusted pursuant to § 1051.75 of this chapter;

(2) An amount obtained by multiplying the total pounds of protein, other solids, and butterfat contained in producer milk by the protein, other solids, and butterfat prices respectively; and

(3) An amount obtained by multiplying the pounds of skim milk and butterfat for which a value was computed pursuant to § 1051.60(i) of this chapter by the producer price differential as adjusted pursuant to § 1051.75 of this chapter for the location of the plant from which received.

§ 1051.72 Payments from the producer-settlement fund.

No later than the 18th day after the end of each month (except as provided in § 1000.90 of this chapter), the market administrator shall pay to each handler the amount, if any, by which the amount computed pursuant to § 1051.71(b) of this chapter exceeds the amount computed pursuant to § 1051.71(a). If, at such time, the balance in the producer-settlement fund is insufficient to make all payments pursuant to this section, the market administrator shall reduce uniformly such payments and shall complete the payments as soon as the funds are available.

§ 1051.73 Payments to producers and to cooperative associations.

(a) Each handler shall pay each producer for producer milk for which payment is not made to a cooperative association pursuant to paragraph (b) of this section, as follows:

(1) *Partial payment.* For each producer who has not discontinued shipments as of the date of this partial payment, payment shall be made so that it is received by each producer on or before the last day of the month (except as provided in § 1000.90 of this chapter) for milk received during the first 15 days of the month from the producer at not less than the lowest announced class price for the preceding month, less proper deductions authorized in writing by the producer.

(2) *Final payment.* For milk received during the month, payment shall be made so that it is received by each producer no later than the 19th day after the end of the month (except as provided in § 1000.90 of this chapter) in an amount not less than the sum of:

(i) The hundredweight of producer milk received times the producer price differential for the month as adjusted pursuant to § 1051.75 of this chapter;

(ii) The pounds of butterfat received times the butterfat price for the month;

(iii) The pounds of protein received times the protein price for the month;

(iv) The pounds of other solids received times the other solids price for the month;

(v) Less any payment made pursuant to paragraph (a)(1) of this section;

(vi) Less proper deductions authorized in writing by such producer, and plus or minus adjustments for errors in previous payments to such producer subject to approval by the market administrator;

(vii) Less deductions for marketing services pursuant to § 1000.86 of this chapter; and

(viii) Less deductions authorized by CDFA for the California Quota Program pursuant to § 1051.11 of this chapter.

(b) *Payments for milk received from cooperative association members.* On or before the day prior to the dates specified in paragraphs (a)(1) and (2) of this section (except as provided in § 1000.90 of this chapter), each handler shall pay to a cooperative association for milk from producers who market their milk through the cooperative association and who have authorized the cooperative to collect such payments on their behalf an amount equal to the sum of the individual payments otherwise payable for such producer milk pursuant to paragraphs (a)(1) and (2) of this section.

(c) *Payment for milk received from cooperative association pool plants or from cooperatives as handlers pursuant to § 1000.9(c).* On or before the day prior to the dates specified in paragraphs (a)(1) and (2) of this section (except as provided in § 1000.90 of this chapter), each handler who receives fluid milk products at its plant from a cooperative association in its capacity as the operator of a pool plant or who receives milk from a cooperative association in its capacity as a handler pursuant to § 1000.9(c) of this chapter, including the milk of producers who are not members of such association and who the market administrator determines have authorized the cooperative association to collect payment for their milk, shall pay the cooperative for such milk as follows:

(1) For bulk fluid milk products and bulk fluid cream products received from a cooperative association in its capacity as the operator of a pool plant and for milk received from a cooperative association in its capacity as a handler pursuant to § 1000.9(c) of this chapter during the first 15 days of the month, at not less than the lowest announced class prices per hundredweight for the preceding month;

(2) For the total quantity of bulk fluid milk products and bulk fluid cream products received from a cooperative association in its capacity as the operator of a pool plant, at not less than the total value of such products received from the association's pool plants, as determined by multiplying the respective quantities assigned to each class under § 1000.44 of this chapter, as follows:

(i) The hundredweight of Class I skim milk times the Class I skim milk price for the month plus the pounds of Class I butterfat times the Class I butterfat price for the month. The Class I price to be used shall be that price effective at the location of the receiving plant;

(ii) The pounds of nonfat solids in Class II skim milk by the Class II nonfat solids price;

(iii) The pounds of butterfat in Class II times the Class II butterfat price;

(iv) The pounds of nonfat solids in Class IV times the nonfat solids price;

(v) The pounds of butterfat in Class III and Class IV milk times the butterfat price;

(vi) The pounds of protein in Class III milk times the protein price;

(vii) The pounds of other solids in Class III milk times the other solids price; and

(vii) Add together the amounts computed in paragraphs (c)(2)(i) through (vii) of this section and from that sum deduct any payment made pursuant to paragraph (c)(1) of this section; and

(3) For the total quantity of milk received during the month from a cooperative association in its capacity as a handler under § 1000.9(c) of this chapter as follows:

(i) The hundredweight of producer milk received times the producer price differential as adjusted pursuant to § 1051.75 of this chapter;

(ii) The pounds of butterfat received times the butterfat price for the month;

(iii) The pounds of protein received times the protein price for the month;

(iv) The pounds of other solids received times the other solids price for the month; and

(v) Add together the amounts computed in paragraphs (c)(3)(i) through (v) of this section and from that sum deduct any payment made pursuant to paragraph (c)(1) of this section.

(d) If a handler has not received full payment from the market administrator pursuant to § 1051.72 of this chapter by the payment date specified in paragraph (a), (b), or (c) of this section, the handler may reduce pro rata its payments to producers or to the cooperative association (with respect to receipts described in paragraph (b) of this section, prorating the underpayment to the volume of milk received from the cooperative association in proportion to the total milk received from producers by the handler), but not by more than the amount of the underpayment. The payments shall be completed on the next scheduled payment date after receipt of the balance due from the market administrator.

(e) If a handler claims that a required payment to a producer cannot be made because the producer is deceased or cannot be located, or because the cooperative association or its lawful successor or assignee is no longer in existence, the payment shall be made to the producer-settlement fund, and in the event that the handler subsequently locates and pays the producer or a lawful claimant, or in the event that the handler no longer exists and a lawful claim is later established, the market administrator shall make the required payment from the producer-settlement fund to the handler or to the lawful claimant, as the case may be.

(f) In making payments to producers pursuant to this section, each handler shall furnish each producer, except a producer whose milk was received from a cooperative association handler described in § 1000.9(a) or (c) of this chapter, a supporting statement in a form that may be retained by the recipient which shall show:

(1) The name, address, Grade A identifier assigned by a duly constituted regulatory agency, and payroll number of the producer;

(2) The daily and total pounds, and the month and dates such milk was received from that producer;

(3) The total pounds of butterfat, protein, and other solids contained in the producer's milk;

(4) The minimum rate or rates at which payment to the producer is required pursuant to the order in this part;

(5) The rate used in making payment if the rate is other than the applicable minimum rate;

(6) The amount, or rate per hundredweight, or rate per pound of component, and the nature of each deduction claimed by the handler; and

(7) The net amount of payment to the producer or cooperative association.

§ 1051.74 [Reserved]

§ 1051.75 Plant location adjustments for producer milk and nonpool milk.

For purposes of making payments for producer milk and nonpool milk, a plant location adjustment shall be determined by subtracting the Class I price specified in § 1051.51 of this chapter from the Class I price at the plant's location. The difference, plus or minus as the case may be, shall be used to adjust the payments required pursuant to §§ 1051.73 and 1000.76 of this chapter.

§ 1051.76 Payments by a handler operating a partially regulated distributing plant.

See § 1000.76 of this chapter.

§ 1051.77 Adjustment of accounts.

See § 1000.77 of this chapter.

§ 1051.78 Charges on overdue accounts.

See § 1000.78 of this chapter.

Administrative Assessment and Marketing Service Deduction

§ 1051.85 Assessment for order administration.

On or before the payment receipt date specified under § 1051.71 of this chapter, each handler shall pay to the market administrator its pro rata share of the expense of administration of the order at a rate specified by the market administrator that is no more than 8 cents per hundredweight with respect to:

(a) Receipts of producer milk (including the handler's own production) other than such receipts by a handler described in § 1000.9(c) of this chapter that were delivered to pool plants of other handlers;

(b) Receipts from a handler described in § 1000.9(c) of this chapter;

(c) Receipts of concentrated fluid milk products from unregulated supply plants and receipts of nonfluid milk products assigned to Class I use pursuant to § 1000.43(d) of this chapter and other source milk allocated to Class I pursuant to § 1000.44(a)(3) and (8) of this chapter and the corresponding steps of § 1000.44(b), except other source milk that is excluded from the computations pursuant to § 1051.60 (h) and (i) of this chapter; and

(d) Route disposition in the marketing area from a partially regulated distributing plant that exceeds the skim milk and butterfat subtracted pursuant to § 1000.76(a)(1)(i) and (ii) of this chapter.

§ 1051.86 Deduction for marketing services.

See § 1000.86 of this chapter.

Subpart D—Miscellaneous Provisions

§ 1051.90 Dates.

See § 1000.90 of this chapter.

[**Note:** The following will not appear in the Code of Federal Regulations.]

Marketing Agreement Regulating the Handling of Milk in the Proposed California Marketing Area

The parties hereto, in order to effectuate the declared policy of the Act, and in accordance with the rules of practice and procedure effective thereunder (7 CFR part 900), desire to enter into this marketing agreement and do hereby agree that the provisions referred to in paragraph I hereof, as augmented by the provisions specified in paragraph II hereof, shall be and are the provisions of this marketing agreement as if set out in full herein.

I. The findings and determinations, order relative to handling, and the provisions of § 1051.1 to 1051.90 [47] of this chapter all inclusive, of the order regulating the handling of milk in the proposed California [48] marketing area (7 CFR part 1051 [49]); and

II. The following provisions: § 1051.91 [50] of this chapter Record of milk handled and authorization to correct typographical errors.

(a) Record of milk handled. The undersigned certifies that he/she handled during the month of May 2017 [51], _____hundredweight of milk covered by this marketing agreement.

(b) Authorization to correct typographical errors. The undersigned hereby authorizes the Deputy Administrator, or Acting Deputy Administrator, Dairy Programs, Agricultural Marketing Service, to correct any typographical errors which may have been made in this marketing agreement.

Effective date. This marketing agreement shall become effective upon the execution of a counterpart hereof by the Department in accordance with section 900.14(a) of the aforesaid rules of practice and procedure.

In Witness Whereof, the contracting handlers, acting under the provisions of the Act, for the purposes and subject to the limitations herein contained and not otherwise, have hereunto set their respective hands and seals.

Signature

By (Name) _____

(Title) _____

(Address) _____

(Seal)

Attest _____

Dated: March 23, 2018.

Bruce Summers,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2018–06167 Filed 3–30–18; 8:45 am]

BILLING CODE 3410–02–P

[47] First and last section of order.

[48] Name of order.

[49] Appropriate part number.

[50] Next consecutive section number.

[51] Appropriate representative period for the order.

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FEDERAL REGISTER PAGES AND DATE, APRIL

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CFR PARTS AFFECTED DURING APRIL

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List March 29, 2018

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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.

Date of FR publication	15 days after publication	21 days after publication	30 days after publication	35 days after publication	45 days after publication	60 days after publication	90 days after publication
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